Designation: E2538 – 06 (Reapproved 2011)

An American National Standard

Standard Practice for Defining and Implementing Pharmacotherapy Information Services within the Electronic Health Record (EHR) Environment and Networked Architectures[1]

This standard is issued under the fixed designation E2538; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

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]

E1239 Practice for Description of Reservation/Registration-Admission, Discharge, Transfer (R-ADT) Systems for Electronic Health Record (EHR) Systems

E1340 Guide for Rapid Prototyping of Information Systems

E1384 Practice for Content and Structure of the Electronic Health Record (EHR)

E1578 Guide for Laboratory Informatics

E1633 Specification for Coded Values Used in the Electronic Health Record

E1714 Guide for Properties of a Universal Healthcare Identifier (UHID)

E1715 Practice for An Object-Oriented Model for Registration, Admitting, Discharge, and Transfer (RADT) Functions in Computer-Based Patient Record Systems

E1744 Practice for View of Emergency Medical Care in the Electronic Health Record

E1762 Guide for Electronic Authentication of Health Care Information

E1869 Guide for Confidentiality, Privacy, Access, and Data Security Principles for Health Information Including Electronic Health Records

E1985 Guide for User Authentication and Authorization

E1986 Guide for Information Access Privileges 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.

Current edition approved May 1, 2011. Published June 2011. Originally approved in 2006. Last previous edition approved in 2006 as E2538 06. DOI: 10.1520/E2538-06R11.

[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.

E1987 Guide for Individual Rights Regarding Health Information (Withdrawn 2007)[3]
E1988 Guide for Training of Persons who have Access to Health Information (Withdrawn 2007)[3]
E2017 Guide for Amendments to Health Information
E2066 Guide for Validation of Laboratory Information Management Systems
E2084 Specification for Authentication of Healthcare Information Using Digital Signatures (Withdrawn 2009)[3]
E2085 Guide on Security Framework for Healthcare Information (Withdrawn 2009)[3]
E2086 Guide for Internet and Intranet Healthcare Security (Withdrawn 2009)[3]
E2145 Practice for Information Modeling
E2147 Specification for Audit and Disclosure Logs for Use in Health Information Systems
E2171 Practice for Rating-Scale Measures Relevant to the Electronic Health Record
E2457 Terminology for Healthcare Informatics
E2473 Practice for the Occupational/Environmental Health View of the Electronic Health Record
P110 Proposed Guide to Assist in the Defining, Procuring, Installing, and Implementing of a Computerized Hospital Pharmacy System[4]

2.2 *ANSI/IEEE Standards:*[5]
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:*[5]
ANSI/HL7 Interface Standard v2.4, v2.5, v3.0
HL7 Message Development Framework v3.3, Dec. 1999

2.4 *ANSI/ADA Standards:*[5]
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:*[5]
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

[3] The last approved version of this historical standard is referenced on www.astm.org.
[4] Withdrawn 1988.
[5] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

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
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 Processes[6]
ANSI X12[5]
CEN ENV 1613 Medical Informatics—Messages for the exchange of laboratory information[7]
CEN ENV 1614 Healthcare Informatics—Structure for nomenclature, classification and coding of properties in clinical laboratory sciences[7]
CEN EN 12017 Medical Informatics Vocabulary (MIVoc)[7]
CEN EN 12264 Categorical Structures of Systems of Concepts—Model for Representation of Semantics (MOSE)[7]
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. 1993[6]
ANSI/CLSI ASTP2 Point of Care In-vitro Diagnostic Testing[5]
CLSI AUTO1-A Laboratory Automation: Specimen Container/Specimen Carrier[8]
CLSI AUTO2-A Laboratory Automation: Bar codes for Specimen Container Identification[8]
CLSI AUTO3-A Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices and Information Systems[8]
CLSI AUTO4-A Laboratory Automation: Systems Operational Requirements, Characteristics and Information Elements[8]
CLSI AUTO5-A Laboratory Automation: Electromechanical Interfaces[8]
CLSI LIS-1A Specification for Low Level Protocol to Transfer Messages between Clinical Laboratory Instruments and Computer Systems[8]
CLSI LIS-2A Specification for Transferring Information between Clinical Instruments and Computer Systems[8]
CLSI LIS-3A Guide for Procurement of a Clinical Laboratory Information Management System (CLIMS)[8]
CLSI LIS-5A Specification for Transferring Clinical Observations between Independent Computer Systems[8]
CLSI LIS-7A Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory[8]
CLSI LIS-8A Guide for Functional Requirements of Clinical Laboratory Information Management Systems[8]
CLSI LIS-9A Guide for Coordination of Clinical Laboratory Services in an Electronic Health Record Environment and Networked Architectures[8]
CLSI POCT1 Point of Care Connectivity[8]
DICOM Supplement 15 Visible Light Image, Anatomic Frame of Reference, Accession and Specimen for Endoscopy, Microscopy, and Photography[9]
EIA/IEEE J-Std-016 Standard for Information Technology, Software Life Cycle Processes, Software Development, Acquirer-Supplier Agreement[10]
IUPAC/IFCC Silver Book: Compendium of Terminology and Nomenclature of Properties in Clinical Laboratory Sciences[11]
IUPAC/IFCC Properties and Units in Clinical Laboratory Sciences X Properties and Units in General Clinical Chemistry[11]
IUPAC/IFCC Properties and Units in Clinical Laboratory Sciences XII Properties and Units in Clinical Pharmacology and Toxicology[11]
NCPDP SCRIPT v9.0[12]
RxNorm[13]

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 E2457, 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. **E1384**

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. **E1384**

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

[6] Available from the Association for Advancement of Medical Instrumentation, 1110 N. Glebe Rd., Suite 220, Arlington, VA 22201-4795.
[7] Available from the European Committee for Standardization, 36 rue de Stassart, B-1050 Brussels, Belgium.
[8] Available from the Clinical and Laboratory Standards Institute, 940 West Valley Rd., Suite 1400, Wayne, PA 19087-1898.
[9] Available from NEMA, Suite 1752, 1300 N. 17th St., Rosslyn, VA 22209.
[10] Available from the Institute of Electrical and Electronics Engineers, Inc., 1828 L St., NW, Suite 1202, Washington, DC 20036-5104.
[11] Available from the IUPAC Secretariat, PO Box 13757, Research Triangle Park, NC 27709-3757.
[12] Available from the National Council for Prescription Drug Programs, 9240 E. Raintree Dr., Scottsdale, AZ 85260-7518.
[13] Available from Reference and Web Services, National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894.

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

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

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

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 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 E2066.

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 E2145. Table 2 gives an example of such a matrix. The technique, detailed further in 5.2, has been described by Zachman (**1**)[14] as the information systems architecture (ISA) framework and has been implemented using

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

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. Indentification 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. Healthcae 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

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 pharmcotherapy services Provide integrated Decision Support	24 Hr Service Just-in-time inventory Continuous Resource Mgt Immediate Claims processing	Pharmacy Clinical Laboratory Practitioner Clientele Suppliers Payors 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

several software tools (**2-5**). From examination of this matrix format, further modeling of the business components, the 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 E2145, 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 E1340 and E2145.)

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 **(6)**. 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 E1715 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 **(7)**.) 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 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

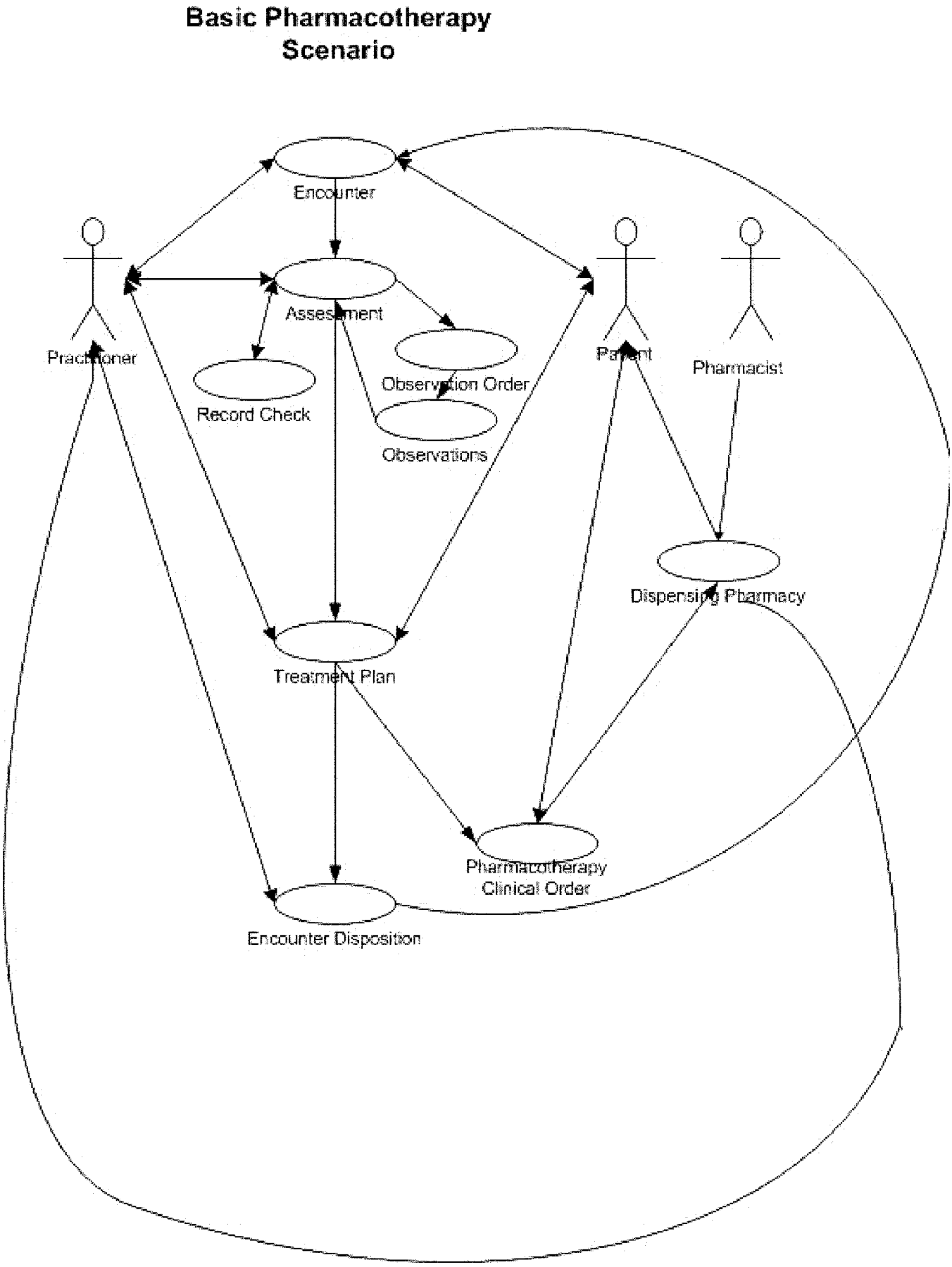

FIG. 1 Use-Case/Actor Model for a Physician Office Pharmacotherapy Situation

in Guides E1762, E1869, E1985, E1986, E1987, E2084, E2085, E2086 and Specification E2147 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 E1762, E2017 and Specification E2084 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 E1578 and E2066) 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 **(8)** 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 E1744) 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 E1869, E1986, E1987, E1988, E2085, and E2086 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 E1239 to acquire that demographic data (see Practice E1715) 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 E1384. 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 E1384 and Specification E1633 as references, in addition to any working documentation of the embryonic CDIM. The specific clinical views, such as that for EMS defined in Practice E1744 or Practice E2473 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 E1384, 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 E1633.

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 E1239, 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 E1714 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 E1744), 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 E1384. 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 E1384) 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 E2171) can be clearly seen.

6.3.10 *Ambulatory Care—Family Practice*—Family practice is probably the most fundamental care setting in healthcare, 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 E1239 and E1384.

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

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

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*(**9**) 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 (**10**), 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 (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) **(11)**, 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 E1384 and Specification E1633 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 etal (**8**) 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.ncpdp.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 E1239) 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.

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

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

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 P110, 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 (**7**) 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

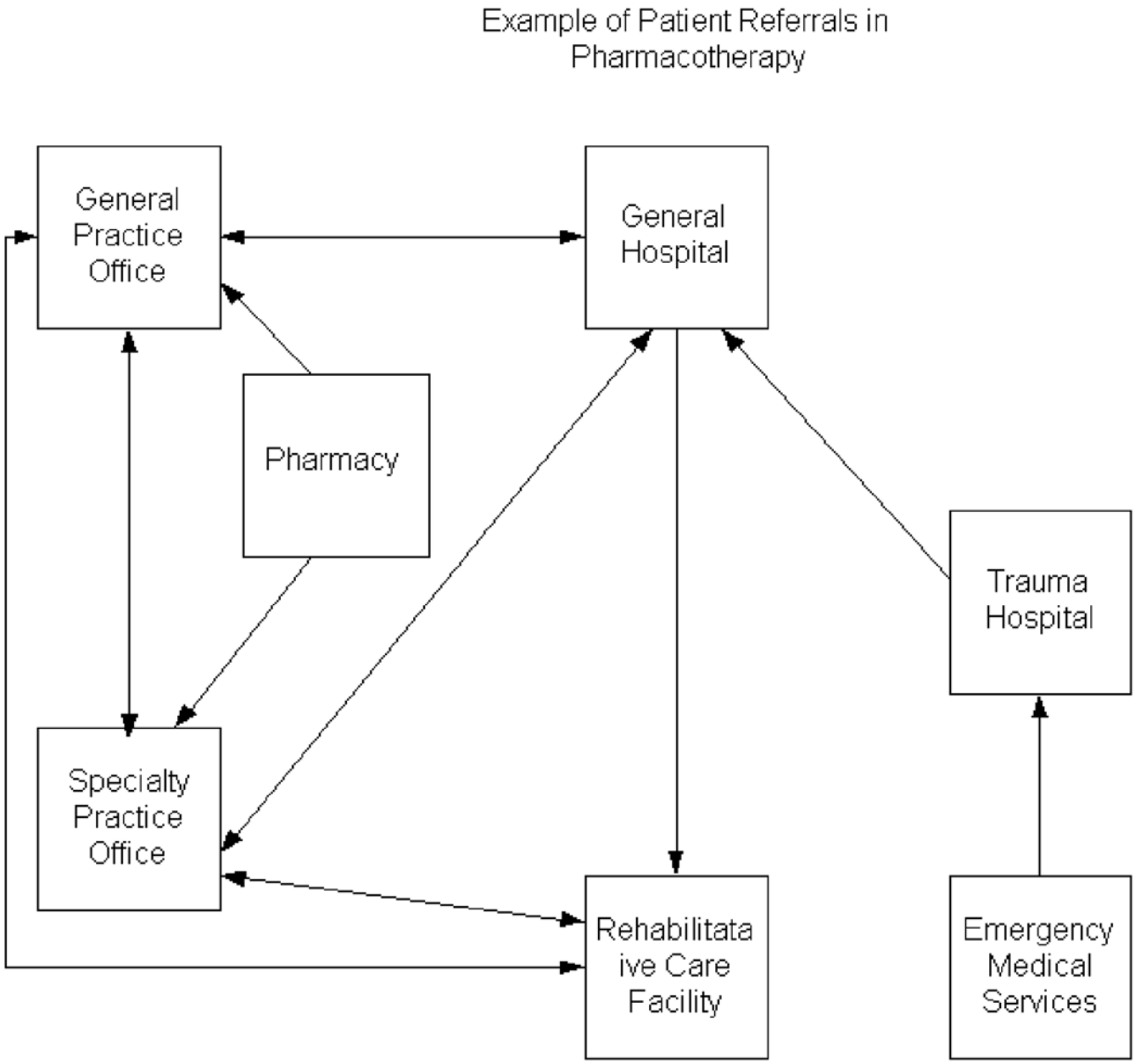

FIG. X1.1 Referral Patterns

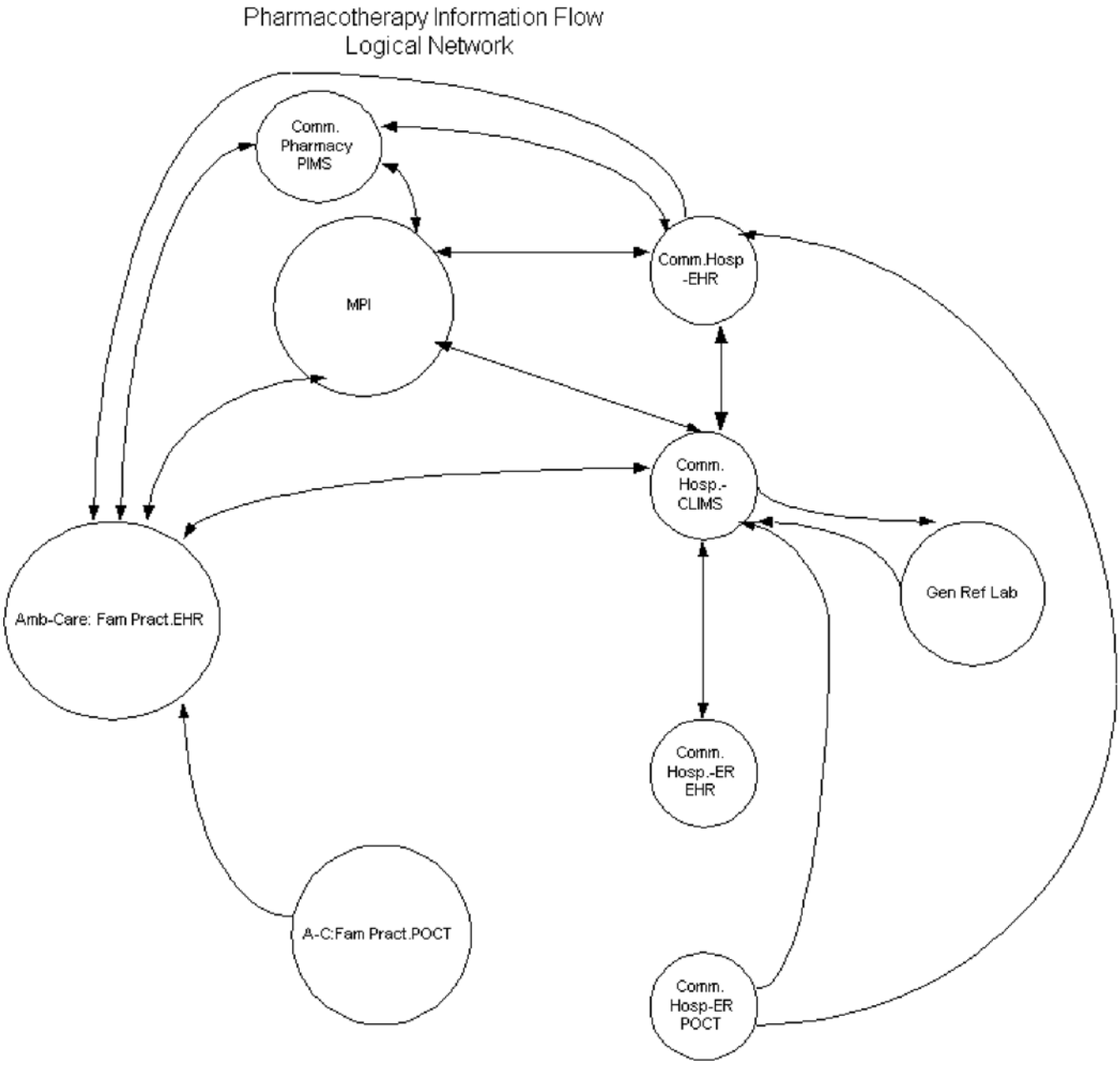

FIG. X1.2 Logical Network

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.

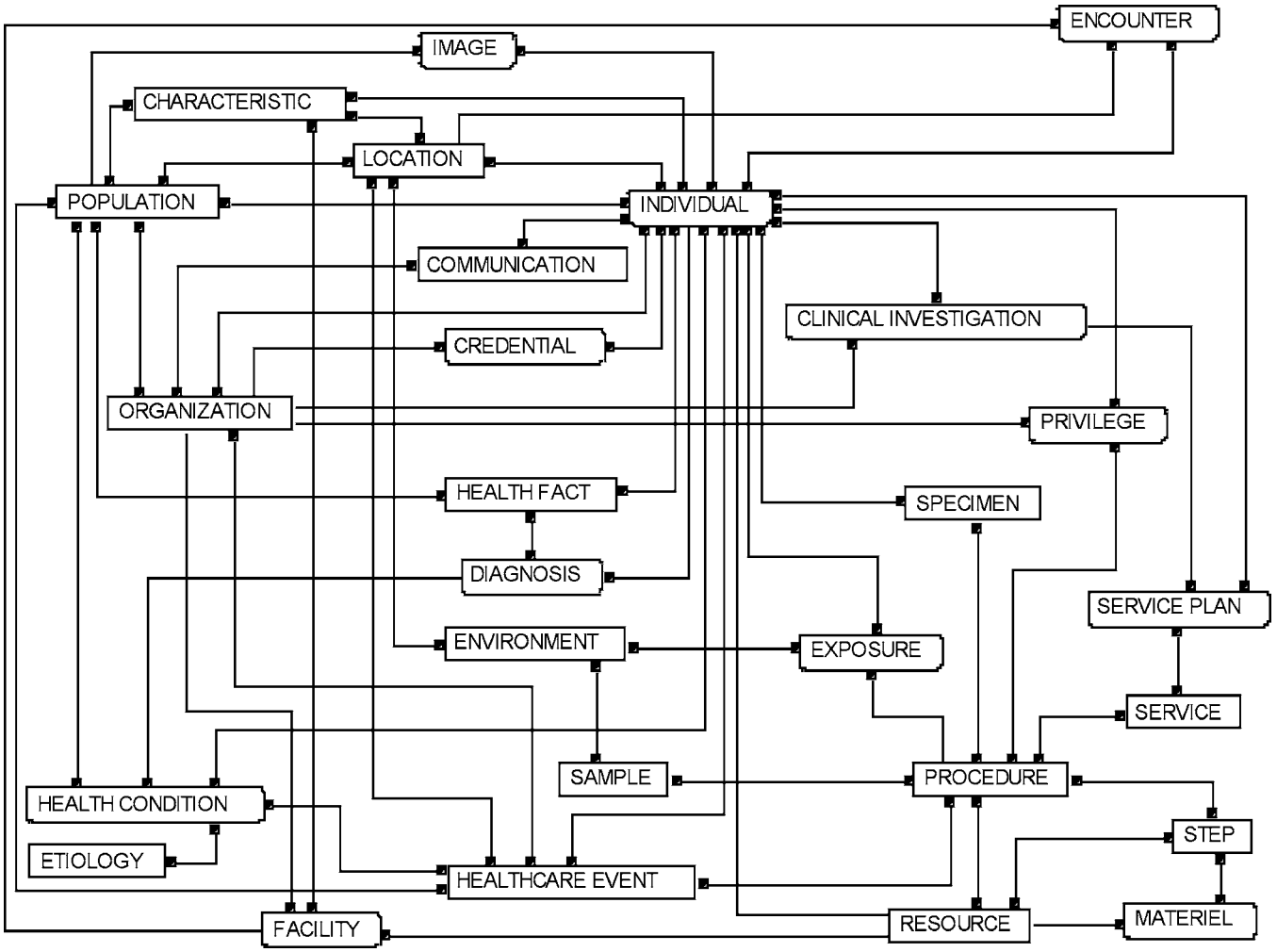

FIG. X2.1 ADA Clinical Concept Data Model (ADA 1039)

ORGANIZATION:
Organization
Healthcare Enterprise
Healthcare Provider
Employer
Customer
Vendor

FACILITY:
Healthcare Treatment Facility
Location
Work Location
Facility Bed
Facility Schedule
Pharmacy

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

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
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

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

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	**CCDM Object**
ORGANIZATION Organization Name Organization Address Region Identifier Organization Phone	ORGANIZATION
HEALTHCARE ENTERPRISE ADA 1000.5 Healthcare Enterprise Identifier (NPI) Healthcare Enterprise Name	ORGANIZATION
HEALTHCARE PROVIDER Healthcare Enterprise Identifier ---------->ORGANIZATION Healthcare Identifier (NPI) Healthcare Enterprise Name Healthcare Category---------->HEALTHCARE CATEGORY	ORGANIZATION
HEALTHCARE PROVIDER ADA 1000.5 **Provider/Practitioner Name** Provider Address	

Provider Taxonomy Category
Provider ID
Provider Agency ID

EMPLOYER — ORGANIZATION
Employer ID----------->ORGANIZATION
Number of Employees
Commercial segment----------->STANDARD INDUSTRIAL CODE

CUSTOMER — ORGANIZATION
Customer ID
Organization----------->ORGANIZATION
Individual Contact----------->PERSON

VENDOR — ORGANIZATION
Vendor ID
Organization----------->ORGANIZATION

FACILITY

Data Object	**CCDM Object**
HEALTHCARE TREATMENT FACILITY	FACILITY
HEALTHCARE TREATMENT FACILITY ADA 1000.6	
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
Individual Identifier (Multiple)
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
Patient Home Address
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
Practitioner Name ---------->PERSON
Practitioner National Provider ID
Practitioner Profession, Occupation, Specialty------>OCCUPATION
Practitioner Address
Practitioner Electronic Signature

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	
Family Member Relationship	
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	
Patient Name----------->PERSON	
Consent Signed/Admit Agreement	
Patient Rights Acknowledgement	
Directive to Physician	

PERSON RECORD LOCATION — INDIVIDUAL
Person---------->PERSON
Record Location ID
Date of Earliest Entry
Date of Latest Entry

RECORD RELEASE INSTANCE — INDIVIDUAL
Release of Information Datetime
Type of Information Released
Person Releasing

ORGAN/TISSUE DONOR AGREEMENT — RESOURCE
Segment II: Legal Agreements
Patient Name---------->PERSON
Consent Signed/Admit Agreement
Patient Rights Acknowledgement
Directive to Physician

RESEARCH STUDY AGREEMENT — RESOURCE
Patient Name---------->PERSON
Datetime of Agreement
Text of Agreement

PATIENT SUBSCRIBER RELATIONSHIP — RESOURCE
Patient Name---------->PERSON

RELEASE OF INFORMATION REQUEST — RESOURCE
Patient Name---------->PERSON
Type of Action
Type of Information

RECORD RELEASE INSTANCE — RESOURCE
Patient Name---------->PERSON
Release of Information Datetime
Type of Action
Type of Information Released
Person Releasing
Purpose of Release
Released to
Person Authorizing

GUARDIAN — INDIVIDUAL
Patient Name---------->PERSON
Guardian Name---------->PERSON

Segment III: Financial
PAYMENT SOURCE — RESOURCE
Patient Name---------->PERSON
Payment Source
Payer Group No
Payment Sponsor
Address of Sponsor

STAKEHOLDER — INDIVIDUAL
Stakeholder Name---------->PERSON

STAKEHOLDER ROLE — INDIVIDUAL
Stakeholder---------->STAKEHOLDER
Stakeholder Role ID---------->ROLE

STAKEHOLDER IDENTIFIER — INDIVIDUAL
Stakeholder ID
Stakeholder Name---------->STAKEHOLDER

EPISODE — ENCOUNTER
*EPISODE OF CARE: [ASTM: Healthcare Episode, RIM 0.87: EPISODE]
Patient Name---------->PERSON
(Episode_Identifer_id) — 14001.A0031
Description
Episode_type_cd
list_closed_in
Outcome_txt
Recurring_service_indicatior

HEALTHCARE FACILITY ENCOUNTER ADA 1000.8 — ENCOUNTER
Datetime of Encounter
Encounter Patient---------->PATIENT
Name of Facility of Encounter---------->HEALTHCARE ENTERPRISE

Encounter ID
Encounter status
Type of Encounter
Reason for Visit
Patient Chief Complaint
Problem ID (M)
Encounter status
Comments

HEALTHCARE FACILITY ENCOUNTER RECEIPT — ENCOUNTER
Encounter ID----------> HEALTHCARE FACILITY ENCOUNTER
Facility Type

Type of Encounter

Confidentiality Status

Episode ID
Mode of Injury
Nature of Injury
Chief Complaint
Health Condition/Problem ID (M)---------->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
Disposition
Disposition Date time
Disposition Destination
Patient Instructions
Disposition Note
Disposition Note Signature
Encounter Charges
Disposition Type
Followup Action
Followup target date

DISPOSITION DIAGNOSIS — ENCOUNTER
Disposition Diagnosis Name---------->DIAGNOSIS
Diagnosis Type

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
Practitioner Electronic Signature

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 Rum 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
Datetime of Test (Multiple)
Clinical Order ID---------->CLINICAL ORDER/SERVICE REQUEST
Name of Requested Test---------->MEASUREMENT
Test Ordering Facility---------> HEALTHCARE TREATMENT FACILITY
Test Ordering Practitioner---------> HEALTHCARE PRACTITIONER
Test Performing Facility---------> WORK LOCATION
Test Performer---------> LABORATORY WORKER
Datetime Result Reported
Test Report Text (for Textual Reports)
Interpretation
Microorganism Requested (M)
Microorganism Attribute (M)
Microorganism Comments
Test Comments

RESULT OF PROCEDURE/OBSERVATION — HEALTH FACT
Patient Name---------->PERSON
Datetime of Test (Multiple)
Clinical Order ID---------->CLINICAL ORDER/SERVICE REQUEST
Name of Requested Test---------->MEASUREMENT
Analyte/Measurement/Observation Name (M)------->MEASUREMENT
Analyte/Measurement/Observation Value
Analyte/Measurement/Observation Unit of Measure------>UNIT OF MEASURE

Health Condition

PROBLEM/HEALTH CONDITION — HEALTH CONDITION
Segment V: Health Condition/Problem ADA 1000.14 — HEALTH CONDITION
Patient ID---------->PATIENT
Health Condition/Problem ID
Health Condition/Problem Name---------->HEALTH CONDITION
Health Condition/Problem Time of Onset
Health Condition/Status
Etiology---------->ETIOLOGY

DIAGNOSIS — DIAGNOSIS
RECEIPT DIAGNOSIS
Patient ID---------->PATIENT
Encounter ID---------->HEALTHCARE FACILITY ENCOUNTER
Health Condition/Problem ID---------->PROBLEM/HEALTH CONDITION
Encounter Receipt Diagnosis---------->DIAGNOSIS
Encounter Receipt Health Status

Segment X: Clinical Orders ADA CONCEPT MODEL: COMMUNICATION

CLINICAL ORDER/SERVICE REQUEST — SERVICE PLAN
Patient ID---------->PATIENT
Clinical Order ID
Encounter ID---------->HEALTHCARE FACILITY ENCOUNTER
Clinical Order Datetime
Clinical Order Full Text

MEDICATION
Segment XII Medications — SERVICE
Patient ID---------->PATIENT
Datetime of Medication Clinical Order/Prescription

Encounter ID---------->HEALTHCARE FACILITY ENCOUNTER
Medication Name---------->DRUGPRODUCT
Prescription Number
Prescriber ID---------->HEALTHCARE PRACTITIONER
Prescriber Location---------->LOCATION
Problem ID---------->HEALTH CONDITION
Reason for Administration
Status of Prescription/Order
Dose
Unit
Form
Route
Frequency
Medication Administration Device
Medication Administration Method
Interval/Frequency
Instructions for Use
Total doses prescribed/refill
Number of Refills
Date of Refill (M)
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
Treatment Plan ID
Treatment Plan Description
Health Condition/Problem ID---------->HEALTH CONDITION/PROBLEM
Treatment Plan Phase (M)
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 — HEATHCARE 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	RESOURCE
SERVICE [ADA 1000.16]	
Service Identifier	
Service Term	
Service Type	
Service Description	
SERVICE REQUISITION	RESOURCE
Stock Item	
STOCK ITEM	MATERIEL
Stock Item Product ID	
Stock Item Name	
Manufacturer	
Manufacturer ID----------->MANUFACTURER	
Manufacturer Name	
Product ID (M)	
Public Health Agency	ORGANIZATION
Public Health Agency Organizational ID---->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	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	
WORK SHEET	HEALTHCARE EVENT

FISCAL

Data Object	**CCDM Object**
ACCOUNT	RESOURCE
Account ID	
ACCOUNT RECEIVABLE	RESOURCE
Billing Account ID	
PATIENT ACCOUNT	RESOURCE
Billing Account ID	
Medicare Number	
Medicare A effective Data	
Medicare B effective dat	
Medicaid Number	
GUARANTOR	INDIVIDUAL
*GUARANTOR Role:[ASTM/RIM 0.87;GUARANTOR; X12N SUBSCRIBER]	
financial_class-id	
household_annual_income_amt	00778
household size_qty	00779
| Contract Amount	00156
| Contract Code	00154
| Contract Effective Date	00155
| Contract Period	00157

| Interest Code	00158
| Household size_qty	
| Household_record_amt	
HEALTHCARE BENEFIT PLAN	RESOURCE
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	
termination_dttm	
INSURER	ORGANIZATION
Insurer ID	
Insurer Name----------->ORGANIZATION	
INSURANCE COVERAGE	RESOURCE
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	
ACCOUNT PAYABLE	RESOURCE
Account_id----------->ACCOUNT	00236
BILL FOR SERVICES	RESOURCE
BILLING_INFORMATION_ITEM [RIM 0.87]	
Bill Id	
Vendor ID----------->VENDOR	
Purchase Order ID----------->PURCHASE ORDER	
Condition_cd	00563/00541/00555
Occurance_cd	0545/00559
occurance_dt	00559
occurance_span_cd	00542/00546/00560
occurance_span_from_dt	0543/00547/00560
occurance_span_through_dt	00544/00548/00560
Quantity_amt	00532
Quantity_type_cd	
Value_amt	00539/00558
Value_cd	00539/00558
BILLING ACCOUNT	RESOURCE
PATIENT_BILLING_ACCOUNT [RIM 0.87]	
account_id----------->ACCOUNT	00236
Patient ID----------->PATIENT	
adjustment_cd	00731
authorization_information	00439
billing_status_cd	00457/00171
certification-required_ind	00505
current_unpaid_balance_amt	00176
delete_dt	00165
deleted_account_reason_cd	00164
expected_insurance_plan_qty	
expected_payment_source_cd	
notice_of_admission_dt	00449
notice_of_admission_ind	00448
patient_financial_caps_cd	
price_schedule_class	00151
purge_status_cd	00717
purge_status_dt	00718
report_of_eleigibility_dt	
retention_ind	
signature_on_file_dt	00729
special_progr_cd	00719
stoploss_limit_ind	00808
suspend_charges_ind	00806
total_adjustment_amt	00178
total_charge_amt	00177
total_payment_amt	00179
HEALTHCARE CLAIM	RESOURCE
CLAIM: [X12N]	RESOURCE

Claim Id
Patient ID---------->PATIENT
datetime type code
diagnosis_related_group_code
discharge_percent
frequency_code
from_datetime
identification_number
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) Chen, P., *ACM Transactions in Database Systems Research*, 1976.
(7) Moore, J. W., *Software Engineering Standards: a Users Road Map*, IEEE, Washington, DC, 1998.
(8) Young, D. C., Nipper, H., and Hicks, J., and Uddin, D., *Clinician and Chemist: The Relationship of the Laboratory and the Physician*, AACC, 1979.
(9) *LOINC Users' Guide*, Regenstrief Institute, Inc., Indianapolis, IN.
(10) Forrey, A. W., McDonald, C. J., et al, *Clinical Chemistry*, Vol 42, 1996, pp. 81-90.
(11) HL7 Framework for Message Development, Health Level Seven Inc., Ann arbor MI.