ASTM INTERNATIONAL

Designation: E2538 – 06 (Reapproved 2011)

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

## 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.*

1.8 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

## 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 (Withdrawn 2017)[3]

E1340 Guide for Rapid Prototyping of Information Systems (Withdrawn 2017)[3]

E1384 Practice for Content and Structure of the Electronic Health Record (Withdrawn 2017)[3]

E1578 Guide for Laboratory Informatics

E1633 Specification for Coded Values Used in the Electronic Health Record (Withdrawn 2017)[3]

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 (Withdrawn 2017)[3]

E1744 Practice for View of Emergency Medical Care in the

---

Electronic Health Record (Withdrawn 2017)[3]

E1762 Guide for Electronic Authentication of Health Care Information (Withdrawn 2017)[3]

E1869 Guide for Confidentiality, Privacy, Access, and Data Security Principles for Health Information Including Electronic Health Records (Withdrawn 2017)[3]

E1985 Guide for User Authentication and Authorization (Withdrawn 2017)[3]

E1986 Guide for Information Access Privileges to Health Information (Withdrawn 2017)[3]

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 (Withdrawn 2017)[3]

E2066 Guide for Validation of Laboratory Information Management Systems (Withdrawn 2015)[3]

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 (Withdrawn 2017)[3]

E2147 Specification for Audit and Disclosure Logs for Use in Health Information Systems (Withdrawn 2017)[3]

E2171 Practice for Rating-Scale Measures Relevant to the Electronic Health Record (Withdrawn 2017)[3]

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

---

[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.

Data Interchange-Coding Methods and Principles

ISO 12200 Computer Applications in Terminology—Machine-Readable Terminology Interchange Format (MARTIF)—Negotiated Interchange

ISO 12620 Computer Applications in Terminology—Data Categories

ISO IS 12207 Information Technology—Software Life Cycle Processes

ISO IS 15188 Project Management Guidelines for Terminology Standardization

ISO 15189 Quality Management in the Clinical Laboratory

ISO DIS 15193 Measurement of Quantities in Samples of Biologic Origin—Reference Methods

ISO DIS 15194 Measurement of Quantities in Samples of Biologic Origin—Reference Materials

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 [Multi-purposeInternet 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.

---

[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.

3.2.3 *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.

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

**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 |

pharmacotherapy shall be placed into the broader context of this practice and linked to CLSI LIS-9A. Thus, this practice should be used to first organize the global domain and then the interconnected subdomains.

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

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

**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 |

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 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

---

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

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
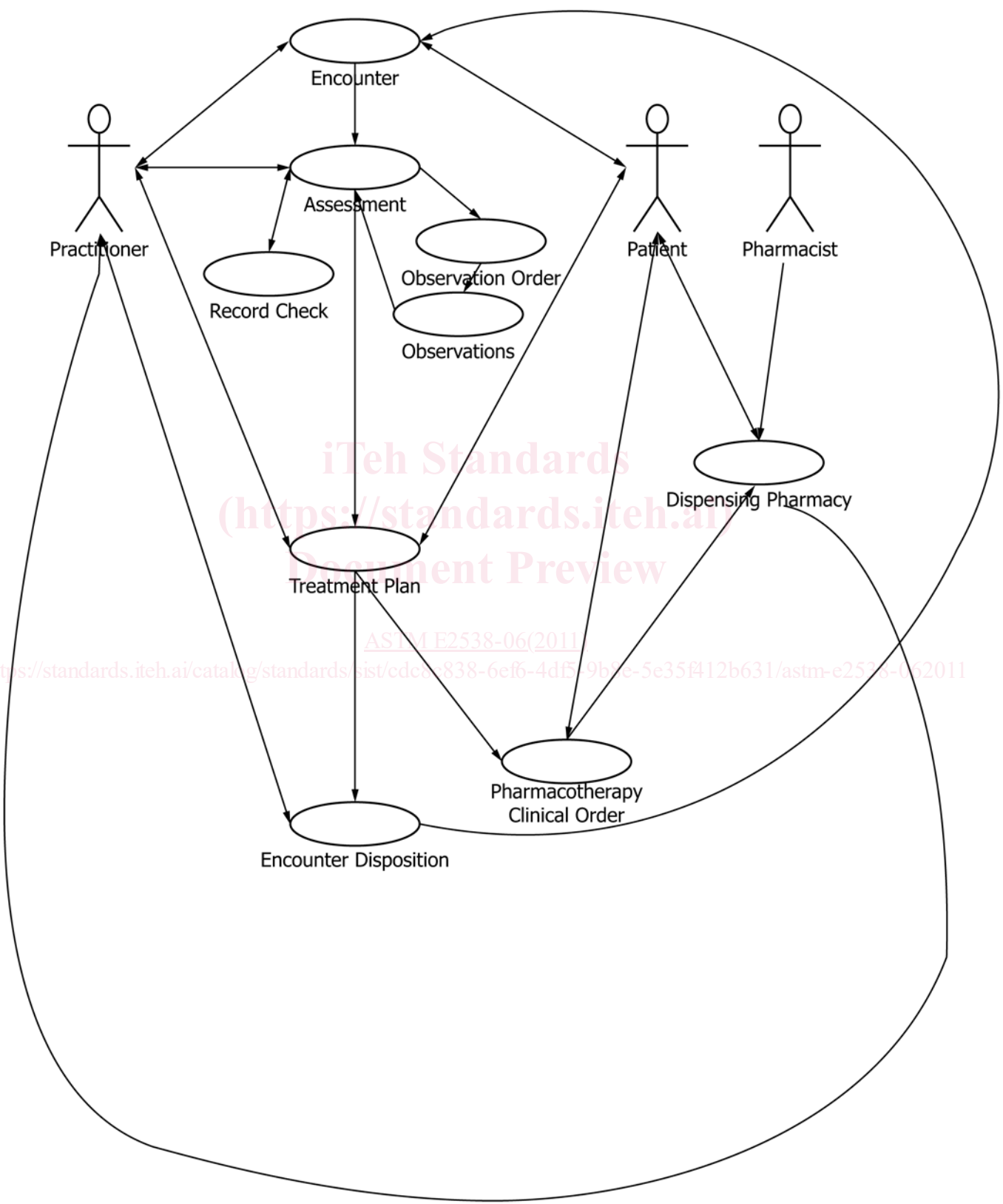
7

# Basic Pharmacotherapy
## Scenario



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

will probe the perspectives of the practitioners in some of the settings of care that will require pharmacotherapy information support. Privacy, Confidentiality and Security Concerns given in Guides 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

11