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

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## 1. Scope

1.1 This guide covers all types of healthcare services, including those given in acute care hospitals, nursing homes, skilled nursing facilities, home healthcare, and specialty care environments as well as ambulatory care. 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). At this time, the standard vocabulary reflects more traditional care. As the standard evolves in the next revisions, the vocabulary will more adequately encompass the entire continuum of care through all delivery models, health status measurement, preventive case, and health education content.

1.2 This guide has five purposes. The first is to identify the content and logical structure of a Electronic Health Record (EHR). The record carries all health related information about a patient over time. It includes such things as observations or descriptions of the patient (for example, the physician's or nurse practitioner's history and physical, laboratory tests, diagnostic imaging reports), provider's orders for observations and treatments, documentation about the actions carried out (for example, therapies or drugs administered), patient identifying information, legal permissions, and so on.

1.2.1 The second goal is to define the relationship of data coming from diverse source systems (for example, clinical laboratory information management systems, order entry systems, pharmacy information management systems, dictation systems), and the data stored in the Electronic Health Record. Recalling that the EHR is the primary repository for information from various sources, the structure of the EHR is receptive to the data that flow from other systems.

1.2.2 Third, in order to accelerate the adoption of EHRs, this guide provides a common vocabulary, perspective, and references for those developing, purchasing, and implementing EHR systems, but it does not deal either with implementation or procurement.

1.2.3 Fourth, this guide describes examples of a variety of views by which the logical data structure might be accessed/displayed in order to accomplish various functions.

1.2.4 Fifth, this guide relates the logical structure of the EHR to the essential documentation currently used in the healthcare delivery system within the United States in order to promote consistency and efficient data transfer. It maps to the clinical data currently in existing data systems and patient care records.

## 2. Referenced Documents

2.1 *ASTM Standards:*

E 792 Guide for Selection of a Clinical Laboratory Information Management System[2]

E 1238 Specification for Transferring Clinical Observations Between Independent Computer Systems[2]

E 1239 Guide for Description of Reservation/Registration-Admission, Discharge, Transfer (R-ADT) Systems for Electronic Health Record (HER) Systems[2]

E 1381 Specification for Low-Level Protocol to Transfer Messages Between Clinical Instruments and Computer Systems[2]

E 1394 Specification for Transferring Information Between Clinical Instruments and Computer Systems[2]

E 1460 Specification for Defining and Sharing Modular Health Knowledge Bases (Arden Syntax for Medical Logic Modules)[2]

E 1467 Specification for Transferring Digital Neurophysiological Data Between Independent Computer Systems[2]

E 1633 Specification for the Coded Values Used in the Electronic Health Record[2]

E 1712 Specification for Representing Clinical Laboratory Procedure and Analyte Names[2]

E 1714 Guide for Properties of a Universal Healthcare Identifier (UHID)[2]

E 1715 Practice for an Object-Oriented Model for Registration, Admitting, Discharge, and Transfer (RADT) Functions in Computer Based Patient Record Systems[2]

E 1769 Guide for Properties of Electronic Health Records and Record Systems[2]

E 1869 Guide for Confidentiality, Privacy, Access and Data Security Principles for Health Information Including Computer Based Patient Records[2]

[1] This guide is under the jurisdiction of ASTM Committee E31 on Healthcare Informatics and is the direct responsibility of Subcommittee E31.19 on Electronic Health Record Content and Structure.

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[2] *Annual Book of ASTM Standards*, Vol 14.01.

E 1985 Guide for User Authentication and Authorization[2]
E 1986 Guide for Information Access Privileges to Health Information[2]
E 1987 Guide for Individual Rights Regarding Health Information[2]
E 1988 Guide for Training of Persons who have Access to Health Information[2]
E 2017 Guide for Amendments to Health Information[2]
E 2084 Specification for Authentication of Healthcare Information Using Digital Signatures[2]
E 2085 Guide on Security Framework for Healthcare Information[2]
E 2086 Guide for Internet and Intranet Healthcare Security[2]
E 2147 Specification for Audit and Disclosure Logs for Use in Health Information Systems[2]

2.2 *ISO Standards:*[3]

IS 5218 1977 Information Interchange—Representation of Human Sexes
IS 1000 1981 SI Units and Recommendations for the Use of Their Multiples and of Certain Other Units
IS 2955 1983 Information Processing—Representation of SI and Other Units in Systems with Limited Character Sets
IS 8072 1984 Information Processing Standard—Open System Interconnection Transport Service Definition
IS 8601 1988 Data Elements and Interchange Formats—Information Interchange (Representation of Dates and Times)
IS 6937:1994 Information Technology—Coded Graphic Character Set for Text Communication (Revision of Parts 1 and 2)
IS 10367:1991 Standardized Coded Graphic Character Sets for Use in 8 Bit Codes

2.3 *Other Health Informatics Standards:*

HL7 Health Level Seven (HL7) Version 2.2 1994[4]
ACR/NEMA DICOM Version 3.0[5]
NCPDP National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Format Version 3 Release 2, 1992[6]
ANSI ASC X12: Version 3, Release 3 (1992)[7]
X12.84 Healthcare Enrollment and Maintenance Transaction Set (834)[8]
X12.85 Healthcare Claim Payment Transaction Set (835)[8]
X12.87 Healthcare Claim Transaction Set (837)[8]

2.4 *ANSI Standards:*[8]

X3.30:1985 [R 1991] Representation for Calendar Date and Ordinal Date
X3.4:1986 [R 1992] Coded Character Sets—American National Standard Code for Information Interchange (7-bit ASCII)
X3.43:1986 [R 1992] Information Systems Representation of Local Time of Day for Information Interchange
X3.50:1986 [R 1992] Representations for U.S. Customary, SI, and Other Units to Be Used in Systems with Limited Character Sets
X3.51:1994 Representations of Universal Time, Local Time Differentials, and United States Time Zone References for Information Interchange

## 3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *admitting diagnosis*—a statement of the provisional condition given as the basis for admission to the hospital for study.

3.1.2 *ambulatory care*—also called "outpatient care," that preventive or corrective healthcare, or both, provided in practitioner's office or clinic setting, or in the hospital on a nonresident basis (that is, not requiring overnight stay and not included in the census). While many inpatients may be ambulatory, the term ambulatory usually implies that the patient has come to a location other than his or her home and has departed that same day. (Ambulatory care includes nonmedical healthcare sites, for example, acupuncture.)

3.1.3 *ambulatory surgery center*—a free-standing or hospital-based facility offering surgical procedures on patients who are admitted and discharged from the facility on the day of the surgery.

3.1.4 *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.

3.1.5 *clinic*—an outpatient facility providing a limited range of healthcare services, and assuming overall healthcare responsibility for the patients.

3.1.6 *clinic patient*—admitted for diagnosis or treatment or follow-up on an ambulatory basis; the clinic assumes overall medical responsibility for the patient.

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

3.1.8 *electronic health record (EHR)*—previously known as Computer-based Patient Record (CPR), an electronic patient record that resides in a system specifically designed to support users by providing accessibility to complete and accurate data, alerts, reminders, clinical decision support systems, links to scientific knowledge, and other aids.

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

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

3.1.11 *encounter*—(*1*) An instance of direct (usually face-to-face) interaction, regardless of the setting, between a patient and a practitioner vested with primary responsibility for diagnosing, evaluating or treating the patient's condition, or both, or providing social worker services. (Encounters do not include ancillary services visits or telephone contacts.) (*2*) A

[3] Available from ISO, 1 Rue de Varembe, Case Postale 56, CH 1211, Geneve, Switzerland.
[4] Available from HL7, Mark McDougall, Executive Director, 900 Victors Way, Suite 122, Ann Arbor, MI 48108.
[5] Available from ACR/NEMA.
[6] Available from NCPDP, 4201 North 24th Street, Suite 365, Phoenix, AZ 85016.
[7] Available from DISA (Data Interchange Standards Association).
[8] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment.

3.1.12 *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.

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

3.1.14 *home healthcare*—clinical care provided or supervised by a practitioner, administered at the patient's home or place of residence, thus allowing the patient to remain at home during an illness. Home healthcare also addresses care for people with permanent alterations in their health or functional status.

3.1.15 *hospice*—a program emphasizing psychosocial support and home physical care, with inpatient care when needed, for 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 provide diagnosis and treatment for patients.

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

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 at least 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 *long-term care*—healthcare rendered in a non-acute-care facility and to a patient in resident or non-resident status; such illness is not severe enough to require an acute care facility, but is in need of continual supervision and assistance by healthcare practitioners.

3.1.23 *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.

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

3.1.27 *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.

3.1.27.1 *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 *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.

3.1.29 *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.

3.1.30 *primary patient record (primary record of care)*—the record that is used by healthcare professionals while providing patient care services to review patient data or document their own observations, actions, or instructions. (Same as patient health record.)

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*—admitted exclusively to 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 a hospital episode that affect the

treatment received or the length of stay.

3.1.37 *secondary patient record*—a record that is derived from the primary record and contains selected data elements to aid nonclinical 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 *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 1982 (UB-82) version.

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

## 4. Significance and Use

4.1 *The Body of This Guide has Four Parts*:

4.1.1 The first part (Section 5) identifies all items of information carried in the traditional paper record using the source oriented structures common to paper records. For example, physician notes are recorded in one place, nurses' notes in another and EKG's in still another, according to the department that produces the report. 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 (Section6) 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 organization and content (common data model) of a EHR that is presented as a model. It is not a blueprint for constructing or implementing a EHR system. The model deals with the major structures and content of the EHR and with the relationships of the data elements that comprise it. 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 Data structures used to store goals and criteria which are used to control the process (for example, quality assurance, utilization review, etc.) are complex, and are evolving very rapidly at the present time; they will merely be referenced in this standard. Likewise, explicit structures for dealing with all special cases (for example, observations made on twins in utero and the record created after they are born) are also not included. They are mentioned to suggest compromises that trade complexity with feasibility. However, as experience with EHRs is gained these objects will be more fully defined **(1-3)**.[9] There are many different ways to implement physical structures that could map into the model presented. It is emphasized again that this standard should neither impede technical progress nor define the precise manner in which the EHR system is implemented. However, implementations should be mappable to the model presented here, especially when considering interfaces to outside systems.

4.1.3.2 At this time, this model defines neither all of the detailed implemented physical structures in some systems nor all of the functional capabilities that may have been implemented. This standard should not limit the inventiveness of developers, and we can not presume to know the capabilities that future technologies may bring. The focus is both upon 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. At the outset it cannot be guaranteed that independent EHRs will have the same degree of commonality but it is assumed that any mappings between different patient identifiers, different test or location identifiers occurs at the interface to the EHR. This perspective does not imply any lack of support for national conventions for these entities but rather provides an evolutionary path to their adoption.

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

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 considers what should be the minimum data elements contained in the EHR. What has been described as the "Longitudinal Health Record" (a very short precis 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 easy. 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 a electronic health record data dictionary (Annex A1).

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 has increased the fragmentation of the traditional health record. Ad hoc health records are generated and kept at the site of the service. This fragmentation of the health records is medically undesirable: it leads to duplication of data gathering for patient histories, it obscures long term clinical trends, it leads to duplication of tests and unnecessary diagnostic studies, and it results in delays in needed testing and treatment. Also, it causes annoyance, dissatisfaction, and concerns about quality and safety on the part of the patient. 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. The primary goal of this guide is to characterize the patient health record and to define the necessary aspects of the primary medical care documentation.

4.2.3 The patient's health record consists of the original documentation of the services provided at the various care sites. Ideally it should also include the results of tests and outcomes of treatments prescribed at any of those encounters. 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. It should also include the rationale for services.

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

4.2.4.1 It will solve the logistic problems of the paper health/medical record. Information can be accessed from multiple locations.

4.2.4.2 It will provide efficient communication of information to support coordination of services between care practitioners.

4.2.4.3 For information that is stored in a structured and computer understandable fashion, the EHR will provide automatic reminders and alerts to avoid errors of omission and commission, improve the usage of preventive care services, and shape practice patterns to more uniform standards.

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 a EHR described here provides a general guideline regarding storage of different kinds of information, suggests minimal content requirements in specified circumstances and promotes common approaches to documentation in other care settings. 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.

**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 |

**TABLE 1** *Continued*

| Category | Subcategory | Examples and Components |
|---|---|---|
| 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 | (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 |
| | | 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 |

**TABLE 1** *Continued*

| Category | Subcategory | Examples and Components |
|---|---|---|
| | | Thorax/lungs Px<br>Breasts Px<br>Heart Px, etc. |
| | Toxic exposures<br>Nursing assessments | |
| Legal documents | Surgical releases<br>Organ donor permissions<br>Advance directives (release of documents) | ... |
| Schedules (surgery/clinic, etc.) | Requests for resource<br>Assignment of resource<br>Documentation of delivery to resource and return | Send patient to eye clinic |
| Supplies and equipment | Consumables (4×4's)<br>Attachments | ... |

## 5. Catalog of Primary 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. Table 2 lists just a few of the many separate variables that can be required to record the eye exam particulars required for detailed outcomes assessment.

5.3 In the traditional record the degree of granularity 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 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.

**TABLE 2 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. |

## 6. Operational Considerations

6.1 Because the record of care is a working tool in clinical practice, the day-to-day operational aspects that affect the record's structure need to be considered before assembling components of the EHR into an integrated whole. A number of these considerations enumerated here 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 issues must be addressed at the organizational level. The tasks are:

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

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

6.2.3 Propose views (synopses) of the patient care record, visits or episodes which might be prepared in each healthcare delivery setting and which should be accessible locally or sent to included in the unified longitudinal record, or both.

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 and promotes efficient data transfer through adoption of a common record transfer convention.

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

6.2.7 Identify and reference appropriate coding systems consistent with current health reporting retrieval, analysis, and

reimbursement needs.

6.2.8 Specify data security and confidentiality measures to be addressed through consideration of the required data access, update, and retrieval procedures.

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. 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). Refer to Table 3 for a complete list. Coded values, particularly, point to referential master tables. In those tables, the term that is human understandable may have a number of code values from different coding systems associated with it. Indeed, they may even be in 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. Suffice it to say that in defining the data elements of the EHR in Section 7 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. See, for example, Specification E 1238 or the HL7 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.

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 **(11)** 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.

**TABLE 3 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 |

6.4.2 *Identification of the Healthcare Setting*—The healthcare location and setting information shall be captured by using specific synopsis data sets that are preestablished for each setting; such data also serves as an index of the individual's pattern of healthcare. 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 transfer format to be defined by ASTM.

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 **(7)**. This information allows repeated and accurate identification of patients from one care setting in another; it also provides the link for the collection of 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 identification elements that are preestablished for each setting. Software may be used to identify and collect a health status survey of salient clinical facts that will be tagged 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 patient computer-based records must be established within the organizational policy structure. This policy must provide for privacy protection for both patients and providers which conforms to published confidentiality statutes, standards, and professional guidelines; direct professionals practicing in the facility; provide physical security for data use; and provide software support which identifies and monitors all user access to the system. (See Guide E 1769 and other ASTM standards

for confidentiality and privacy.)

6.6.1 *Privacy of Patient Health Records*—Access to patient health records is controlled to maintain privacy. The major axioms of patient health record privacy are:

6.6.1.1 All patients and healthcare professionals with access to patient records shall have the right to be informed about EHR content maintained.

6.6.1.2 Every adult patient, or his or her legal representative, shall have the right to inspect and copy all information stored in his/her electronic health record.

6.6.1.3 Standards for patient authorization to disclose information from their record shall be established.

6.6.1.4 Every patient shall have the right to amend their record to correct incomplete or inaccurate data.

6.6.1.5 An administrative policy should be used to enforce need-to-know access. This policy should include appropriate sanctions for unauthorized access, use, or release of information.

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 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 research committee of the organization maintaining that data and such release 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:

6.7.1.1 Department of defense/composite healthcare system **(1)**,

6.7.1.2 Uniform hospital discharge data set **(2)**,

6.7.1.3 Basic ambulatory medical care data set **(3)**,

6.7.1.4 Minimum uniform data set for home care **(4)**,

6.7.1.5 Minimum hospice data set **(5)**,

6.7.1.6 Minimum data set for long-term care **(6)**,

6.7.1.7 Health record core data set **(7)**,

6.7.1.8 Occupational health data set **(8)**,

6.7.1.9 Emergency medical information data set **(9)**,

6.7.1.10 Summarized health profile **(10)**, and

6.7.1.11 The nursing minimum data set **(11)**.

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

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; these criteria should also specify retention according to clinical value. The clinical value of data elements over time and those designated for a longitudinal record should likewise be identified.

6.9 *Master Tables*:

6.9.1 A basic approach to defining EHR content is through master tables and data views. These can be used within the construct of this guide. A master table is a list of variables that represent the range of attributes currently defined for a given subject. Table 2 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 E 1238. By using master tables we can provide both a short term and a long term approach to methodically addressing EHR content so it can be coordinated and implemented through organizational systems development plans. By developing the master tables from these resources, users can apply the standard in diverse settings. Users would use this guide with the appropriate master tables to select standard recommended and optional vocabulary to define the EHR vocabulary in their organization. It is recognized that 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. Much of the same applies to supplies and equipment. The idea of maintaining a “catalogue” or definition table for items such as supplies, orders, observations and equipment is a powerful construct. It permits easy additions and extensions to the universe of items in a given class. (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. Catalogue tables were widely used to implement pharmacy systems (where each drug in the formulary is represented in the catalogue) and laboratory systems (where each orderable battery and each discrete reportable test has its own catalogue entry). 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. They are an essential (though abstract) component of an EHR as described here, where they will be used to represent (at least) the various species of observations and their attributes.

6.9.3 The notion of observations in its most general sense 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 **(12)** 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. These tables make it possible to 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 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 E 1715, 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.

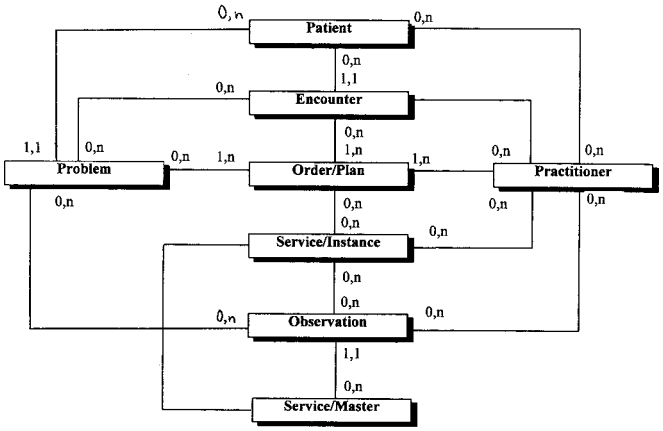


**FIG. 1 Patient Record Object Model**

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, birthdate, 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

**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.

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.

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. 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 precis 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*—Table 5 outlines the classes of settings that maintain a patient record of care which contains the identified segments to some degree.

7.5 *Segment One, 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.

**TABLE 5 Sites of Care**

| | |
|---|---|
| Ambulance/aid-car | Hospital, government |
| Ambulatory surgery facility, free-standing | Hospital, outpatient department |
| Ambulatory surgery facility, hospital-based | Hospital, psychiatric |
| Birthing center, free-standing | Hospital, rehabilitation |
| Birthing center, hospital-based | Hospital, trauma center LVL 1 |
| Clinic/health center, comp outpatient rehabilitation | Imaging services facility, free-standing |
| Clinic/health center, dental | Independent laboratory |
| Clinic/health center, free-standing | Industrial health/occupational health center |
| Clinic/health center, health maintenance organization | Intermediate care facility |
| Clinic/health center, outpatient mental health | Intermediate care facility-mentally retarded |
| Clinic/health center, pain | Mental health multiservice organization |
| Clinic/health center, rural | Mental health partial care organization |
| Clinic/health center, urgent care center, walk-in, free-standing | Private office, group, fee-for-service |
| | Private office, group, prepaid |
| Clinic/health center, vision | Private office, solo practice |
| Custodial care facility | Residential treatment center, emotionally |
| Day care center | Disturbed children |
| End-stage renal disease treatment facility | Residential school |
| Home health | Retirement center |
| Hospice, free-standing | School clinic/infirmary |
| Hospital, acute care | Sheltered employment workshop |
| Hospital, acute care with psychiatric services | Skilled nursing facility/nursing home |
| Hospital, burn center | Special education program |
| Hospital, cancer | Substance abuse treatment facility, resident |
| Hospital, children's | Nursing center |
| Hospital, emergency room | Vocational rehabilitation unit |

7.6 *Segment Two, 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 Three, 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 Four, 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 Five, 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.

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 Six, 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 Seven, Exposure to Hazardous Substances*:

7.11.1 The what, where, when, and how data on actual orpotential 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 radiologic 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 Eight, 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 least not often, at each encounter. Recommended and optional attributes of patient history are included in a master table.

7.13 *Segment Nine, 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, psycho-social 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. 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 psycho-social assessment to compose over-all 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 Ten, 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, a 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, and perhaps practically impossible, 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 a large degree of commonality across all types of orders. Since the message objective is a specific patient, a copy of all orders for that patient shall be filed in the patient's care record. This follows current accountability practice regarding the manual record and its legal status as the record of care received by a patient. 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 preexisting templates, or sets of templates, that contain preassigned 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. This group also helps ensure that various subordinate practitioners do not exceed the bounds of their training by ordering, unaided, procedures they have not yet been qualified to use. 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 cosigning 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.

7.15 *Segment Eleven, 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 Twelve, 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 Thirteen, 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 Fourteen—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 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 inter-relations 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 Fourteen A, 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 subsegment 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 Fourteen B—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.

7.18.4 *Segment Fourteen C, 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