Designation: E1384 – 07 (Reapproved 2013)

An American National Standard

Standard Practice for Content and Structure of the Electronic Health Record (EHR)[1]

This standard is issued under the fixed designation E1384; 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 covers all types of healthcare services, including those given in ambulatory care, hospitals, nursing homes, skilled nursing facilities, home healthcare, and specialty care environments. They apply both to short term contacts (for example, emergency rooms and emergency medical service units) and long term contacts (primary care physicians with long term patients). The vocabulary aims to encompass the continuum of care through all delivery models. This practice defines the persistent data needed to support Electronic Health Record system functionality.

1.2 This practice has four purposes:

1.2.1 Identify the content and logical data structure and organization of an Electronic Health Record (EHR) consistent with currently acknowledged patient record content. The record carries all health related information about a person over time. It may include history and physical, laboratory tests, diagnostic reports, orders and treatments documentation, patient identifying information, legal permissions, and so on. The content is presented and described as data elements or as clinical documents. This standard is consistent with eXtensible Markup Language (XML). See Document Type Definition (DTD) 2.1 and W3CXML Schema 1.0

1.2.2 Explain the relationship of data coming from diverse sources (for example, clinical laboratory information management systems, order entry systems, pharmacy information management systems, dictation systems), and other data in the Electronic Health Record as the primary repository for information from various sources.

1.2.3 Provide a common vocabulary for those developing, purchasing, and implementing EHR systems.

1.2.4 Provide sufficient content from which data extracts can be compiled to create unique setting "views."

1.2.5 Map the content to selected relevant biomedical and health informatics standards.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E1238 Specification for Transferring Clinical Observations Between Independent Computer Systems (Withdrawn 2002)[3]

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

E1633 Specification for Coded Values Used in the Electronic Health Record

E1639 Guide for Functional Requirements of Clinical Laboratory Information Management Systems (Withdrawn 2002)[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

E1769 Guide for Properties of Electronic Health Records and Record Systems

E2118 Guide for Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures (Withdrawn 2002)[3]

E2369 Specification for Continuity of Care Record (CCR)

E2473 Practice for the Occupational/Environmental Health View of the Electronic Health Record

E2538 Practice for Defining and Implementing Pharmacotherapy Information Services within the Electronic Health Record (EHR) Environment and Networked Architectures

HL7

2.2 *Other Health Informatics Standards:*

HL7 Health Level Seven (HL7) Version 2.2 1994[4] (Version 2.4 and 2.5)

NCPDP National Council for Prescription Drug Programs

[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 April 15, 2013. Published April 2013. Originally approved in 1991. Last previous edition approved in 2007 as E1384 – 07. DOI: 10.1520/E1384-07R13.

[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.

[3] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from HL7, Mark McDougall, Executive Director, 900 Victors Way, Suite 122, Ann Arbor, MI 48108.

***A Summary of Changes section appears at the end of this standard**

(NCPDP) Telecommunication Standard Format Version 3 Release 2, 1992[5]
ANSI ASC X12: Version 3, Release 3 (1992)[6]
X12.84 Healthcare Enrollment and Maintenance Transaction Set (834)[7]
X12.85 Healthcare Claim Payment Transaction Set (835)[7]
X12.87 Healthcare Claim Transaction Set (837)[7]

2.3 *ANSI Standards:*[7]
HL7 EHR TC Electronic Health Record-System Functional Model, Release 1 February, 2007
Health Information Management and Technology: Glossary, American Health Information Management Association, 2006

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *admitting diagnosis*—a provisional description of the reason why a patient requires care in an inpatient hospital setting.

3.1.2 *ambulatory care*—preventive or corrective healthcare services provided on a nonresident basis in a provider's office, clinic setting, or hospital outpatient setting. The term ambulatory usually implies that the patient has come to a location and has departed that same day. (Ambulatory care includes medicine such as acupuncture, specialty clinics for consultation services and retail care centers used for short term immediate services.)

3.1.3 *ancillary service visit*—appearance of an outpatient in a unit of a hospital or outpatient facility to receive service(s), test(s), or procedures; it is ordinarily not counted as an encounter for healthcare services.

3.1.4 *clinic*—an outpatient facility providing a limited range of healthcare services, and assuming overall healthcare responsibility for the patients. See also *ambulatory care*.

3.1.5 *clinic patient*—a patient who is registered for the purpose of diagnosis or treatment or follow-up on an ambulatory basis.

3.1.6 *continuing care retirement community*—an organization established to provide housing and services, including healthcare, to people of retirement age.

3.1.7 *electronic health record (EHR)*—an electronic health record is any information related to the past, present or future physical/mental health, or condition of an individual. The information resides in electronic system(s) used to capture, transmit, receive, store, retrieve, link and manipulate multimedia data for the primary purpose of providing health care and health related services.

3.1.8 *emergency patient*—a patient admitted to emergency room service of a hospital for diagnosis and therapy requiring immediate healthcare services.

3.1.9 *emergency services*—immediate evaluation and therapy rendered in urgent clinical conditions, sustained until the patient can be referred to his or her personal practitioner for further care.

3.1.10 *encounter*—(*1*) the direct personal contact between a patient and a physician or other person who is authorized by state licensure law and, if applicable, by medical staff bylaws to order or furnish healthcare services for the diagnosis or treatment of the patient. (*2*) A contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment. Contact may be via an electronic visit.

3.1.11 *episode*—one or more healthcare services received by an individual during a period of relatively continuous care by healthcare practitioners in relation to a particular clinical problem or situation.

3.1.11.1 *episode of care (EOC reimbursement)*—a category of payments made as lump sums to providers for all healthcare services delivered to a patient for a specific illness or over a specified time period or both; also called bundled payments because they include multiple services and may include multiple providers of care.

3.1.12 *free standing ambulatory surgery center*—a) A free standing outpatient surgical facility is a separate facility that exists primarily to provide services in connection with surgical procedures that do not require inpatient hospitalization. b) An outpatient surgical facility that has its own national identifier; is a separate entity with respect to its licensure, accreditation, governance, professional supervision, administrative functions, clinical services, record keeping, and financial and accounting systems; has as its sole purpose the provision of services in connection with surgical procedures that do not require inpatient hospitalization; and meets the conditions and requirements set forth in the Medicare Conditions of Participation.

3.1.13 *health maintenance organization*—an organization that provides health coverage to voluntary enrollees in return for prepayment of a set fee, regardless of the services used.

3.1.14 *home health*—a) An umbrella term that refers to the medical and non-medical services provided to patients and their families in their places of residence. b) The provision of medical and non-medical care in the home or place of residence to promote, maintain, or restore health or to minimize the effect of disease or disability.

3.1.15 *hospice*—an interdisciplinary program of palliative care and supportive services that addresses the physical, spiritual, social and economic needs of terminally ill patients and their families.

3.1.16 *hospital*—an establishment with an organized medical staff with permanent facilities that include inpatient beds and continuous medical/nursing services and that provides diagnostic and therapeutic services for patients as well as overnight accommodations and nutritional services.

3.1.17 *hospital-based outpatient care*—a subset of ambulatory care utilizing the hospital staff, equipment, and resources to render diagnostic, preventive or corrective healthcare, or both.

[5] Available from NCPDP, 4201 North 24th Street, Suite 365, Phoenix, AZ 85016.
[6] Available from DISA (Data Interchange Standards Association).
[7] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

3.1.18 *inpatient admission*—the formal acceptance by a hospital of a patient who is to be provided with room, board, and continuous nursing service in an area of the hospital where patients generally stay overnight.

3.1.19 *intermediate care facility (ICF)*—an institution which primarily provides health-related care and services to individuals who do not require the degree of care or treatment which a hospital or skilled nursing facility is designated to provide, but who, because of their physical or mental condition, require care and services.

3.1.20 *length of stay (LOS)*—the total number of patient days for an inpatient episode, calculated by subtracting the date of admission from the date of discharge. If a patient is admitted and discharged on the same date, the LOS is one day.

3.1.21 *licensed practitioners*—an individual at any level of professional specialization who requires a public license/certification to practice the delivery of care to patients. A practitioner can also be a provider.

3.1.22 *longitudinal patient record*—a permanent, coordinated patient record of significant information, in chronological sequence. It may include all historical data collected or be retrieved as a user designated synopsis of significant demographic, genetic, clinical and environmental facts and events maintained within an automated system.

3.1.23 *long-term care*—healthcare rendered in a non-acute-care facility and to a patient in resident or nonresident status to chronically ill, aged, disabled or mentally handicapped individuals who are in need of continual supervision and assistance by healthcare practitioners.

3.1.24 *non-licensed practitioner*—an individual without a public license/certification who is supervised by a licensed/certified individual in delivering care to patients.

3.1.25 *outpatient care*—see *ambulatory care*.

3.1.26 *observation*—any aspect or attribute of a patient that can be described at a particular time. Examples include serum glucose finding, a chest x-ray impression, a bone density scan result, vital signs and a progress note.

3.1.27 *partial hospital program*—facilities of the hospital are regularly used on a scheduled basis for care during a substantial number of daytime or nighttime hours.

3.1.28 *patient health record*—the primary legal record documenting the healthcare services provided to a person, in any aspect of healthcare delivery. This term is synonymous with: medical record, health record, patient care record (primary patient record), client record, resident record. The term includes routine clinical or office records, records of care in any health-related setting, preventive care, life style evaluation, research protocols, special study records and various clinical databases.

3.1.28.1 *Discussion*—As the repository of information about a single patient, this information is generated by healthcare professionals as a direct result of interaction with a patient or with individuals who have personal knowledge of the patient (or with both). The record contains information about the patient and other individuals as they relate to the health of the patient, for example, family history, caregiver support.

3.1.28.1 *Personal health record*—An electronic or paper record of health information compiled and maintained by the patient or others for patient use (**1**) .

3.1.29 *patient record system*—the set of components that form the mechanism by which patient records are created, used, stored, and retrieved. A patient record system is usually located within a healthcare provider/practitioner setting. It includes people, data, rules and procedures, processing and storage devices (for example, paper and pen, hardware and software), and communications and support functions.

3.1.30 *primary diagnosis*—the diagnosis of the condition that is primarily responsible for the patient's symptoms and signs and has the greatest impact on the patient's health, or is the most resource-intensive to treat.

3.1.31 *principal diagnosis*—a statement of the condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care.

3.1.32 *provider*—a business entity which furnishes healthcare to a consumer; it includes a professionally licensed practitioner who is authorized to operate a healthcare delivery facility.

3.1.33 *referred (patient)*—registered exclusively for special diagnostic/therapeutic service of the hospital for diagnosis/treatment on an ambulatory basis. Responsibility remains with the referring practitioner.

3.1.34 *resident care facility*—a residential facility that provides regular and emergency health services, when needed, and appropriate supporting services on a regular basis.

3.1.35 *school special education*—specifically designed instruction provided by qualified teachers within the context of school, aimed at the acquisition of academic, vocational, language, social, and self-care skills. Includes adapted physical education and use of specialized techniques to overcome intrinsic learning deficits.

3.1.36 *secondary diagnosis*—a statement of those conditions coexisting during an encounter that affect the treatment received or the length of stay.

3.1.37 *secondary patient record*—a record that is derived from the record used by healthcare practitioners while providing patient care services and it contains selected data elements to aid non-clinical persons (that is, persons not involved in direct patient care) in supporting, evaluating, or advancing patient care. Patient care support refers to administration, regulation, and payment functions. Patient care evaluation refers to quality assurance, utilization review and medical or legal audits. Patient care advancement refers to research. These records are often combined to form what the committee terms a secondary data base (for example, an insurance claims data base).

3.1.38 *sheltered employment*—employment provided in a special industry or workshop for the physically, mentally, emotionally, or developmentally handicapped.

3.1.39 *short stay ambulatory care*—a patient admitted to the hospital for an intended stay of less than 24 h, considered to be an outpatient and not included in inpatient hospital census statistics.

3.1.40 *skilled nursing facility*—a long term skilled facility with an organized professional staff and permanent facilities that provides continuous nursing and other health related services.

3.1.41 *UB-92 uniform bill*—a standardized uniform billing form required by federal authorities for Medicare claims and is used as an industry standard. It replaces the 1992 (UB-92) version.

3.1.42 *vocational rehabilitation*—evaluation and training aimed at assisting a person to enter or reenter the labor force.

4. Significance and Use

4.1 *This Guide has Four Parts:*

4.1.1 The first part (Section 5) identifies items of information carried in the traditional paper record organized by the source oriented structures common to paper records. The purpose of this section is to remind users of the spectrum of information that shall be accommodated by the logical structure of a EHR and to present a point of reference for the more abstract description of the patient record that follows.

4.1.2 The second part (Section 6) presents a number of operational principles, including such matters as privacy and security that should guide the implementation and operation of EHRs.

4.1.3 The third part (Section 7) describes a logical data organization and content (common data model) of an EHR. It is not a blueprint for constructing or implementing a EHR system. The model presents an organization according to the major informational structures and content of the EHR. The focus is on the structure required to store all clinically relevant patient information: those that describe the patient's state; the actions directed at the patient variables; and the actions initiated to diagnose, educate, or treat the patient. These are regarded as repository functions of the EHR. This standard does not describe all of the data structures required by applications that might use information contained in the EHR. In particular, the data structures used to control and guide the process of care such as utilization review or quality assurance, and the goals or thresholds (for example, mean length of stay) that might be used to judge the patient's care are not included.

4.1.3.1 There are many different ways to implement physical structures that could map into the model presented. It is emphasized that this standard should neither impede technical progress nor define the precise manner in which the EHR system is implemented.

4.1.3.2 The focus of this guide is on the kinds of information that should be included and upon a global description of the organization of that data within the EHR. This guide does not deal in detail with issues related to charges and billing for patient care, only the documentation required to support usual charging and administrative issues.

4.1.3.3 This standard deals with the health information as it would be stored in the EHR, not as it would be sent as a message to or from the EHR. Pains have been taken to be sure that the information content from existing healthcare informatics messages that lie within the scope of the EHR can be mapped into the EHR structure. Where mappings are one-to-one, the EHR data elements have been cross referenced with the message fields. However, the EHR is not just a collection of messages. It makes stronger assumptions about the context in which it exists, so there is not perfect correspondence between the structure and content of messages on the one hand and the EHR on the other.

4.1.3.4 This guide applies across a range of scales. Though the ultimate goal is a EHR that spans the entire nation and the lifetime of an individual, the reality is that EHRs are mostly of much smaller scope (for example, within institutions, communities, or states) and these can be implemented much sooner. This standard is intended to apply equally to all scopes of time and place. Within the scope of a EHR, all master tables and code systems (for example, service catalog, patient registry, patient identifier) will be held in common. It denotes extensions of text content for document format standards and references standard XML designation for document section tags.

4.1.4 The fourth part (Sections 8, 9, 10) describes some alternative views (subsets of information presented in various orderings) of the content and proposes the minimum data elements contained in the EHR. What has been described as the "Longitudinal Health Record" (a very short précis of the patient's entire history) falls into this category. A set of "views" will serve as the user interface to the EHR for various customers. When all of the data is available in a EHR, providing different views of that data to satisfy various user needs and perspectives will be facilitated. Further, the kinds of views that are "required" and their dependencies (differing by institution, by specialty, by health/medical problem, by practitioner) will evolve over time. Section 10 is a repository of data elements to be used as an electronic health record data dictionary (Annex A1) **(2)**.

4.2 *General—Healthcare Documentation:*

4.2.1 A patient's health record plays five unique roles: (*1*) It represents that patient's health history, that is, a record of the patient's health states and the health services provided, over time. (*2*) It provides a method for clinical communication and care planning among the individual healthcare practitioners serving the patient. (*3*) It serves as the legal document describing the healthcare services provided. (*4*) It is a source of data for clinical, health services, and outcomes research. (*5*) It serves as a major resource for healthcare practitioner education.

4.2.2 Keeping complete and accurate records is an essential part of patient care management. Increasing specialization in healthcare and population mobility have increased the fragmentation of the traditional health record. The EHR offers a unified, coordinated, complete repository of patient health information. It includes such things as treatments, prescriptions, test results, diagnostic impressions, and significant genetic, environmental, and clinical healthcare data.

4.2.3 The person's health record consists of the original documentation of their health information and of the associated health and clinical services provided at the various care sites including the results of tests and outcomes of treatments. Each care site will require basic data that may be common to all care sites, data specific to that particular type of care site, and data unique to the individual care site.

4.2.4 The EHR serves all of the functions of the traditional record but has many advantages.

4.2.4.1 It solves the logistic problems of easy access to the paper health/medical record. Information can be concurrently accessed from multiple locations.

4.2.4.2 It will provide efficient communication of information to support coordination of services between care practitioners (See Specification E2369).

4.2.4.3 It calls for data content to be stored so that it links to automatic reminders and alerts to avoid errors of omission and commission.

4.2.4.4 By providing cross-patient retrievals it will provide the statistics needed by clinical, outcomes, health services and policy researchers as well as administrators and managers, to define better policies and practices to improve the healthcare process and make it efficient.

4.2.5 The longitudinal healthcare record, which is the brief synopsis of the significant facts derived from the primary documentation, can be constructed from views of the elements described here.

4.3 *The Role of Standards in Healthcare Documentation:*

4.3.1 Healthcare informatics standards are essential for an efficient and affordable EHR. Even within a single institution, much of the information that should be stored in the EHR will come from other electronic sources. Message standards are needed to ensure that this data can be transmitted from a source system and received and stored with a EHR without requiring human intervention. The need for information from other healthcare facilities (the hospital would like nursing home records when the patient is admitted and vice versa when the patient is discharged) is even greater. Finally, standard terminology, codes, and formats are the sine qua non for aggregating many EHRs for research and policy purposes.

4.3.2 The model for an EHR described here provides a general guideline that describes the data and data organization for an EHR and recommends minimal content requirements. It promotes common approaches to documentation. The model should be flexible enough to permit the storage of any kind of patient information deemed important by an individual provider, ensure that a minimum set of patient data is maintained, as well as information required by diagnostic and therapeutic services of the future.

5. Catalog of Health Record Contents by Source

5.1 This section describes the content of the current paper oriented record by source of data. The purpose of this section is to depict the full range of data that will compose the EHR but described in familiar terms.

5.2 Within the traditional record of care we find the kinds of information shown in Table 1. As Table 1 shows, many categories of information exist, and they can often be broken down into ever more detailed categories depending upon who collects the information and how it is to be used. For example, the physical examination can be broken down into the traditional categories, but subcategories may be possible and, indeed, required. For example, the physical exam of the eye might be recorded as a family of procedures or as a single unit. While one ophthalmologist might break the exams into many subcategories; for example, lid and exterior muscles, conjunctiva, cornea, anterior chamber, and retina; another might not. When more completely structured, the granularity of such exams can be very fine.

5.3 In the traditional record the degree of granularity (expressed detail level) and the degree of structure may vary considerably depending upon specialty, the particular provider, the clinical problem, the kind of care (hospital, office visit, nursing home). The spectrum runs from complete free text (some visit notes) to free text broken down by subheadings of differing degrees (standards formats) of granularity to fully structured data collection instruments (where all questions have multiple choice, coded, or numeric answers). But the degree of granularity can vary among structured data collection instruments, and free text may or may not be allowed as an "escape." Thus, the EHR must also accommodate varying degrees of granularity in the recording of the same clinical information within one patient's record.

5.4 *Structured Data versus Free Text*—It is important to distinguish between two main ways of recording patient information. Some is recorded as free text (for example, the dictated visit note) and some structured data, that is, the information is broken into discrete data elements (single concept types) and the value(s) of each data element is recorded as discrete values (that is, terms codes, or surrogate codes such as multiple choice responses) or number values (for example, laboratory test results). Practically, the computer can "understand" structured data because it has a defined context, but it cannot easily understand free text because it has to determine a context. However, the computer can "process" free text and convert it into a structured form. Encoders that convert free text diagnostic phrases to specific ICD9-CM or CPT codes are examples. Professionally trained coders provide quality oversight of encoders.

5.5 Further complicating matters is the great variation among institutions, specialties, and practitioners in the degree to which they record patient information as free text versus structured responses. Some test results may be represented as structured. However, a formal standard for a fully structured representation for lab reports is complex and continues to be under development.

5.6 In some hospitals nursing notes are highly structured, with many separate questions calling for multiple choice options for recording patient's status; in other hospitals the notes are pure text. Major portions of obstetrical histories are recorded on multiple choice instruments in some institutions, as free text in others, and many of these documents originate in the physician's office. Radiologists break their reports of X-ray studies into description and impression, both of which are recorded as free text. Echocardiograms are usually reported as a set of discrete measurements (for example, left ventricular diameter, ejection fraction for echocardiograms).

5.7 There are many reasons for preferring structured to free text observations. (At the very least, the impressions of imaging studies diagnosis reported at visits and surgeries should be reported in structured forms.) However, rigorous structuring imposes time cost on the observer. In particular,

when reporting a patient's perceptions, anxieties, or other conversationally acquired information, it is impossible to predict what will be said. Forcing such information into a predetermined structure may degrade the richness of the content and could lead to erroneous interpretation of meaning. In some areas traditionally handled through free text, history and physical examinations, hospital discharge summaries, etc., standards are being developed to apply structure (formats). Yet, these areas are just underway. Given historical preferences, and the mass of existing free text information, the EHR must accommodate both structured and free text reporting for the foreseeable future. It may even have to accommodate structured or free text values, or both, for the same variable, depending upon who does the recording. In addition, the EHR must accommodate information from outside sources, such as lab work from a pervious admission at another facility. Free text processing is available through several approaches. The encoding of text into machine codes has been one approach. Term analysis, internal coding, and pattern mapping for clinical fact extraction also can be done. This area is in rapid development and should be monitored for application to EHR systems.

TABLE 1 Contents of the Traditional Patient Record

Category	Subcategory	Examples and Components
Patient registration information	Identifying information	Sex, birth date, race
	Locating information	Home address, home phone, work phone
	Insurance information	Name of plan
	Guarantor information	...
Patient problem list	...	Problem number
		Problem name
		Date of onset, status
Patient extended encounters	Hospitalization admission records	Insurance information (for current encounter), guarantor information (for current encounter), chief complaint, diagnoses, clinical variables (observations, tests, measurements), final diagnosis/problem, corrections to registration information, procedures performed, etc.
	Practitioner hospital notes	
	Practitioner visit notes	
	Home healthcare notes	
	Hospital discharge summary	
Encounters	Office/clinic visit	
	Home healthcare visit	
	Practitioner visit within extended stay	
	Emergency room visit	
Patient care plans	Clinical roadmaps	Assessment data
	Chronic disease management	Plans delineating therapy, education, scheduled appointments
	Plans for specific patient problems	
Orders	Medication orders/prescription	
	Test orders (Lab Tests)	(both continuing orders, for example, Hgb QAM, and point orders, for example, glucose stat)
	Diet orders	
	Other treatment orders	
	Physical therapy order	
	Occupational therapy order	
	Respiratory therapy order	
	Nursing treatments order	
	Other observation orders	
	Nursing observations (also independent of orders)	
	Consults (to variety of clinical specialists)	
	Nursing interventions	
Service Instances	Confirmation of receipt of orders	
	Documentation of completion of each step of process (for example, MAR report)	
Procedures	Surgical procedure	Pre-procedure orders, pre-operative diagnosis, procedure identifier, provider(s) performing procedures, permissions for procedure, procedure note, duration of procedure, medication used, immunizations, complications, final diagnosis, post-operative orders, after care plans
	Outpatient procedures	
	Invasive diagnostic studies	
	Bedside procedures	
	Imaging studies	Thyroid scan, chest X-ray, cardiac echoes, OB ultrasound, vascular dopplers, cardiac catheterizations
	Physiologic tracings	EEGs, EKGs, prenatal monitors, cardiac monitors
	Other special studies	Glaucoma fields, pulmonary function, sleep studies
	Practitioner notes	Physicians', nurses', physical therapists', etc., notes
	Provider discrete observation	Blood pressure, heart rate, skin fold thickness, eye tonometry, infant's head circumference
	Identifying information	Patient's name and identifying number
	Health history	Chief complaint

TABLE 1 *Continued*

Category	Subcategory	Examples and Components
		Source of history
		Present illness
		Family Hx
		Social Hx
		Functional status Hx
		Travel Hx
		Occupational Hx
		Childhood disease Hx
		Surgical procedures Hx
		Allergy Hx
		Medication Hx
		Review of systems
		Smoking Hx total
		Smoking Hx current, etc.
	Physical exam	General status Px
		Vital signs Px
		Skin Px
		Head Px
		Eyes Px
		Ears Px
		Nose Px
		Mouth/throat/teeth Px
		Thorax/lungs Px
		Breasts Px
		Heart Px, etc.
	Lab Data	
	Toxic exposures	
	Nursing assessments	
Legal documents		
	Surgical releases	...
	Organ donor permissions	
	Advance directives (release of documents)	
Schedules (surgery/clinic, etc.)	Requests for resource	Send patient to eye clinic
	Assignment of resource	
	Documentation of delivery to resource and return	
Supplies and equipment	Consumables (4×4's)	...
	Attachments	

6. Operational Considerations

6.1 Operational aspects that affect the record's structure and use need to be addressed in any approach to EHR development. These include: General Principles, Data Types, Identifiers, Initiation of the Record, Access to the Record, Essential Data Elements, Retention of the Record, and Referential or Master Tabular Data.

6.2 *General Principles*—In identifying and defining the general content and structure of the patient health record for the design of systems, certain operational principles apply.

6.2.1 Identify the patient health record as the main patient-specific clinical repository component of all health information systems and, as such, the primary repository source of all documentation of clinical care.

6.2.2 Establish standard minimal components of all patient records, and their content, in all healthcare delivery environments.

6.2.3 Accommodate compilation of data into views (synopses) of the patient care record, visits or episodes appropriate to each healthcare delivery setting, including a patient's personal health record, and which should be accessible locally and included in the unified longitudinal record.

6.2.4 Ensure that the standardized content conforms to the known health data standards.

6.2.5 Define the logical structure of the patient record which, when used for electronic health record systems, enables consistency in the data organization.

6.2.6 Specify data element definitions that conform to standard nomenclature and are mapped to related formally approved standards.

6.2.7 Identify and reference coding systems consistent with current health reporting retrieval, analysis, and reimbursement needs (See NCPDP, ANSI ASC X12, X12.84, X12.85, and X12.87).

6.2.8 Specify data security and confidentiality measures.

6.2.9 Identify the long-term and short-term clinical value of the data elements contained in the patient health record.

6.2.10 Ensure a patient role in contributing all reported data as appropriate for EHR content development and outcomes assessment.

6.3 *Data Types*—Each of the data elements identified have representations of their data values that fit into a limited number of classes called data types. Consistent with HL7 standards and Specification E1633, these include person names, addresses, text, phone numbers, numeric values, dates and times and "coded" (terms and their surrogate codes from a variety of systems). Table 2 is a list of data types found in HL7. Coded values, particularly, point to referential master tables. In those tables, the term that is human understandable may have

TABLE 2 Data Types

Value	Description
AD	Address
CE	Coded entry (for example, Test Ids, Dx codes)
CK	Composit ID with check digit
CM	Composit miscellaneous
CNA	Composit ID and person name
CQ	Composit quality with units <number> ^ <units>
ID	Identifier
MO	Money
NM	Numeric
PN	Person name
RP	Reference pointer
ST	String for short text and numerics
TN	Telephone number
TS	Time stamp (date and time)
TX	Bulk text

a number of code values from different coding systems associated with it, including different languages. When communicating with other systems using messages, a coding system identifier and the code value for that term in the identified system must all be associated with the value for the data element of interest. The date-time data type permits varying degrees of granularity from day, hours to even decimal seconds; a time zone offset from Greenwich Mean Time can also be used. One of these values sets will be used for each data element defined. Messaging standards may require additional subtypes which will be defined within those standards.

6.4 *Identifiers*— Identification of persons (patients, practitioners) and places (healthcare facilities, locations, and workstations) is an important component of the data collection process. The original source healthcare location information shall be captured for each event of care by using provider identification elements that are established for each setting. Check digits for the provider and patient record number should be included (See Guide E1714).

6.4.1 *National Patient Health Identifier*—Each individual patient should be assigned a unique healthcare code number. Fields for the identifiers for blood relatives and, where appropriate, spouses (**3**)[8] should be included in the patient record to allow these related records to be found when appropriate. The number attributes should be unique, permanent, atomic (a single data item), concise, controllable, assignable, universal, unambiguous, used solely for healthcare and compatible with current standards. It shall provide protection of confidentiality and privacy.

6.4.2 *Identification of the Healthcare Setting*—The healthcare location and setting information shall be captured by using specific synopsis data sets (Specification E1633) that are pre-established for each setting. Information technology can be used to facilitate the recording of these data sets. The system shall be capable of receiving and storing this data regardless of the medium but in conformance with the standard HL7 and ASTM transfer format.

6.5 *Initiation and Construction of the Patient Health Record:*

6.5.1 *Registration/Reservation Establishing the Patient Health Record*—Patients must be registered into an established EHR system by capturing the demographic information which identifies the patient and opens a formal patient record (**4**). This information allows repeated and accurate identification of patients from one care setting to another and provides the link for additional healthcare information over time.

6.5.2 *Identification of Patients :*

6.5.2.1 The original source health care location information shall be captured for each event of care by using provider defined identification elements that are pre-established for each setting and stored as a longitudinal view of the original source record or transferred to a patient designated longitudinal health record system.

6.5.2.2 *Authentication of Data Entries*—All data entries will be authenticated by user identification, and date and time entries will be recorded automatically.

6.5.3 *Registration and Establishment of the EHR Record for Newborns*—At birth, a newborn record will be initiated as a patient health record. From the obstetric record of the mother the following data shall be transferred to the newborn's record:

6.5.3.1 Infant's full name,

6.5.3.2 Date of birth,

6.5.3.3 Sex,

6.5.3.4 Explicit identification of both parents,

6.5.3.5 Synopsis of abnormal prenatal findings and events,

6.5.3.6 Synopsis of perinatal abnormal events,

6.5.3.7 Genetic synopses of both parents, and

6.5.3.8 Significant socioeconomic facts on family circumstances.

6.6 *Access to Records*—Policies and procedures for access to electronic health records must comply with federal and state laws and be established within the organizational policy structure.

6.6.1 *Privacy of Patient Health Records*—Access to patient health records is controlled to maintain privacy. See Guide E1769 and other ASTM standards for confidentiality and privacy (**5**).

6.6.2 *Release of Records for Clinical, Administrative and Research Purposes*—Records shall be released for clinical uses that provide direct care services to patients in line with Health Insurance Portability and Accountability Act (HIPAA), state statute and appropriate consent policies and procedures. Administrative needs for patient data to be drawn from the electronic health record shall be processed within appropriate legal guidelines and established health facility patient data confidentiality and security programs. Research use of patient data which is drawn from the EHR shall be provided as aggregate, unidentified data whenever possible. Research projects which seek the use of identified patient data shall be reviewed by the appropriate committee of the organization and shall conform to the patient data confidentiality and security program guidelines. Automated systems shall provide the necessary checks needed.

6.7 *Essential Data Elements:*

6.7.1 Minimum data sets for descriptive purposes have been determined from the health records in major clinical settings and these have been previously published. They are:

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

6.7.1.1 Department of defense/composite healthcare system (**6**),
6.7.1.2 Uniform hospital discharge data set (**7**),
6.7.1.3 Basic ambulatory medical care data set (**1, 8**),
6.7.1.4 Minimum uniform data set for home care (**8**),
6.7.1.5 Minimum hospice data set (**9**),
6.7.1.6 Minimum data set for long-term care (**10, 11**),
6.7.1.7 Health record core data set (**4**),
6.7.1.8 Occupational health data set (**12**),
6.7.1.9 Emergency medical information data set (**12**),
6.7.1.10 Summarized health profile (**13**), and
6.7.1.11 The nursing minimum data set (**3**).

6.7.2 Recommended content of patient care records has also been developed and published by accrediting and certifying organizations and Medicare and Medicaid regulations. These include the Joint Commission on Accreditation of Healthcare Organization (JCAHO), the National Committee on Quality Assurance (NCQA) and others (**14, 5**).

6.8 *Retention of Records*—Patient health record retention criteria for both written and electronic records must be established to conform to the requirements of Federal and state statutes.

6.9 *Master Tables:*

6.9.1 A basic approach to defining EHR content is through master tables and data views. A master table is a list of variables that represent the range of attributes currently defined for a given subject. Table 3 is an example of an excerpt from a master table. Others are standard coding systems such as ICD9, a problem list directory, a catalogue of risk assessment questions organized as reference for patient reported status as well as short tables illustrated within this standard and discussed in Specification E1633. By using master tables we can provide both a short term and a long term approach to methodically addressing EHR content. By developing the master tables from these resources, users can apply the standard in diverse settings. Users would use this practice with the appropriate master tables to select standard recommended and optional vocabulary to define the EHR vocabulary in their organization. Overlap will occur among the tables. Master tables can be developed and refined as necessary. They also provide the means of proposing minimum content as well as the more detailed and comprehensive content by EHR areas. Master tables examples that reflect EHR content vocabulary are:

6.9.1.1 Complete patient health history variables,
6.9.1.2 Complete patient self reporting history questions catalogue,
6.9.1.3 Complete patient assessment/physical exam variables,
6.9.1.4 Patient self reporting functional status reporting items (for example, SF-36, Dartmouth 9),
6.9.1.5 Health outcomes variables,
6.9.1.6 Master table of vital signs variables,
6.9.1.7 Master table of instrument monitoring variables, and
6.9.1.8 Master table of laboratory tests, etc.

6.9.2 Tests, supplies and equipment have attributes when considered in the abstract (separately from results or use in a particular patient). These are attributes that would be listed in a catalogue of the available tests, supplies or equipment. The attributes of a test might be when it could be obtained, the preparation requirements for specimens, the price, the normal range, the units and so on. By maintaining a "catalogue" or definition table for items such as supplies, orders, observations and equipment, easy additions and extensions can be made. (New tests and observations can be created without having to redefine the universe, or rewrite programs.) More attributes can also be added to the item to give the universe of entities new behaviors with little or no effect on the previous version of the world. Most laboratory systems, pharmacy systems, billing systems, inventory systems and other systems that must deal with large numbers of discrete items use a general object, or file to carry context-insensitive attributes and "pointers," or indexes, to refer to the entry of interest. Tables are used by the long-surviving EHRs. For example, these attributes are now found in LOINC and SNOMED code systems.

6.9.3 An observation is a term that is used to mean any aspect of a patient that can be described at a particular time. It follows Allan Rector's idea of an observation (**15**) a serum glucose, a chest X-ray impression, a Glasgow coma score, each of the questions on a health or functional status, (for example, SF-36, D-9), a history of present illness, urine output and nurses notes are each an observation. An observation is an attribute of a patient, that is, an atomic unit or "chunk" in which clinical information is recorded. The observation, however, cannot stand alone. It has a context and general attributes that define that context that are independent of the particular patient's observation, such as: units of measure in which it is reported, its name and synonyms, its class, information about how it is grouped in reports or where it is stored and so forth. This context-independent data is stored in master tables. Tables accommodate different degrees of granularity and easily adapt to change. New entries are easily added to these tables since new concepts arise continually in patient care. It is again important to note that this document describes observations in an implementation independent fashion using a notation that depicts logical relationships but implies no implementation technique. Data element segments and grouping are used but other logical relationships could also be used. In any case master tables hold the context insensitive data

TABLE 3 Ophthalmology Exam Variables

Pupils	
OD pupil	OS cornea cannot be assessed
OS	OS shallow anterior chamber
	OS cornea cannot be assessed
Amsler Grid	
OD Amsler Grid	Anterior Chamber Findings
OS Amsler Grid	OD AC normal
	OD AC flare only
Corneal Examination	OD AC cells only
OD normal cornea	OD AC keratic precipitates
Guttata w/o edema	OD AC posterior synechiae
OD confluent guttata w/o edema	OD pupil mydriatis
OD corneal edema	OD pupil irregular
OD central corneal opacity	OD shallow AC
OD corneal dystrophy or degeneration	OD Transillumination defects, etc.

while the groupings of data elements deal with the context sensitive relationships that establish the observation's meaning.

6.9.4 When selected few observations are gathered in a particular setting, a simpler structure can be employed. For example, if a diabetes clinic wished to capture only 20 variables (for example, diastolic and systolic blood pressure, blood glucose, hemoglobin Alc, weight, pulse, foot lesions (present/absent) etc.) one record per visit might be created and specific fields defined for just those specific observations. A master term table would not be needed. But if other requirements arise, this approach is very rigid, limited and does not work well in the general case. A EHR may have 10 000, or more kinds of observations (there may be 5000 different laboratory tests that could be recorded, for example). Further, observations may be recorded multiple times by different providers during the same visit. The rigid structure cannot accommodate that situation.

7. The Overall Structure of the Electronic Health Record

7.1 The discussion of the structure of the EHR must relate the major entities (objects) of the record to the identified record segments. The clinical heart of the EHR is the core of the entities: patient, provider, problem, encounters, orders, services and observations. The record segments that relate to these entities are shown in Fig. 1. The focus of these relationships is the RADT object model, dealt with in Practice E1715 that provides the foundation for linking the entities in Fig. 1 to the detailed inventory of data elements given in Annex A1. Table 4 shows how the segments currently accommodate the entities.

7.1.1 Notice that most of the entities listed in Fig. 1 have their own attributes. For example, the patient has the attributes of sex, race, birth date, etc. Each order includes attributes that identify the item(s) ordered, the date of the order, the ordering provider, the urgency of the order (stat, now, routine, etc.), the ordering instructions can be further broken down into amount, frequency, duration, special conditions for many orders. These will all be presented in detail in Section 9.

7.1.2 For some of these entities, the industry has enough experience with them that the overall structure is well understood and easy to describe. In some information areas, especially those that are represented by free text in the traditional record, much is yet to be learned.

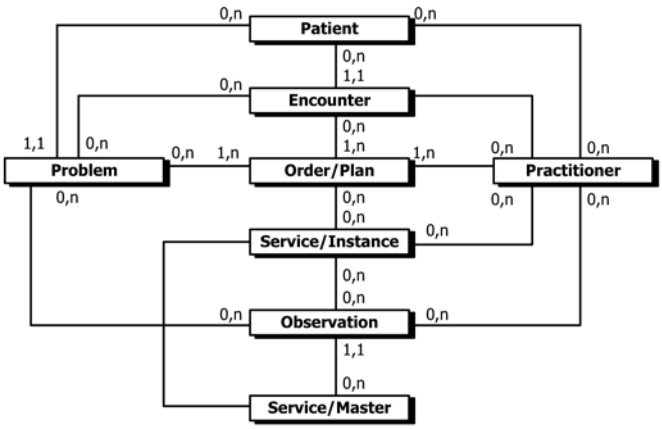

FIG. 1 Patient Record Object Model

TABLE 4 Patient Record Content Structure Data Categories, Segments and Entity Relationships

Data		Category and Segments	Entity
Administrative Data			
I		Demographics	Patient
II		Legal agreements	Patient
III		Financial information	Patient
IV		Provider/practitioner	Provider
Clinical Data: Problem/Diagnoses			
V		Problem list	Problem
Clinical Data: History			
VI		Immunization	Service instance
VII		Hazardous stressor exposure	Observation
VIII		Health history	Observation
Clinical Data: Assessments/Exams			
IX		Assessments	Observations
*		Patient reported data	Observation
Clinical Data: Care/Treatment Plans			
X		Clinical orders	Orders
Clinical Data: Services			
XI		Diagnostic tests	Observations
XII		Medications	Service instance
XIII		Scheduled appointment/ events	Encounter
Administrative Data: Encounters			
XIV	a	Administrative data	Patient
	f	Encounter disposition[A]	Encounter
Clinical Data: Encounters			
	b	Chief complaint/ diagnoses	Observation
	c	Clinical course	Observation
	d	Therapy/procedures	Service instance

[A] These are new concepts or reordered data, or both. Note that the clinical heart of the EHR is the core of the entities (Objects). The record segments that relate to these are shown.

7.2 *Perspective*—Representing the overall structure of the record is difficult since it is complex and has a number of dimensions. It also can be viewed from many perspectives. Four of these are: chronological, by encounter/episode, by problem, and by topic. Each of these views looks at the same stored data in a different way. There can be many perspectives and even more ways of displaying the same data. This guide must represent the complex storage structure in two dimensions. Therefore, in Appendix X1 several notational conventions are used. One of these is a "pointer" followed by a target segment or external master table. This allows data values in these tables to be referenced without clouding the basic structure being illustrated. These representations are not intended to imply implementation techniques but, rather, logical relationships. Another difficult task is that of representing the data needs of different settings in a manner that captures the diversity and complexity of the observations as they relate to service instances and requests. These aspects will be further expanded in the discussion of the appropriate segments.

7.3 *Segment Categories:*

7.3.1 In order to provide a comprehensive structure for the EHR record, it must be organized into major segments that are clearly identified and to which information can be consistently added from one setting and episode to another over time. The

segments were identified through analysis of the content of the existing data sets and each segment describes and represents a category or type of information that can be seen in all patient care records.

7.3.2 As noted in Table 4, these segments have been regrouped for a more universal understanding of administrative and clinical uses of the data. The following discussion deals with the essential data elements in each segment. The entire list is summarized in Appendix X1 and each element's attributes are detailed in Annex A1, which gives a definition and form of representation. These elements may be utilized in different constellations in different settings, but each element's meaning remains the same wherever it is used.

7.3.3 Segments 1 to 13 (see Table 4) contain elements that are widely used in all settings and apply to both patient record and the longitudinal précis regardless of setting. They are not specific to any one episode or encounter though they may be initiated or updated during an encounter. The way they reflect the relationships shown in Fig. 1 and Table 4 will be discussed in the following sections.

7.4 *Occurrence and Utilization of Record Segments in Different Settings*—Patient and client records across care sites include content in this model to some degree. Acute care, ambulatory care, long term care, home health care, emergency care and special alternative care settings all maintain legal patient or client records that contain required content consistent with this standard.

7.5 *Segment 1, Demographics*—These are personal data elements, sufficient to identify the patient, collected from the patient or patient representative and not related to health status or services provided. Some of these elements may require updating at each encounter or episode and must satisfy various national standards and regulations such as a Joint Commission Standard, conditions of participation for Medicare, uniform hospital discharge, ambulatory, and long term care data sets.

7.6 *Segment 2, Legal Agreements* —This includes data elements indicating legally binding directions or restraints on patient healthcare, release of information and disposal of body or body parts, or both, after death.

7.7 *Segment 3, Financial*—This segment contains the references to the financial bodies that will cover the cost of care. This segment may be referred to from within the record, as during encounters/episodes. Such reference would obviate the need for a redundant collection of such data during the visit.

7.8 *Segment 4, Provider/Practitioners :*

7.8.1 This segment contains in one place the descriptive data about each provider/practitioner and may then be referenced when recording data about the events of healthcare. This includes the provider identifying data on the primary organization, or establishment responsible for the availability of healthcare services for a specific episode or encounter.

7.8.2 Practitioner identifying data elements are those associated with the individuals licensed or certified to deliver care to patients, who had face-to-face contact with the patient, and provided care based on independent judgment.

7.9 *Segment 5, Problem List:*

7.9.1 This includes specified clinical problems, a diagnosis summary and stressor exposure, an ongoing list of clinically significant health status events and factors, resolved and unresolved, in a patient's life. This list should contain all past and existing diagnoses, pathophysiological states, potentially significant abnormal physical signs and laboratory findings, disabilities, and unusual conditions. Other factors such as social problems, psychiatric problems, risk factors, allergies, reactions to drugs or foods, behavioral problems or other health alerts may be included. The problem list is to be amended as more precise definitions of the problems become available. Controlled vocabulary for problem lists may be contained in a problem list directory master table.

7.9.2 This segment contains a master list of all of a patient's problems or diagnoses. It may be referenced, as noted in 7.18.2 in presenting the diagnostic summary beginning each encounter/episode. All problems or diagnoses initially recorded in a specific encounter/episode will also be entered in this master list. A permanent history of all problems associated with the patient should be maintained.

7.9.3 Whenever possible, identification of risk factors (health alerts) that should be known prior to implementing any health services should be included in this section. They can be considered to be instances of a special type of patient problem and include allergies, contagious conditions, and adverse reaction to specified treatments.

7.10 *Segment 6, Immunizations*—Considered a component of patient health history, this segment contains, chronologically, all immunizations administered to the patient and their current status. This synopsis may also be copied to an emergency record to accompany medical alert data. Acquired (active or passive) or induced immunity or resistance to particular pathogens produced by deliberate exposure to antigens is included.

7.11 *Segment 7, Exposure to Hazardous Substances:*

7.11.1 The what, where, when, and how data on actual or potential exposure to all biological, physical or chemical agents that might be associated with adverse health effects are listed in this segment. This segment should provide data for epidemiological studies to determine correlation of disease with exposure to environmental stressors.

7.11.2 Because of the potentially long latency period in exposure to hazardous substances before the appearance of effects, the chronological record of exposure—both in the workplace and out, where appropriate—to hazardous chemical, physical, biological, or radiological stressors to the body is contained in this segment. It has particular importance when accessed as part of the synoptic record because its completeness acts as a prompt to providers/practitioners long removed in time or space, or both, from the original entry that the signs and symptoms of health conditions may be due to previous exposure. Absence of such data does not rule out such exposure but presence provides direct clues needed to identify the possible causes of an observed condition.

7.12 *Segment 8, Family/Prenatal/Cumulative Health/ Medical/Dental Nursing History*—The long term relevant natural family and patient history and signs which would aid

practitioners in predicting or diagnosing illness, or actual or potential alterations in health, or predicting outcome of the patient's care are all the focus of this segment. The historic record of previous signs and symptoms complements the problem list in itemizing, in an integral way, the manifestations of prior disease, illness or health status not yet documented in the problem. It characterizes those already present in that list and it takes the form of a categorized list of questions of the form: "Have you ever_____<If so, when>" During each encounter/episode this list may be updated by the preface: "Since the last visit have you ever_____<If so, when>" so that the most recent observations can be added to the growing list. This integral process then collects the most reliable observations from the patient, (historically categorized in patient records) review of systems, and nursing history or other method, and adds them to the historic body of (at the time) freshly collected data. Ideally, this process begins during gestation and the initial observations are transferred from the mother's record to that of the newborn at birth. Fresh observations are added throughout the patient's lifetime. If continuity can be maintained, the practitioner need not have to reconstitute the early record at each encounter. Recommended and optional attributes of patient history are included in a master table.

7.13 *Segment 9, Assessments/Exams :*

7.13.1 Assessments/exams characterizes the patient's health status in tandem with the history. Depending upon the setting, this segment may include a general or specialty medical or dental exam or assessments by nursing, dietary, social service, therapy or dental hygiene specialists, or all of these. The assessments may be all-inclusive or may relate only to hands-on care of very special problems (that is, particular body systems, psychosocial assessment, dental, vision communication, etc.). All data pertinent to pre- and perinatal care including monitoring during delivery are also included in a post-delivery exam assessment. Details of the actual delivery for the newborn are to be entered in the specific section containing health factors of the neonate. Recommended attributes of assessments/exams are identified in master tables.

7.13.2 This segment records the observations of the practitioner during structured and systematic examinations of the patient's body during encounters/episodes. It contains objective observations and measurements that quantify attributes of each body system (See 5.2.22 of Specification E1633). These are the same body systems about which patient questions are asked during the history. Such common categories allow characterization of expressed problems with observational evidence in explicit common terms and measures that, over time, allow practitioners to follow the course of illness and recovery. This focuses on the physical assessment of the patient and is combined with appropriate psychosocial assessment to compose overall patient assessment status. These observations complement the diagnostic terms described in 7.15. They also relate to the effects of therapeutic interventions, such as medications, as described in 7.16.

7.14 *Segment 10, Care/Treatment Plans and Orders:*

7.14.1 Data entries that direct a patient's treatment includes detail data on deliverance of orders and compliance with any diagnostic or therapeutic treatment plans, whether written, oral or standing.

7.14.2 A care treatment plan may be a broad perspective program that identifies planned clinical encounters, education and scheduled events related to specific diagnosis or set of problems (for example, diabetes). It may also be a short term tool applied, for instance, in acute care or other setting that arranges interdisciplinary roles to carry out therapies, nursing services and other activities. While not always explicitly defined, care plans are typically based on protocols and guidelines. In some cases, they are developed via consensus.

7.14.3 A clinical order is an action-oriented message describing an intervention in the health of a specific patient originated by, or under the supervision of, an authorized practitioner. A clinical order has legal implications regarding responsibilities for the ordered intervention as well as quality of care implications that may be assessed by supervisory bodies or clinical researchers, or both. It is therefore necessary to specify the logical structure of this message and to define the representations to be used for each constituent data element. The clinical order acts also as a communication and coordination mechanism for all of the practitioner and ancillary professionals who may participate in the actions set in motion by the order. The clinical order structure is complex and may be thought of as a network structure because of the complexity of relationships between specific data elements within the clinical order and other data elements located elsewhere in the care record. Because this complex structure is difficult to represent by means of two dimensional paper forms, there is no explicit manual-mode model for this kind of data structure. Paper records have relied on plain text representations in recording the order. In practice these relationships among the data elements have been implicit in the inculcated practices of professional training. This guide attempts to explicitly define this structure.

7.14.4 Since a clinical order is a message, it has a heading and a body. The heading specifies the originator, the object patient, the routing and the addressee(s). The body contains a structure that is greatly dependent upon the action addressee but does have commonality across all types of orders. Since the message objective is a specific patient, it serves as the legal business record and the original documentation of all orders for that patient and is a designated part of the patient's care record. Other copies may be stored for use by the action or information addressees, as appropriate. A given clinical order may be more appropriately created by means of pre-existing templates, or sets of templates, that contain pre-assigned data.

7.14.5 The data elements in each order are in the following functional groups:

7.14.5.1 Those that identify the patient,

7.14.5.2 Those that identify the action or ancillary service,

7.14.5.3 Those that identify the orderer(s),

7.14.5.4 Those that control the timing or delivery of services, or both,

7.14.5.5 Those that describe the requested service and conditions of delivery,

7.14.5.6 Those that document the delivery of results, and

7.14.5.7 Those that are used for quality assurance.

7.14.6 The logical structure in Appendix X1 lists these data elements showing their structural relationships within the message and the data elements to which they may be related in other segments of the clinical record.

7.14.7 *Orderer Group of Data Elements*—The elements in this group provide a means of tracking the initiation and responsibilities for each order. At the same time, these steps must, many times, be started in the absence of a practitioner having adequate authority to fully initiate the procedure or service ordered. In hospitals, the actions of the nursing staff and health practitioner students or those in training may require review and validation by co-signing for services having major health or cost implications from the aspect of accountability. Institutional policy must provide the criteria for expeditious action in identifying services needing higher permission levels from the responsible staff; this two-tier approach allows actions to be initiated in a timely fashion but yet rescinded, if appropriate. Therefore, the data elements in this group identify the needed information applying to a wide variety of situations. Nevertheless, not all elements may apply in a given situation.

7.14.8 *Action/Ancillary Service Data Elements*—The elements in this group identify the action performers and the type and priority of the order.

7.14.9 *Order Content Data Elements*—This group of data elements conveys the explicit service/actions desired for the patient. It may include patient data extracted from other segments of the record, as required to conduct the services or to carry out the action. Each ancillary service or treatment site must be able to define the data which will be required in this group in order to be able to carry out the ordered actions. Such data requirements will be found in appropriate subordinate files and will control, by prompting, the construction of the text of the order to meet these requirements. Modifications to the order shall be appended to the original text while other data elements shall document the course of each modification.

7.14.10 *Result Group*— This group of data elements documents the delivery of the result data from the service or action, as appropriate, while the results themselves are stored separately in the appropriate segments of the record.

7.14.11 *Quality Assurance Group of Data Elements*—This group of data elements documents the circumstances of actions that are exceptions to the routine process for each ordered action or service. They assume that a process is evaluating the specific criteria for each clinical order in order to establish the regular bounds. Because healthcare must deal with the unexpected and the unusual, recording of events that are unusual because they are outside the bounds of routine experience in no way implies that they are not required for treatment. Rather, these data elements flag such events so that they can be easily recognized for review. That they were reviewed is also documented in order to ensure that significant findings are not overlooked.

7.14.12 *Orders and Alerts*—Clinical orders may be designed to interact with clinical decision support functions which generate alerts or reminders or both that offer interventions to the orderer by analyzing the order and comparing it to specific criteria such as patient physical status (for example, lab results), drug contraindications or other situations and notifying the provider so that a recommended modification may be considered. Specific data from CDS application may or may not be included in the record.

7.15 *Segment 11, Diagnostic Tests*—Significant details of tests performed aid the practitioner in the diagnosis, management and treatment of the patient. Documentation of the results from the clinical laboratory, radiology, nuclear medicine, pulmonary function and any other diagnostic examinations would be included. This segment contains the chronological list of all diagnostic tests ordered and conducted on the patient. The attribute data about each such test reference the order, problem list, appropriate physical exam or medication segments, or all of these that may relate to the monitoring of therapeutic interventions to either measure therapeutic effects or detect adverse affects. It should be remembered that the problem list, encounters and physical exam segments may, likewise, contain references to specific dates and types of tests that are associated with those problems, encounters or examinations and which help document the full implications of the meaning of such tests.

7.16 *Segment 12, Medications:*

7.16.1 A list of all long term medications and significant details on all medications prescribed or administered, or both, in the course of, or as a consequence of, an encounter or episode.

7.16.2 This segment contains data about the therapeutic chemical substances and treatments that have been prescribed as interventions in the disease process. All of the attributes of the order described in 7.14 are linked to this record by reference to the orders segment. Additional attributes provided by the pharmacist are also added to the record, including adverse affects reported in the history or the physical exam segments, or both. The problem list that identifies the problem being treated may also be referenced.

7.17 *Segment 13, Scheduled Appointments/Events*—This segment includes the list of planned or scheduled appointments that implement a treatment plan. It includes attributes that characterize the planned services, location and practitioners that constitute the plan.

7.18 *Segment 14—Encounters/Episodes :*

7.18.1 The concept of an encounter is usually defined to be a face-to-face session of the patient with a practitioner during which information about the patient's health status is exchanged. The encounter record should capture the facts relating to the events that took place—whether they occur in an inpatient setting or an ambulatory care environment. Certain information that characterizes the time, place and circumstances of the initiation of the encounter are first required. Then the information characterizing the patient's condition and reason for seeking care must be recorded. Next, the identification and characterization of the patient's problem(s), including referencing the encounter to the problem list must be included. Finally, the interventions ordered, the response to the actions performed, the departure condition and the required follow-up actions must be recorded, including a record of the

services rendered. Because the circumstances leading to an encounter may be as direct as inpatient rounds by the attending physician to emergency room care (for example, traumatically injured patients), the data collected in the encounter may vary from brief to extensive. The collected data may not include all data elements identified, if these elements are not applicable to a given encounter. The logical structure shown in Appendix X1, however, identifies the minimal essential data elements that may comprise the ambulatory portion of the encounter record.

7.18.1.1 A discussion of this segment must first explain that the pointer arrows leading from the identified data elements to a logical file mnemonic is intended to portray that element is represented in a lexicon. The lexicon has associated attributes that are not dependent upon the context of the term in the encounter record, and the recorded element is the index into this lexicon. This notation enables discussion of the complexity of interrelationships among data elements of the record that occur across and within segment boundaries. In order to reflect how the structure of the record parallels the practitioner's thought processes, these logical interrelations must be depicted using a generic convention and the data that are global to the individual encounter must be so identified in order to foster data independence wherever possible. This means avoidance of recording redundant data when that data are independent of the context. It also means using a key identifier or term to represent that invariant data which is stored in a logical list that can be referenced from within the context. This procedure avoids a common error in forms design in which specific instances, or data values, of a given data element are identified as separate data elements. A specific instance of a class name, for example, might be a specific drug or a unique lab test name. Use the above notation to convey membership in a lexicon name class.

7.18.2 *Segment 14A, Administrative/Diagnostic Summary:*

7.18.2.1 These are the data elements clarifying time/date, location, type and source of encounter or episode as they differ from information already contained in the related major segments (7.5 – 7.17). These should include the problems and the list of admitting and all other diagnoses which are a factor in the patients care during the specific episode or encounter and which should be added to the patient's problem list in 7.9.

7.18.2.2 This sub segment contains all of the data that characterizes the origin of the episode and the manner of arrival at the provider's facility, including the condition of the patient. It also summarizes the administrative conditions concerning the termination of treatment, excepting the disposition that is contained in 7.18.6.

7.18.3 *Segment 14B—Chief Complaint Present Illness/ Trauma Care*—This contains health/medical/nursing dental history reference to Section 8 and history of chief complaint and reasons why the patient came in for care. This will include a review of systems as appropriate to the individual case and reference Section 9 as described in 7.13. It also includes reported pre-hospital care of emergency patients and assessment of the nature of traumatic injury and the results of stabilizing interventions.

To illustrate: Chief complaint is listed in Table A1.1 Number 14001.A023 as "The reason for the episode/encounter and patient's complaint and symptoms reflecting his/her own perceptions of his needs. The history taking clinician then frames this in the History of Present Illness which is a statement of the current state of the patient's health at the time of the health history updating.

7.18.4 *Segment 14C, Progress Notes/Clinical Course:*

7.18.4.1 This includes the components that form an ongoing chronological picture and analysis of the clinical course of the patient during an episode or encounter. This segment is applicable for any healthcare setting. These elements serve as a means of communication and interaction between members of the healthcare team. They may also occur as narrative or flow sheets. They constitute the record of patient response to therapies, procedures and other events.

This segment includes the content of electronic communications between patient and providers that document response to treatment or observations or both sent to providers by patients through web portals or through personal health records or both.

7.18.4.2 This subsection contains all those data elements that characterize the clinical course of care and the condition of the patient. They will link to tests, therapies and procedures and will be represented by test or flow sheets.

7.18.5 *Segment 14D, Therapies:*

7.18.5.1 This includes significant details on all preventive or therapeutic, or both, services performed at the time of the episode or encounter or scheduled to be performed before the next episode or encounter. This subsection would not include any surgery performed in an operating room or that could be documented under either Segment 12 (7.16) or 7.18.6. Transfusions, physical, occupational, nursing, respiratory, rehabilitative and mental health therapies would be included.

7.18.5.2 These elements are recorded to characterize all of the conditions of non-medication therapy, and they represent interdisciplinary therapy programs and results.

7.18.6 *Sub Segment 14E, Procedures :*

7.18.6.1 This includes significant details on all procedures performed in an operating room for diagnostic, exploratory, or definitive treatment purposes.

7.18.6.2 This subsection contains data that characterizes those procedural events that accompany treatment of the patient, exclusive of laboratory phases of diagnostic procedures, which are recorded in Segment 11.

7.18.7 *Segment 14F, Disposition:*

7.18.7.1 This subsection identifies the circumstances under which the patient terminated the encounter or episode and includes data about the length of stay, condition of patient on disposition, recommended treatment and other information necessary for follow-up care.

7.18.7.2 This subsection contains that data that characterizes the conditions under which the encounter or episode was completed and the arrangements for appropriate follow-up either by the current or by other providers. It contains information needed to maintain continuity of care over several episodes or multiple encounters.

8. Alternative Views of the Logical Structure

8.1 The EHR requires content depth and retrieval flexibility. The proposed approach expands the idea of user specific data