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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 E 1384; 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:

1.2.1Identify the content and logical structure 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.

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:*

E792Guide for Selection of a Clinical Laboratory Information Management System[2]

E 1238 Specification for Transferring Clinical Observations Between Independent Computer Systems

E 1239Guide for Description of Reservation/Registration-Admission, Discharge, Transfer (R-ADT) Systems for Automated Patient Care Information Systems[2]

E1381Specification for Low-Level Protocol to Transfer Messages Between Clinical Instruments and Computer Systems[2]

E1394Specification for Transferring Information Between Clinical Instruments and Computer Systems[2]

E1460Specification for Defining and Sharing Modular Health Knowledge Bases (Arden Syntax for Medical Logic Modules)[2]

E1467Specification for Transferring Digital Neurophysiological Data Between Independent Computer Systems[2] Practice for Description of Reservation/Registration-Admission, Discharge, Transfer (R-ADT) Systems for Electronic Health Record (EHR) Systems

E 1633 Specification for the Coded Values Used in the Computer-Based PatientElectronic Health Record

E1712Specification for Representing Clinical Laboratory Test and Analyte Names[2]

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

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards ; Vol 14.01.*volume information, refer to the standard's Document Summary page on the ASTM website.

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

E1714Guide for Properties of a Universal Healthcare Identifier² 1639 Guide for Functional Requirements of Clinical Laboratory Information Management Systems

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

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

E 1769Guide for Properties of Electronic Health Records and Record Systems²

2.2 ISO Standards:

IS 52181977 Information Interchange—Representation of Human Sexes

IS 10001981 SI Units and Recommendations for the Use of Their Multiples and of Certain Other Units

IS 29551983 Information Processing—Representation of SI and Other Units in Systems with Limited Character Sets

IS 80721984 Information Processing Standard—Open System Interconnection Transport Service Definition

IS 86011988 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 10367:1991Standardized Coded Graphic Character Sets for Use in 8 Bit Codes

2.3 Guide for Properties of Electronic Health Records and Record Systems

E 2118 Guide for Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures

E 2369 Specification for Continuity of Care Record (CCR)

E 2473 Practice for the Occupational/Environmental Health View of the Electronic Health Record

E 2538 Practice for Defining and Implementing Pharmacotherapy Information Services within the Electronic Health Record (EHR) Environment and Networked Architectures

ASTM/HL7 Continuity of Care Document, 2007

2.2 Other Health Informatics Standards:

HL7Health Level Seven (HL7) Version 2.2 1994 Health Level Seven (HL7) Version 2.2 1994³ (Version 2.4 and 2.5)

NCPDP National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Format Version 3 Release 2, 1992⁴

ACR/NEMA DICOM Version 3.0

ANSI ASC X12: Version 3, Release 3 (1992)⁵

NCPDP National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Format Version 3Release 2, 1992

X12.84 Healthcare Enrollment and Maintenance Transaction Set (834)⁶

X12.85 Healthcare Claim Payment Transaction Set (835)⁶

X12.87 Healthcare Claim Transaction Set (837)⁶

2.3 ANSI Standards:⁶

HL7 EHR TC Electronic Health Record-System Functional Model, Release 1 February, 2007

ANSI ASC X12:Version 3, Release 3 (1992)

X12.84Healthcare Enrollment and Maintenance Transaction Set (834)

X12.85Healthcare Claim Payment Transaction Set (835)⁸

X12.87Healthcare Claim Transaction Set (837)⁸

2.4 ANSI Standards:⁸

X3.30:1985[R1991] Representation for Calendar Date and Ordinal Date

X3.4:1986[R1992] Coded Character Sets—American National Standard Code for Information Interchange (7-bit ASCII)

X3.43:1986[R1992] Information Systems Representation of Local Time of Day for Information Interchange

X3.50:1986 [R1992] Representations for U.S. Customary, SI, and Other Units to Be Used in Systems with Limited Character Sets

X3.51:1994Representations of Universal Time, Local Time Differentials, and United States Time Zone References for Information Interchange

Health Information Management and Technology: Glossary, American Health Information Management Association, 2006

² Available from International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland.

³ Available from HL7, Mark McDougall, Executive Director, 900 Victors Way, Suite 122, Ann Arbor, MI 48108.

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

⁴ Available from NCPDP, 4201 North 24th Street, Suite 365, Phoenix, AZ 85016.

⁵ Available from ACR/NEMA.

⁵ Available from DISA (Data Interchange Standards Association).

⁶ Available from NCPDP, 4201 North 24th Street, Suite 365, Phoenix, AZ 85016.

⁶ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

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

3.1.2 *ambulatory care*—also called "outpatient care," that is a comprehensive term for all types of health care provided in an outpatient setting. It may include 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). The term ambulatory usually implies that the patient has come to a location and has departed that same day. (Ambulatory care includes alternative (healthcare vice medicine) medicine, healthcare care, for example, acupuncture.) —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 *ambulatory surgery center*—a freestanding 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 for healthcare services.

3.1.5 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*.

3.1.6 3.1.5 *clinic patient*—admitted for diagnosis or treatment or follow-up on an ambulatory basis.

3.1.7 —*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.

3.1.8

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.

3.1.9

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

3.1.10

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

3.1.11 3.1.10 *encounter*—(1) An instance of direct provider/practitioner to patient 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. () *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.*

3.1.12 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 healthcare*—clinical care provided or supervised by a practitioner, administered at the patient's place of residence. 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*—a program emphasizing psychosocial support and home physical care, with inpatient care when needed, for terminally ill patients and their families. —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 providing diagnosis and treatment for patients.~~ —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.

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; such illness is not severe enough to require an acute care facility, but the patient is in need of continual supervision and assistance by healthcare practitioners.~~ —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.

~~3.1.27~~

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.

~~3.1.27.1~~

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~~

3.1.28.2 *Personal health record*—An electronic or paper record of health information compiled and maintained by the patient or others for patient use **(5)**.

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.

~~3.1.29~~

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.

~~3.1.30~~

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.

~~3.1.31~~

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.

~~3.1.32~~

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.

3.1.33

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.

3.1.34

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.

3.1.35

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

3.1.36 *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 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).

3.1.37 *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.

3.1.38

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.

3.1.39

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.

3.1.40 *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 *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 usingorganized 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 organizespresents 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 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. The focus is both upon the kinds of information that should be included

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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.

4.1.3.2 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 considers what should be proposes the minimum data elements contained in the EHR. What has been described as the "Longitudinal Health Record" (a very short precisprécis 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).) (18).

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 hashave 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 E 2369).

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 regarding storage of different kinds of informationthat

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. Test Some test results are commonlymay 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

TABLE 1 *Continued*

Category	Subcategory	Examples and Components
	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
		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

TABLE 1 *Continued*

Category	Subcategory	Examples and Components
		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~~ Legal documents	~~Surgical releases~~	
	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 documents (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.~~

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. ~~These~~ Consistent with HL7 standards and Specification E 1633, 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 2 ~~for~~ is a ~~complete list.~~ 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 a number of code values from different coding systems associated with ~~it. Indeed, they may even be in~~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 E 1714).

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>ˆ <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

6.4.1 *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 (**1**)[7] 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 E 1633) 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 ~~transfer format to be defined by ASTM.~~ 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 (**2**) . 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 E 1769 ~~and other ASTM standards for confidentiality and privacy.~~ and other ASTM standards for confidentiality and privacy (**12**).

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

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[7] Available from DISA (Data Interchange Standards Association).

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

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:

6.7.1.1 Department of defense/composite healthcare system (**3**),

6.7.1.2 Uniform hospital discharge data set (**4**),

6.7.1.3 Basic ambulatory medical care data set (**5, 6**),

6.7.1.4 Minimum uniform data set for home care (**6**),

6.7.1.5 Minimum hospice data set (**7**),

6.7.1.6 Minimum data set for long-term care (**8, 9**),

6.7.1.7 Health record core data set (**2**),

6.7.1.8 Occupational health data set (**9̶10**),

6.7.1.9 Emergency medical information data set (**10**),

6.7.1.10 Summarized health profile (**1̶1̶13**), and

6.7.1.11 The nursing minimum data set (**1**).

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 (**11, 12**).

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 E 1633. 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 g̶u̶i̶d̶e̶practice 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

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	OD Transillumination defects,
degeneration	etc.

on. ~~Much of the same applies to supplies and equipment. The idea of~~ By maintaining a "catalogue" or definition table for items such as supplies, orders, observations and ~~equipment is a powerful construct. It permits~~ 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. ~~6.9.3 The notion of observations~~ For example, these attributes are now found in ~~its most general sense~~ 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 (~~12~~14) 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~~ 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 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.

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
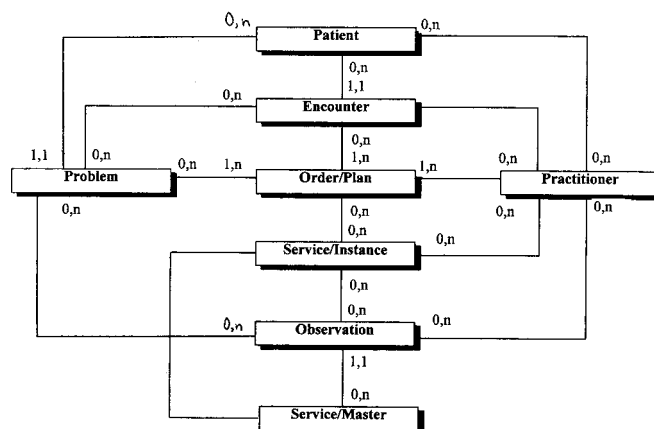

FIG. 1 Patient Record Object Model

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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.

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 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 ~~precis~~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*—~~Table 5 outlines the classes of settings that maintain a patient record of care which contains the identified segments to some degree.~~ —Patient and client records across care sites include

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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,~~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.~~ 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<"~~when>" During each encounter/episode this list may be updated by the preface: "Since the last visit have you ever_____<If so, ~~when<"~~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,~~record at each encounter. Recommended and optional