HL7 EHR System Functional Model:

A Major Development Towards Consensus on Electronic Health Record System Functionality

A White Paper

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Please Note:

The content within this white paper is not content which can be voted on. It is presented strictly as a reference document for those ballot readers that are interested in this additional information. There is some wording used in this White Paper that is normative in other places of the ballot package and able to be voted upon in the EHR System Functional Model Standard Overview document; however, identification of the normative content takes place in the Standard Overview and votes are then placed in the Ballot spreadsheet.

For the remainder of this document, the HL7 EHR System Functional Model and Standard will be referred to as the 'EHR-S Model' or 'the proposed DSTU'.

1. Purpose

The purpose of this White Paper is to provide a comprehensive background for the HL7 EHR System Functional Model that is being balloted as a Draft Standard for Trial Use (DSTU). Much of the information found in the EHR System Functional Model and Standard - Standard Overview document is included in this White Paper, but there will also be a great deal of additional, background information in this document that is out of scope for the brief Standard Overview document. This White Paper will provide additional information about the use of profiles to select applicable functions for use, the context within which this ballot was created, and EHR System related standardization efforts around the world.

2. Overview of HL7 EHR System Functional Model

The HL7 EHR System Functional Model and Standard Draft Standard for Trial Use (DSTU) is intended to provide a summary understanding of functions that may be present in an Electronic Health Record System (EHR-S), from a user perspective, to enable consistent expression of system functionality. This EHR-S Model describes the behavior of a system from a functional perspective and provides a common basis upon which EHR-S functions are communicated. The DSTU can help vendors describe the functions their systems offer, and help those planning new purchases or upgrades to describe the functions they need.

For brevity, this draft standard will be referred to within this document as the "EHR-S Model" or the "proposed DSTU" where the meaning is not ambiguous. A DSTU is a draft standard that incorporates the input from industry prior to becoming a formal ANSI standard. (See Appendix D "What is a DSTU?")

Notably, the EHR-S DSTU does not address whether the EHR-S is a system-of-systems or a single system providing the functions required by the users. The specifics of 'how' EHR-S's are developed or implemented is also not considered to be within the scope of this DSTU now or in the future. It does not address or endorse implementations or technology; neither does it include the data content of the Electronic Health Record (EHR).

This DSTU is not:

- A messaging specification.
- An implementation specification.
- A conformance specification.
- An ANSI Standard.
- An EHR specification. (Note: Electronic Health Records and Electronic Health Record Systems are different entities.)
- A conformance or compliance metric.
- An exercise in creating a definition for an EHR or EHR-S. (ISO is currently addressing this task.)

3. Background

The effective use of information technology is a key focal point for improving healthcare in terms of patient safety, quality outcomes, and economic efficiency. A series of reports from the Institute of Medicine (IOM) identifies a crisis of "system" failure and calls for "system" transformation enabled by the use of information technology. Such a change is possible by "an infrastructure that permits fully interconnected, universal, secure network of systems that can deliver information for patient care anytime, anywhere."(HHS Goals in Pursuing HL7 EHR Functional Standard" in Memorandum to HIMSS from C. Clancy and W. Raub co-chairs of HHS Council on the Application of Health Information Technology, dated November 12, 2003.) A critical foundational component for resolving these system and infrastructure issues is the Electronic Health Record System (EHR-S).

The U.S. Department of Health and Human Services, the Veterans Health Administration as well as the Health Information Management Systems Society and the Robert Wood Johnson Foundation, in a public-private partnership, approached HL7 to develop a consensus standard for defining the functions of an EHR-S. HL7, through its EHR Special Interest Group (EHR SIG), responded by developing an EHR-S Functional Model to be balloted as a Draft Standard for Trial Use (DSTU). Learning important lessons from its earlier DSTU, the HL7 EHR SIG now offers a clearer, more simplified functional outline, while delegating specification of care settings and priorities to individual realms.

HL7's Electronic Health Records Special Interest Group (EHR SIG) was established in the spring of 2002 and in the spring of 2003started to develop a standardized functional specification for Electronic Health Records Systems with the intention of promoting the uptake of Electronic Health Record implementation by standardizing the essential functions of a generic Electronic Health Record System.

Please note: The content within this white paper is presented as a reference document for readers interested in additional information regarding this DSTU. For the remainder of this document, the HL7 EHR-S Functional Model will be referred to as the 'EHR-S Model' or 'Proposed DSTU'.

4. Definitions

Until recently there was no generally agreed definition for an EHR. The first published international EHR technical specification "ISO/TS 18308: 2004 Health informatics-Requirements for an Electronic Health Record Architecture" [1] contains seven different definitions drawn from the United States, Australia, Europe and Canada. These definitions have more similarities than differences but reflect slightly different shades of meaning between different countries and organizations.

Many different names and definitions have been broadly used. These include:

- Electronic Medical Record (EMR)
- Electronic Patient Record (EPR)
- Computerized Patient Record or Computer-based Patient Record (CPR)
- Electronic Health Care Record (EHCR)
- Virtual EHR
- Personal Health Record (PHR)
- Digital Medical Record (DMR)

It is important to note that the DSTU does not attempt to establish another definition for EHR Systems, but chooses to utilize existing definitions that include the concept of EHR Systems as a system (at least one) or a system-of- systems that cooperatively meet the needs of the end user.

4.1 Electronic Health Record Systems (EHR-S) Definitions

In developing the DSTU, HL7 relied on three well-accepted definitions: two provided by the U.S. Institute of Medicine (IOM) and one developed by the European Committee for Standardization/ Comité Européen de Normalisation (CEN).

Existing EHR System Definitions

The Institute of Medicine's 1991 report, *Computerized Patient Record,* defined the EHR System as:

> "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 health care provider setting. It includes people, data, rules and procedures, processing and storage devices (e.g., paper and pen, hardware and software), and communication and support facilities."

The 2003 IOM Letter Report, *Key Capabilities of an Electronic Health Record System*, defined the EHR System as including:

> "(1) longitudinal collection of electronic health information for and about persons, where health information is defined as information pertaining to the health of an individual or health care provided to an individual; (2) immediate electronic access to person- and population-level information by authorized, and only authorized, users; (3) provision of knowledge and decision-support that enhance the quality, safety, and efficiency of patient care; and (4) support of efficient processes for health care delivery."

The 2003 ISO/TS 18308 references the IOM 1991 definition above as well as CEN 13606, 2000:

> "A system for recording, retrieving and manipulating information in electronic health records."

5. HL7 EHR-S Functional Model

5.1 Phased development

The HL7 EHR System Functional Model will be developed using a phased approach.

5.1.1 Draft Standard for Trial Use

The first step of the development will consist of a Draft Standard for Trial Use. This type of standard specification is intended by HL7 to be developed for the distinct purpose of enabling trial use of the specification prior to the balloting of a full-fledged ANSI standard. The DSTU period can last for up to two years and consists of receiving and incorporating industry and HL7 feedback while moving towards the goal of balloting parts or all of the DSTU as an ANSI standard.

The DSTU will consist primarily of a list of Function Names and Function Statements that have been identified through a global development and review process as essential in a care setting now or in the future. The list of functions is analogous to a dictionary, which is an excellent example of a superset (vs. a subset). In this dictionary, Function Names are defined and available for reference or for selection when composing a list of functions that are deemed necessary by the user. In other words, a user of the EHR-S DSTU may want to look up a function to gain an understanding of how that function is used, or, a user may want to select a number of functions to create a document to communicate functional needs to others. As with other dictionaries, the proposed DSTU is expected to evolve over time to reflect empirical needs and uses for EHR-S functions.

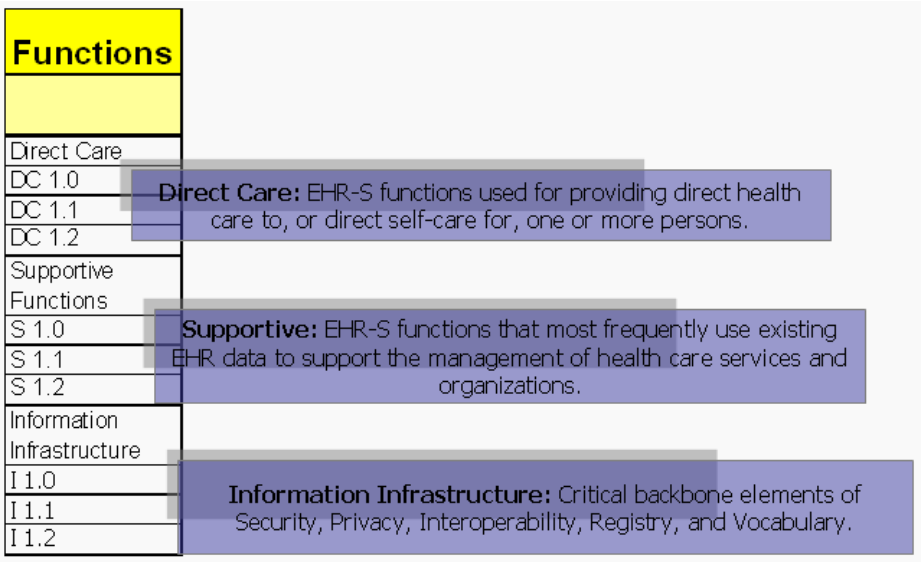
Note that the proposed DSTU is deliberately leaving out conformance criteria. Minimal conformance criteria are planned at the function level, (not the system level) and will state what is needed to determine whether a single function exists. Conformance criteria will be stated in user-oriented, system-behavior language, similar to a Function Name and Function Statement. This will *not* establish conformance criteria for comparing EHR Systems to the entire superset of functions. The development of the minimal conformance criteria will be performed with industry input and guidance.

5.1.2 Next Steps

During the DSTU period, as the standard is applied in healthcare informatics and feedback is being incorporated, the document will be continually refined. After the DSTU period, the lessons learned and good practices developed will be included in the next version of the EHR-S Functional Model which will be balloted as standard. The HL7 EHR SIG will determine both the time and the content when the proposed DSTU will be promoted to full standard status. The HL7 EHR SIG has seen its membership group expand by five fold during the DSTU development phase and is deeply grateful for the immense amount of outside knowledge and expertise that has been brought to this process. It is hoped that this larger group, and others, will continue to participate in the process of modifying the original DSTU into a future standard.

5.2 Functional Model Overview

The EHR-S Functional Model consists of a set of Functions and their associated Functional Descriptors. These functions are divided into three sections: Direct Care, Supportive, and Information Infrastructure.



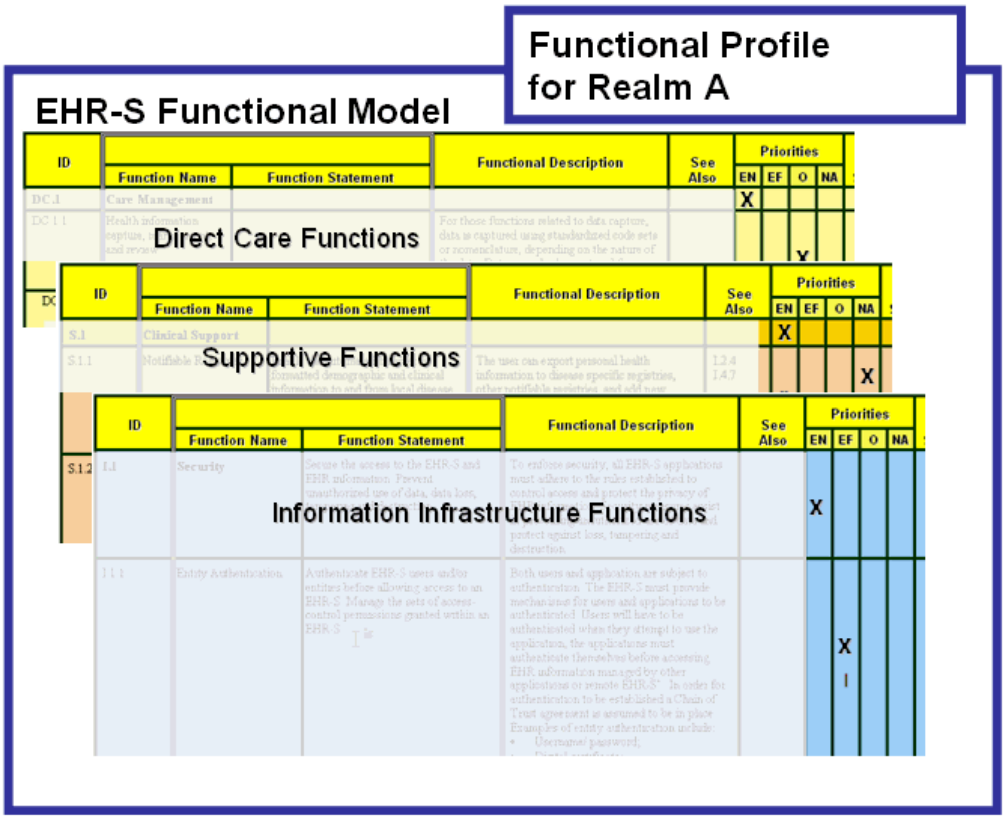
These functions are intended to become the common language used by vendors, providers, regulators, policymakers, and other parties when describing the capabilities of their applications (vendors), their needs (providers) their quality requirements (regulators), or other purposes. Additionally, realm specific HL7 International Affiliates may endeavor to create their own country specific language. (See Functional Profiles below).

5.3 Future development of the Model: Functional Profiles

Profiles help to manage the master list of functions. A “Profile” is a selected set of functions that are applicable for a particular purpose, user, care setting, domain, etc. It is not anticipated that the full set of functions will apply to any single EHR-S implementation. Instead, the functions are profiled for particular care settings and for particular uses. Care

Setting Profiles relate priorities (Essential/Now, Essential/Future, Optional, Not Applicable) to specific functions. Ultimately, self-generated Profiles will express the capabilities of a real system (e.g., a vendor's product or a set of applications) or the needs of a stakeholder (e.g., providers, national health organizations, or insurers).

The expression of Priorities (Essential/Now, Essential/Future, Optional, Not Applicable) allows users to better list what is currently desired for their needs and what is realistically achievable in the near future. (See definitions of Priorities below.)



The possible priorities assigned to a function in a specific Healthcare Delivery Setting may be:

Priority	Description
Essential Now	The function must be feasible to implement now or within 18 months. That is, the function is readily available and the users can implement it. The function must also be critical or key to helping an EHR system address at least one of the following criteria [2]: • Support Delivery of Effective Healthcare • Improve Patient Safety • Facilitate management of chronic conditions • Improve efficiency • Facilitate self-health management
Essential Future	The function should be feasible to implement by users and readily available in the future. The function must be also be critical or key to helping an EHR system address at least one of the following criteria [2]: • Support Delivery of Effective Healthcare • Improve Patient Safety • Facilitate management of chronic conditions • Improve efficiency • Facilitate self-health management
Optional	A level of significance applied to functions in relation to a functional profile. For the average users, the function is deemed an important/desirable but not a critical/key/essential component to an EHR system. It is recognized that for more complex healthcare provider settings, many items deemed optional may be viewed essential to them.
Not applicable/supported	A level of significance applied to functions in relation to a functional profile. The function is deemed an unsuitable component for an EHR system, in relation to a specific functional profile.

5.4 Functional Profile Overview

5.4.1 Realm-specific Profiles and Suggested Approach

The development of a Profile can be done by an individual, an organization, a vendor or a group of subject matter experts. The U.S. Realm reference portion of this ballot package has four examples of Profiles that were created by subject-matter experts from four care environments: Acute Inpatient, Care in the Community, Long-Term Care, and Ambulatory.

These four example profiles are found in the reference portion of the DSTU documents. These profile examples are in not way intended as a benchmark for the selected care settings. They are well-developed examples of how profiling activities may be conducted. Steps include:

a) Identify participants for a workgroup that would create a Profile. The members may vary based on the type of profile, but generally should be subject-matter experts or stakeholders in the area/setting being profiled.

b) Define the area/setting to be profiled and establish the scope. For example, is the profile for a specific function which crosses multiple settings or is it for a single care setting?

c) Review the functional name, statements, descriptions and references in the existing EHR-S Functional Model. Consider these questions: Do the functions in the EHR-S Model apply to this Profile? Are certain functions required, but missing from the Model? (If functionality is missing, please notify HL7's EHR SIG for future revisions to the Model).

d) Review the existing functions in the model for the area/setting profiled to determine each function's priority. Determine whether each function is essential now, essential in the future, optional, or not applicable for the area/setting.

e) Create a use-case scenario or case study for the area/setting profiled. The case study would provide an example of how the functionality of the EHR-S Model would be applied to the area/setting. The use-case/case study would depict situations unique to the area/setting profiled and assist a reader in understanding how the EHR-S Functional Model would be applied in that unique situation or setting. When a function is described in the use-case scenario/case study, the function ID is referenced to tie the example back to the EHR-S Functional Model.

f) Complete the three profile documents (Definition of Area/Setting Profiled, Setting-Specific Model with Priorities, and Case Study) and submit the documents to the EHR SIG for review and comment. (Note: HL7 plans to maintain a library of the Profiles, but the process and procedure is currently not defined.)

5.5 Applications of the EHR System Functional Model

5.5.1 Vendor Perspective

Vendor – The HL7 EHR-S Functional Model & Standard judiciously stays away from implementation issues. The vendor generated innovation and applicable know-how is what will give life to the functions within the model. It is this innovation that is deemed irreplaceable and led the EHR SIG to remain away from the implementation ‘how’ issues. The use of the term ‘systems’ after EHR was purposely put in to indicate that vendors who have niche markets are just as important within the system as vendors who have large EHR products. The Functional Model will provide a communication tool by which a vendor niche product can communicate to a client that they meet all the functions and exceed by a large margin in the target area in which the client is focused.

5.5.2 Provider Perspective

Provider – The HL7 EHR-S Functional Model and Standard will give providers a common language to use when discussing functions that should be present within an EHR-S. By giving the provider a function name and definition that is standard throughout the industry, the provider has increased confidence in universal understanding when purchasing and using EHR-S functions.

5.5.3 Patient Perspective

Patient – The HL7 EHR-S Functional Model & Standard documents key functions that will enable patients to play an important role in their own healthcare. Systems that support these functions will provide decision support tools for self-health management, and make it feasible for patients to update their health records and better communicate with their providers.

Appendix A. Overview of related EHR standards

Purpose of EHR standards

The major purpose of EHR standards (and many other health technology standards) is to facilitate improvements in five main areas:

1. Interoperability
2. Safety/security
3. Quality/reliability
4. Efficiency/effectiveness
5. Communication (i.e. verbal and written communication to improve understandability)

These are clearly all important benefits and most standards will assist to a greater or lesser extent in achieving all five of these benefits. However, interoperability is arguably the single most important benefit of EHR standards since this is the area most lacking in health information management today. Furthermore, without interoperability, the ability to achieve the other three benefits is significantly limited.

Scope of EHR standards

In 2001, ISO/TC 215 established the EHR *ad hoc* Task Group to identify gaps and requirements for international standards for Electronic Health Records. The final report of this Group in 2002 [6] made 10 recommendations. The first three of these recommendations were:

1. ISO/TC 215 should develop a comprehensive consensus definition of the EHR.
2. ISO/TC 215 should define EHR standards as part of a family of standards based on a "system-of-systems" approach that collectively represents the major services in a distributed health-computing environment.
3. ISO/TC 215 should restrict the scope of EHR standards to a conception of the EHR that is concerned with a single subject of care, has as its primary purpose the support of present and future health care, and is principally concerned with clinical information.

The first of these recommendations is in its fourth (and potentially final) Draft Technical Report in the ISO 20514 project [2]. The second and third recommendations are interesting because they implicitly define the scope of EHR standards activity, at least for ISO. There are two quite distinct views on the scope of the EHR and of EHR systems. These have been called the "Core EHR" and "Extended EHR" [2] views. The Core EHR view is that the scope of the EHR (and therefore of EHR systems) is concerned principally with clinical information and the care of individual patients (as per Recommendation 3 above) and excludes other components of a comprehensive clinical information system (such as demographics, security, terminology, and decision support(as per recommendation 2 above)). The Extended EHR view is that the scope of the EHR and EHR systems includes not only the

related EHR "building block" services such as terminology and security, but also non-clinical functions such as patient administration, scheduling, billing, and resource allocation. The issue of EHR/EHR-S scope is discussed further in ISO 20514.

One very practical reason for adopting the more limited scope for the EHR/EHR-S is that it is difficult enough to create EHR standards for even the limited scope. Many would say that it is impossible to create EHR standards if the scope of the EHR/EHR-S is effectively extended to include all of health informatics (and beyond). Rather, "The best way to eat an elephant is in small pieces".

Classification of EHR standards

There is no formally accepted classification of EHR standards. But one approach used in the ISO EHR *ad hoc* Group Report [6] is described below[1].

Core interoperability standards

There are at least six important types of standards that contribute to EHR interoperability, including unique identification of the subject of care and standardized EHR system functionality – but these will be discussed under other headings.

The ISO EHR *ad hoc* Group classification lists four key pre-requisites necessary to achieve semantic interoperability of EHR information, with the first two of these also being required for functional interoperability[2]:

1. A standardized EHR Reference Model (namely, the EHR information architecture) between the sender (or sharer) and receiver of the information.
2. Standardized service interface models to provide interoperability between the EHR service and other components such as demographics, terminology, access control and security services in a comprehensive clinical information system.
3. A standardized set of domain-specific concept models, namely, archetypes and templates for clinical, demographic, and other domain-specific concepts.
4. Standardized terminologies (which underpin the archetypes).

Content standards

Content standards is an important category of standards that can be further subdivided into "content standards for the "HR" and "content standards for EHR systems". EHR content is

[1] The approach to standards classification described here is framed by the ISO RM/ODP methodology [7] and two-level modelling used by both HL7 V3 and the CEN/*open*EHR standards groups. An alternative classification based on the ISO Health Informatics Profiling Framework is also described in [6].

[2] The four points below are reproduced directly from ISO 20514. A further discussion on the key role of interoperability for EHRs can be found in section 4.2 of that document.

explicitly excluded from the DSTU, whereas the functional content for EHR systems is the purpose of the DSTU.

Content standards for the EHR

Content standards for the EHR includes standards for data elements comprising minimum data sets and disease registers such as emergency medicine, diabetes, cancer, and statutory reportable diseases. It may also include standards for the data element content of parts of an EHR (for example, a discharge summary or referral) or for EHRs with a specific focus (for example, the ASTM draft standard for a "Continuity of Care Record" (CCR)).

There may also be standards for transmission of standardized data sets. For example, a standardized HL7 message is being developed for a discharge summary. However, this is an example of a messaging standard and not an EHR standard. Note also that when transmission is required from one standards-based EHR system to another, service-based communication in the form of an EHR extract is more efficient than messaging for EHR content such as discharge summaries and referrals.

Content standards for EHR systems

Content standards for EHR systems refers to functional content of EHR systems (for example, the HL7 EHR System Functional Model DSTU).

Standards for EHR-related services

As mentioned earlier, standards for EHR-related services such as terminology, security, and decision support will normally be considered to be out of scope for EHR standards Technical Committees (TC) and Working Groups (WG) since they will be developed by TCs and WGs dedicated to these areas. There are, however, areas of overlap where it may be appropriate for an EHR TC/WG to work jointly with another specialist TC/WG. A good example is EHR access control and consent management standards. These standards typically contain both a policy element and a technical security element and are best developed jointly by an EHR TC/WG and a Security TC/WG with the former providing input on the policy issues and the latter on technical security matters.

One important EHR-related service which is often not covered by any specialist TC/WG within health informatics standards development organizations (SDOs) is demographics – particularly in regard to client (patient/subject-of-care) identification and provider (clinician) identification. Unique identification of all EHR parties is clearly essential for both medico-legal and interoperability purposes. Note that it is desirable to have a "Unique Identifier" (namely, a unique number) standard for EHR and other purposes, but a "Unique Identifier standard" is not essential for unique identification. ISO/TC 215 and several other health informatics SDOs have or are developing client and provider identification standards that use a combination of demographic attributes for identification, without requiring a unique identification number.

Standards for specific EHR technologies, sectors and stakeholders

The development of EHR standards for particular technologies, health sectors and/or stakeholders should be undertaken only where absolutely necessary to avoid the problem of incompatibility between "special purpose" and "generic" EHR standards. For example, there should be no reason to develop an EHR architecture standard for a Personal Health Record that differs from that of a generic EHR architecture standard.

The need for special interest EHR standards often arises because of the lack of a relevant generic standard. An example of this is the development of EHR architecture and content standards for Health Cards within CEN and ISO to meet the immediate needs of Health Card projects in Europe and elsewhere, before the equivalent generic EHR standards are available. Fortunately, there has been good liaison between the Health Card and EHR Working Groups in CEN and ISO to minimize the possibly of incompatibilities.

There are of course some legitimate examples of the need for special interest versions of generic EHR standards. The HL7 EHR-S DSTU is a good example of the combination of sector-specific specializations within an overarching generic EHR standard. The underlying functional model and function set is the same for all care settings, ensuring overall compatibility, while also allowing the function set to be customized to suit the needs of each particular care setting profile. This is being further extended to embrace the concept of realm-specific specializations so that an ambulatory care profile for the United States may be different from an ambulatory care profile for Canada.

EHR meta standards

This group of standards consists of high-level (Enterprise view in RM/ODP terms) standards such as the ISO Emergency Data Framework, Health Indicators Conceptual Framework, and Health Informatics Profiling Framework. An EHR Enterprise Architecture standard covering the scope, policies and high-level (conceptual/enterprise) architecture for the data management and knowledge management components of the EHR would be another example of an EHR meta standard.

Appendix B: Current International EHR Standards Activities

Overview

There are three main standards bodies currently active in international standards directly related to the EHR. These are ISO (International Standards Organization), CEN (Committee European Normalization - the European Standards Organization), and HL7 (Health Level 7) that is U.S.-based but with now over 20 international affiliates. Within the United States there are many other SDOs that are involved in the development of EHR-related standards, most notably ASTM [8] and the Object Management Group Health Domain Task Force (OMG HDTF) [9]. ASTM has been most active in the area of EHR content standards (e.g. the Continuity of Care Record standard) whilst the HDTF have made a significant contribution to the development of open service specifications such as COAS (Clinical Observation Access Service), PIDS (Person Identification Service), TQS/LQS (Terminology/Lexicon Query Service), and RAD (Resource Access Service). DICOM is the peak international SDO for image storage and communication in health.

ISO/TC 215

ISO/TC 215 [10] is the peak international standards body for EHR and other health informatics standards. However, it is a relative newcomer to health informatics standards, having been established only five years ago.

Some of the standards developed by TC 215 are produced "*de novo*" (e.g. ISO 18308 "Requirements for an EHR Reference Architecture") within the TC 215 working groups, but many others use existing standards from other national and international standards organizations as at least a starting point for an ISO standard. Examples of such organizations are IEEE, CEN, HL7, DICOM, and Standards Australia. Some organizations such as IEEE, CEN, and HL7 have special agreements with ISO that enable their existing standards to be fast-tracked to become ISO standards. For example, HL7 V2.5 is undergoing fast-track adoption by ISO under a new ISO-HL7 Agreement and several CEN standards in the area of medical devices and health cards are being adopted under the ISO-CEN Vienna Agreement.

ISO/TC 215 currently has six working groups:

WG1: Health Records and Modeling Coordination

WG2: Messaging and Communication

WG3: Health Concept Representation

WG4: Security

WG5: Health Cards

WG6: e-Pharmacy

The Chair of TC 215 is currently held by South Korea and the Secretariat is held by the United States through HIMSS.

Some of the recent and current EHR-related standards on the TC 215 work program include:

- Requirements for an Electronic Health Record Architecture (WG1 - ISO 18308)
- Country Identifier Standards (WG1 - ISO 17120)
- Health Indicators Conceptual Framework (WG1 - ISO 21667)
- Health Informatics Profiling Framework (WG1 - ISO 17119)
- EHR Definition, Scope and Context (WG1 - ISO 20514)
- Identification of Subjects of Health Care (WG1 - ISO 17457)
- Framework for Emergency Data Sets (WG1)
- Health Indicators – Definitions, Attributes and Relationships (WG1)
- Architectural Requirements for EHR Systems (WG1)
- Data Types for use in Healthcare Data Interchange (WG2 - ISO 21090)
- Privilege Management and Access Control (WG4 - ISO 22600)
- Functional and Structural Roles (WG4)

CEN/TC 251

CEN is the peak European standards organization that transcends the national standards organizations of its member countries. It has a membership of 22 countries that comprise all of the 15 European Union states (this will become 25 countries in 2004) plus seven other member countries that are not currently part of the EU (Czech Republic, Hungary, Iceland, Malta, Norway, Slovakia, and Switzerland). CEN/TC 251 [11] is the health informatics Technical Committee of CEN.

At present there is only one comprehensive EHR interoperability standard in the world. This is the CEN ENV13606[3] standard that was published in 1999/2000. It built upon the first CEN EHR standard, ENV12265, published in 1995. It was based almost entirely on the Good European Health Record (the original GEHR) but was never implemented. ENV13606 has had limited uptake due mainly to difficulties with implementation inherent in its single-level modeling approach. In November 2001, a decision was taken by CEN to revise

[3] "ENV" denotes a "Pre-standard" (soon to be renamed a "Technical Specification" to comply with ISO terminology) whilst "EN" denotes a full *de jure* European standard. All CEN standards are ENVs for a period of three years which enables implementation experience and feedback before becoming a full standard. At the end of the three year period, a pre-standard can be converted without change to full EN status, or it can be revised to become an EN, or it can be scrapped.

ENV13606 and to adopt the *open*EHR[4]/GEHR archetype methodology[5]. An MOU was signed between CEN and the *open*EHR Foundation [12] to enable the Australian members of *open*EHR to participate in the revision project.

The ENV13606 standard was in four parts but the revised EN13606 will consist of five parts:

- Part 1: Reference Model – a generic information model for communicating one or more EHR extracts (or the entire EHR) of any subject of care (patient/consumer).
- Part 2: Archetype Interchange Specification – a generic information model and language for representing and communicating the definition of individual instances of Archetypes.
- Part 3: Reference Archetypes and Term Lists – a range of Archetypes reflecting a diversity of clinical requirements and settings, as a "starter set" for adopters and to illustrate how other clinical domains might similarly be represented (for example by health professional groups).
- Part 4: Security Features – the information model concepts that need to be reflected within individual EHR instances to enable suitable interaction with the security components that are anticipated to be required in any future EHR deployment.
- Part 5: Exchange Models – a set of models that build on the above parts and can form the basis of message-based or service-based communication.

The revised CEN EN13606 will also include compliance with the HL7 CDA (Clinical Document Architecture) Release 2. This will form a very important harmonization bridge between Europe and the U.S.. A simple schematic diagram of this relationship between *open*EHR, CEN 13606, and HL7 CDA is:

[4] The *open*EHR EHR model is common framework and open specification for structuring, storing and managing patient data so that it can be shared and exchanged between different healthcare providers in a safe and secure manner. *open*EHR is not in itself a standard but is a leading input into the development of CEN and other EHR standards.

[5] A non-technical definition of an archetype is “a model of a clinical or other domain-specific concept which defines the structure and business rules of the concept.” Archetypes may define simple compound concepts such as ‘blood pressure’ or ‘address’, or more complex compound concepts such as ‘family history’ or ‘microbiology result’. They are not used to define atomic concepts such as anatomical terms.

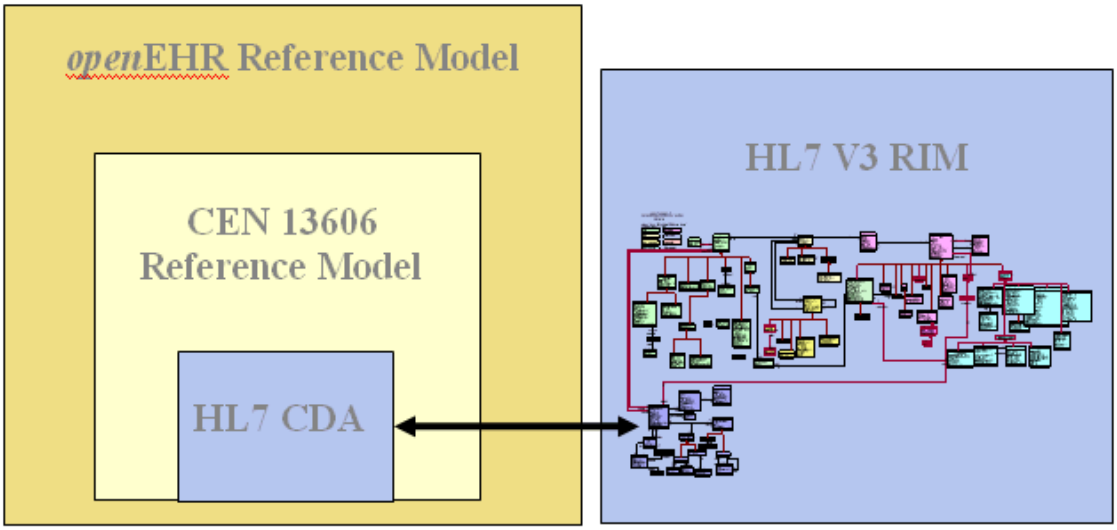


Figure 2 Relationship between HL7 CDA, CEN 13606, and *open*EHR

The complete 5-part standard will be finished in 2004 and will become a full *de jure* standard in the 25 countries of the European Union at that time.

Health Level Seven (HL7) Standards

Health Level Seven (HL7) has traditionally been concerned mainly with interoperability standards. However, in 2000 its mission statement was modified to include the EHR. The first EHR-related HL7 standard development was for the Clinical Document Architecture (CDA). The CDA is not a full EHR specification but it forms an important sub-component of the EHR and is very compatible with the equivalent components in *open*EHR and CEN 13606[6].

The CDA was not initiated as an EHR project but rather as a means of identifying and tracking the numerous clinical documents that are created and transmitted every day in the United States as part of the transcription process. The HL7 EHR-S DSTU project on the other hand, is HL7's first conscious move into EHR standards development. There have been small projects in the past to develop standardized EHR functional specifications but nothing like the scale and potential international importance of the DSTU.

The work of the HL7 Templates, Vocabulary, and Decision Support TCs, whilst not primarily involved in the development of core EHR standards, is clearly also important in providing "building blocks" for the EHR.

EHR-S Interoperability

It is reasonable to assume that the EHR Systems of today and tomorrow will rely on interoperability standards to achieve seamless coordination and cooperation.

[6] A CDA Document is equivalent to a Composition in the CEN/*open*EHR EHR structure.

Conformance using Functional Profiles

Profiles are routinely used to specify unambiguously how a specific application or project conforms to an HL7 standard (Version 2, Version 3, etc.) or to other standards (e.g. DICOM).

The HL7 EHR-S Specification will use Functional Profiles to create specification based on this standard. These specifications may refer to an application by identifying which of the "standard" functions are implemented by an application.

Harmonization

The importance of harmonization of the standards development work being undertaken by the main SDOs cannot be overstated. ISO/TC 215 performs a very important function in promoting and undertaking harmonization at the international level but it is also important for harmonization to be occurring "at the coal face" between the two main regional players in EHR standardization. CEN and HL7 have signed an MOU to further cooperation between the two organizations, with a particular emphasis on harmonization. This effort received a considerable boost in 2002 when Mark Shafarman, the Chair Elect of HL7, joined the 13606 revision Taskforce and has become a regular attendee at CEN meetings. The CEN-HL7 Harmonization is occurring on several fronts:

- CEN/*open*EHR Reference Model with HL7 CDA – This has already been discussed in section 5.3.
- CEN/*open*EHR archetypes with HL7 templates – HL7 templates have many similarities to archetypes and the introduction of the new Archetype Definition Language (ADL) shows great promise for achieving harmonization.
- Data types – these are the lowest level artifacts for interoperability so harmonization of HL7, CEN, and *open*EHR data types is essential to ensure both EHR and messaging interoperability.
- HL7 RIM with CEN and *open*EHR – This is less urgent from an EHR viewpoint than the other harmonization tasks but it is highly desirable in the longer term to have good harmonization between HL7 V3 messaging standards and the EHR standards.

Appendix C: Future International Directions for EHR Standards

As the peak international SDO for health informatics standards, ISO/TC 215 in expected to be the "home" for all future EHR standards of international significance, even though many of these standards will initially be developed in national or regional SDOs. Two years ago there were very few such standards available or under development. Today, the outlook is much more optimistic. The likely source of the main international EHR standards necessary for interoperability and for the improvement of quality and safety in healthcare are discussed below.

EHR interoperability standards

Generic EHR interoperability standards

CEN/TC 251 has foreshadowed its intention to introduce the revised EN13606 standard into ISO/TC 215 under the Vienna Agreement when the project is completed in 2004. It would be possible under this Agreement to introduce 13606 into ISO as a Draft International Standard that could be balloted without modification. However, it is essential for the success of any 13606-based ISO standard that it has broad support beyond Europe and Australia[7] before going to ballot. In particular, U.S. support is seen as essential given the size and importance of this market.

There are very encouraging signs that this will be achievable. European and other international EHR experts are actively participating in HL7's EHR SIG and are working with the HL7 TCs on a range of harmonization activities as outlined above. HL7 experts are also working directly with CEN 13606 and other projects. CEN has also given its permission for the ISO EHR Working Group to participate in the 13606 revision project by receiving the draft CEN documents for review and comment back to the 13606 Taskforce. It is expected that the ISO EHR standard based on CEN EN13606 should be completed and become the international EHR interoperability standard within two years.

The ISO "Data Types for use in Healthcare Data Interchange", based on harmonization of HL7 and CEN data types, will be another important standard for EHR interoperability.

Standardizing archetypes and templates

EN13606 fulfills the first of the four main requirements for EHR interoperability – i.e. a standardized EHR Reference Model. It also enables fulfillment of the third requirement – i.e. a standardized set of clinical and other domain-specific concept models (archetypes and templates). A production quality open source software tool for authoring archetypes and templates will be available in the near future. A number of clinical archetypes have already been built using a prototype Archetype Editor.

[7] The CEN EN 13606 drafts are already being used as the basis for the development of a set of Australian EHR interoperability standards.

The development of archetypes and templates is done by clinicians (physicians, nurses, allied health practitioners etc) and other domain experts rather than IT specialists. This is a major benefit in terms of empowerment and buy-in of EHR system users. It is estimated that around 300 archetypes will be required for each major health specialty/discipline and around 3,000 archetypes to cover all of health (due to significant overlap). It will be essential that the development of archetypes is done using a controlled process to avoid the problem of multiple incompatible versions of the same concept that has plagued the terminology field in the past.

It is preferable that archetype development should be done under the *aegis* of the health professional colleges (e.g. American College of Surgeons, American College of Nursing) in conjunction with an SDO such as HL7, CEN, or ISO. Templates (which are combinations of archetypes for data entry forms, views, etc) will be much more numerous and will mainly be used at a local level, thus requiring a lesser degree of agreement and control.

EHR content standards

There are many areas of need for international EHR content standards, but perhaps a strong candidate for the first of these will be the ASTM Continuity of Care standard as the basis for an ISO standard in this area.

The HL7 EHR-S DSTU is expected to form the basis for the international (ISO) standard for EHR system functionality. Its unique concept of "realm-specific" profiles within a single functional model and a consistent overall framework should find utility in the development of other health informatics standards. Australia has already foreshadowed the development of an Australian realm-specific version of the DSTU and several other countries have also expressed strong interest.

EHR-related standards

There are many important international standards that are required in the areas of security, terminology, and demographics to support comprehensive EHRs and EHR systems. Some of these are already under development or scheduled for commencement within ISO/TC 215, including identification of subjects of healthcare, provider identification, and EHR access control and consent management.

Terminology standards

Terminology is perhaps the most problematic piece of the EHR interoperability jigsaw. Most of the terminology standards produced by health informatics SDOs are meta-standards (i.e. standards about how to build quality terminologies) rather than standardizing the content of actual terminologies. There are exceptions such as the recent ISO standard nursing terminology. Most health terminologies have been developed or have grown from an original core in a rather haphazard way (hence the need for terminology meta-standards for the future development of better quality terminologies). Most large terminologies are "polluted" by a combinatorial explosion of pre-coordinated terms in addition to core atomic terms which makes them difficult to use and sometimes problematic when terms are post-coordinated in EHR systems for decision support and other applications.

Another significant problem with current terminologies, particularly large reference terminologies like SNOMED-CT, is that most are proprietary. To ensure at least *de-facto* standard status, it is necessary for such proprietary terminologies to be ubiquitously available to healthcare providers, usually through a national license.

Fortunately, the advent of archetypes and "micro vocabularies" means that significant interoperability of patient information can be achieved without having to wait for the "big terminology problem" to be solved. HL7 has already developed some 400 micro vocabularies to populate HL7 messages from its Clinical Terminology Service. *open*EHR/CEN is adopting the same strategy for naming nodes of archetypes and to populate list variables within archetypes. These micro-vocabularies enable a significant degree of interoperability without any reliance on the availability of external terminologies. However, they can be bound to any available external terminology such as SNOMED or ICD at run-time. Comprehensive reference terminologies will of course still be required for large groups of terms such as diagnoses, lab tests, and anatomical terms.

Service interface standards

Service interface standards are required to ensure that the various components of an integrated clinical information system (e.g. demographics, terminology, access control/security) can interoperate with the core EHR system. A number of open specifications for health service interfaces have been developed by the OMG [9] but some of these need revision and incorporation into a broader standards framework. HL7 is currently developing a Clinical Terminology Service (CTS) and may build other service specifications in the future. o*pen*EHR is also progressively developing service interface specifications (e.g. demographics) and CEN/TC 251 is currently revising its pre-standard ENV12967, "Health Informatics Service Architecture" (HISA).

More work needs to be done in this area of standardization, particularly in building and agreeing on a common set of service standards which can be moved into ISO for international agreement.

Where do messaging standards fit with the EHR?

Messaging standards such as HL7, DICOM, and UN/Edifact play a crucial role for interoperability between non-EHR systems (e.g. lab, radiology, and pharmacy systems) and EHR systems or between two non-standardized EHR systems (i.e. EHR systems that do not share the same information model. Messaging standards will therefore always be necessary for lab, imaging, and pharmacy orders and results since lab and similar systems do not contain/operate on patient-centered EHRs (since this is neither their primary purpose nor operationally efficient).

The Venn diagram below illustrates that health service messaging has a much larger domain than the EHR. Patient administration, billing and materials management are examples of areas within the scope of messaging but generally considered to be outside the scope of the EHR. Care plans, patient consultation notes and health summaries could possibly be

transmitted as messages[8] but it is much more efficient to transfer EHR extracts directly between such systems using a lower level interoperability technology such as SOAP, RPC, CORBA etc. Of course this is only possible with standards-based EHRs and EHR systems (i.e. EHRs which comply to the same information model and are independent of the EHR systems architecture).

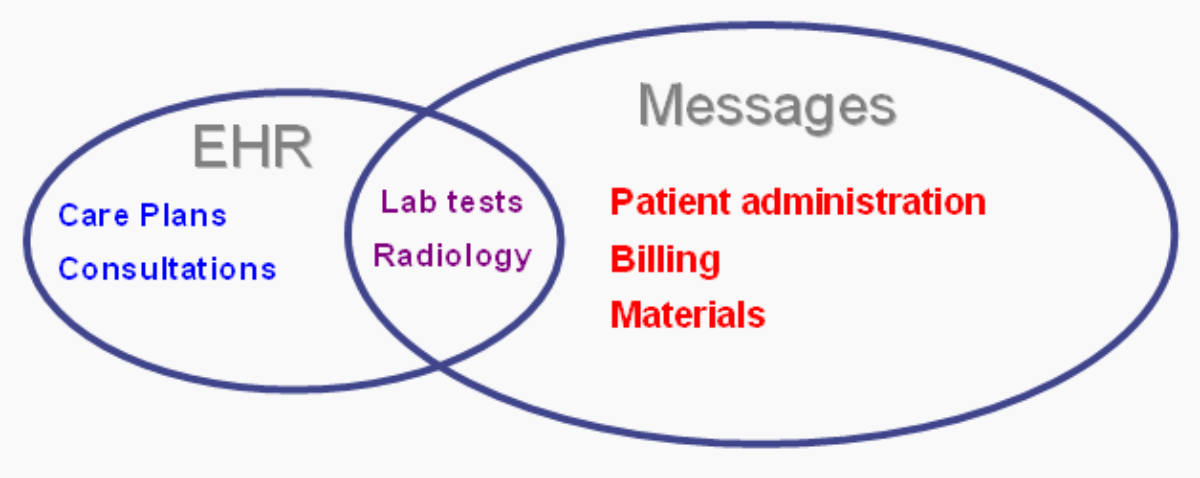


Figure 3 Relationship between messaging and the EHR

Lab tests, radiology and pharmacy are examples of areas where both messaging and the EHR play a role in communication. As stated above, messaging is necessary in these areas when placing orders and receiving results but the results could then be communicated to another standards-based EHR system more easily and efficiently using EHR extracts rather than messages.

It should be noted that archetypes and templates are also applicable to messaging and their use with HL7 V3 RIMs has already been demonstrated.

[8] "Messaging" in its broadest sense could be used to indicate any communication between two systems but the sense in which it is usually used in health informatics is more restricted to formal high-level messaging protocols such as HL7, DICOM, X12 etc.

Appendix D: EHR-S Functional Outline

The EHR-S Functional Outline, consisting of three sections or chapters:

> Direct Care Functions

> Supportive Functions

> Information Infrastructure Functions

Direct Care EHR-S Functions

ID	Name	Statement	Description
DC.1	**Care Management**		
DC.1.1	Health information capture, management, and review		For those functions related to data capture, data may be captured using standardized code sets or nomenclature, depending on the nature of the data, or captured as unstructured data. Care-setting dependent data is entered by a variety of caregivers. Details of who entered data and when it was captured should be tracked. Data may also be captured from devices or other Tele-Health Applications.
DC.1.1.1	Identify and maintain a patient record	Identify and maintain a single patient record for each patient.	Key identifying information is stored and linked to the patient record. Static data elements as well as data elements that will change over time are maintained. A lookup function uses this information to uniquely identify the patient.
DC.1.1.2	Manage patient demographics	Capture and maintain demographic information. Where appropriate, the data should be clinically relevant, reportable and trackable over time.	Contact information including addresses and phone numbers, as well as key demographic information such as date of birth, sex, and other information is stored and maintained for reporting purposes and for the provision of care.
DC.1.1.3	Manage summary lists	Create and maintain patient-specific summary lists that are structured and coded where appropriate.	Patient summary lists can be created from patient specific data and displayed and maintained in a summary format. The functions below are important, but do not exhaust the possibilities.
DC.1.1.3.1	Manage problem list	Create and maintain patient-specific problem lists.	A problem list may include, but is not limited to: Chronic conditions, diagnoses, or symptoms, functional limitations, visit or stay-specific conditions, diagnoses, or symptoms. Problem lists are managed over time, whether over the course of a visit or stay or the life of a patient, allowing documentation of historical information and tracking the changing character of problem(s) and their priority. All pertinent dates, include date noted or diagnosed, dates of any changes in problem specification or prioritization, and date of resolution are stored. This might include time stamps, where useful and appropriate. The entire problem history for any problem in the list is viewable.
DC.1.1.3.2	Manage medication list	Create and maintain patient-specific medication lists.	Medication lists are managed over time, whether over the course of a visit or stay, or the lifetime of a patient. All pertinent dates, including medication start, modification, and end dates are stored. The entire medication history for any medication, including alternative supplements and herbal medications, is viewable. Medication lists are not limited to medication orders recorded by providers, but may include, for example, pharmacy dispense/supply records and patient-reported medications.

DC.1.1.3.3	Manage allergy and adverse reaction list	Create and maintain patient-specific allergy and adverse reaction lists.	Allergens, including immunizations, and substances are identified and coded (whenever possible) and the list is managed over time. All pertinent dates, including patient-reported events, are stored and the description of the patient allergy and adverse reaction is modifiable over time. The entire allergy history, including reaction, for any allergen is viewable. The list(s) include drug reactions that are not classifiable as a true allergy and intolerances to dietary or environmental triggers. Notations indicating whether item is patient reported and/or provider verified are supported.
DC.1.1.4	Manage Patient History	Capture, review, and manage medical procedural/surgical, social and family history including the capture of pertinent positive and negative histories, patient-reported or externally available patient clinical history.	The history of the current illness and patient historical data related to previous medical diagnoses, surgeries and other procedures performed on the patient, and relevant health conditions of family members is captured through such methods as patient reporting (for example interview, medical alert band) or electronic or non-electronic historical data. This data may take the form of a positive or a negative such as: "The patient/family member has had..." or "The patient/family member has not had..." When first seen by a health care provider, patients typically bring with them clinical information from past encounters. This and similar information is captured and presented alongside locally captured documentation and notes wherever appropriate.
DC.1.1.5	Summarize health record	Present a chronological, filterable, and comprehensive review of a patient's EHR, which may be summarized, subject to privacy and confidentiality requirements.	A key feature of an electronic health record is its ability to present, summarize, filter, and facilitate searching through the large amounts of data collected during the provision of patient care. Much of this data is date or date-range specific and should be presented chronologically. Local confidentiality rules that prohibit certain users from accessing certain patient information must be supported.
DC.1.1.6	Manage clinical documents and notes	Create, addend, correct, authenticate and close, as needed, transcribed or directly-entered clinical documentation and notes.	Clinical documents and notes may be created in a narrative form, which may be based on a template. The documents may also be structured documents that result in the capture of coded data. Each of these forms of clinical documentation are important and appropriate for different users and situations.
DC.1.1.7	Capture external clinical documents	Incorporate clinical documentation from external sources.	Mechanisms for incorporating external clinical documentation (including identification of source) such as image documents and other clinically relevant data are available. Data incorporated through these mechanisms is presented alongside locally captured documentation and notes wherever appropriate.
DC.1.1.8	Capture patient-originated data	Capture and explicitly label patient-provided and patient-entered clinical data, and support provider authentication for inclusion in patient history	It is critically important to be able to distinguish patient-provided and patient-entered data from clinically authenticated data. Patients may provide data for entry into the health record or be given a mechanism for entering this data directly. Patient-entered data intended for use by care providers will be available for their use.

DC.1.1.9	Capture patient and family preferences	Capture patient and family preferences at the point of care.	Patient and family preferences regarding issues such as language, religion, culture, etcetera - may be important to the delivery of care. It is important to capture these at the point of care so that they will be available to the provider.
DC.1.2	Care plans, guidelines, and protocols		
DC.1.2.1	Present care plans, guidelines, and protocols	Present organizational guidelines for patient care as appropriate to support order entry and clinical documentation.	Care plans, guidelines, and protocols may be site specific, community or industry-wide standards. They may need to be managed across one or more providers. Tracking of implementation or approval dates, modifications and relevancy to specific domains or context is provided.
DC.1.2.2	Manage guidelines, protocols and patient-specific care plans.	Provide administrative tools for organizations to build care plans, guidelines and protocols for use during patient care planning and care.	Guidelines or protocols may contain goals or targets for the patient, specific guidance to the providers, suggested orders, and nursing interventions, among other items.
DC.1.2.3	Generate and record patient-specific instructions	Generate and record patient-specific instructions related to pre- and post-procedural and post-discharge requirements.	When a patient is scheduled for a test, procedure, or discharge, specific instructions about diet, clothing, transportation assistance, convalescence, follow-up with physician, etcetera. may be generated and recorded, including the timing relative to the scheduled event.
DC.1.3	Medication ordering and management		
DC.1.3.1	Order medication	Create prescriptions or other medication orders with detail adequate for correct filling and administration. Provide information regarding compliance of medication orders with formularies.	Different medication orders, including discontinue, refill, and renew, require different levels and kinds of detail, as do medication orders placed in different situations. The correct details are recorded for each situation. Administration or patient instructions are available for selection by the ordering clinicians, or the ordering clinician is facilitated in creating such instructions. Appropriate time stamps for all medication related activity are generated. This includes series of orders that are part of a therapeutic regimen, e.g. Renal Dialysis, Oncology. When a clinician places an order for a medication, that order may or may not comply with a formulary specific to the patient's location or insurance coverage, if applicable. Whether the order complies with the formulary should be communicated to the ordering clinician at an appropriate point to allow the ordering clinician to decide whether to continue with the order. Formulary-compliant alternatives to the medication being ordered may also be presented.

DC.1.3.2	Manage medication administration	Present to appropriate clinicians the list of medications that are to be administered to a patient, under what circumstances, and capture administration details.	In a setting in which medication orders are to be administered by a clinician rather than the patient, the necessary information is presented including: the list of medication orders that are to be administered; administration instructions, times or other conditions of administration; dose and route, etcetera. Additionally, the clinician is able to record what actually was or was not administered, whether or not these facts conform to the order. Appropriate time stamps for all medication related activity are generated.
DC.1.4	Orders, referrals, and results management		
DC.1.4.1	Place patient care orders	Capture and track orders based on input from specific care providers.	Orders that request actions or items can be captured and tracked. Examples include orders to transfer a patient between units, to ambulate a patient, for medical supplies, durable medical equipment, home IV, and diet or therapy orders. For each orderable item, the appropriate detail, including order identification and instructions, can be captured. Orders should be communicated to the correct recipient for completion if appropriate.
DC.1.4.2	Order diagnostic tests	Submit diagnostic test orders based on input from specific care providers.	For each orderable item, the appropriate detail and instructions must be available for the ordering care provider to complete. Orders for diagnostic tests should be transmitted to the correct destination for completion or generate appropriate requisitions for communication to the relevant resulting agencies.
DC.1.4.3	Manage order sets	Provide order sets based on provider input or system prompt.	Order sets, which may include medication orders, allow a care provider to choose common orders for a particular circumstance or disease state according to best practice or other criteria. Recommended order sets may be presented based on patient data or other contexts.
DC.1.4.4	Manage referrals	Enable the origination, documentation and tracking of referrals between care providers or healthcare organizations, including clinical and administrative details of the referral.	Documentation and tracking of a referral from one care provider to another is supported, whether the referred to or referring providers are internal or external to the healthcare organization. Guidelines for whether a particular referral for a particular patient is appropriate in a clinical context and with regard to administrative factors such as insurance may be provided to the care provider at the time the referral is created.
DC.1.4.5	Manage results	Route, manage and present current and historical test results to appropriate clinical personnel for review, with the ability to filter and compare results.	Results of tests are presented in an easily accessible manner and to the appropriate care providers. Flow sheets, graphs, or other tools allow care providers to view or uncover trends in test data over time. In addition to making results viewable, it is often necessary to send results to appropriate care providers using an electronic messaging systems, pagers, or other mechanism. Results may also be routed to patients electronically or in the form of a letter. Documentation of notification is accommodated.

DC.1.4.6	Order blood products and other biologics	Communicate with appropriate sources or registries to order blood products or other biologics.	Interact with a blood bank system or other source to manage orders for blood products or other biologics. Use of such products in the provision of care is captured. Blood bank or other functionality that may come under federal or other regulation (such as by the FDA in the United States) is not required; functional communication with such a system is required.
DC.1.5	Consents, authorizations and directives		
DC.1.5.1	Manage consents and authorizations	Create, maintain, and verify patient treatment decisions in the form of consents and authorizations when required.	Treatment decisions are documented and include the extent of information, verification levels and exposition of treatment options. This documentation helps ensure that decisions made at the discretion of the patient, family, or other responsible party govern the actual care that is delivered or withheld.
DC.1.5.2	Manage patient advance directives	Capture, maintain and provide access to patient advance directives.	Patient advance directives and provider DNR orders can be captured as well as the date and circumstances under which the directives were received, and the location of any paper records of advance directives as appropriate.
DC.2	**Clinical Decision Support**		
DC.2.1	Manage Health Information to enable Decision Support		
DC.2.1.1	Support for standard assessments	Offer prompts to support the adherence to care plans, guidelines, and protocols at the point of information capture.	When a clinician fills out an assessment, data entered triggers the system to prompt the assessor to consider issues that would help assure a complete/accurate assessment. A simple demographic value or presenting problem (or combination) could provide a template for data gathering that represents best practice in this situation, e.g. Type II diabetic review, fall and 70+, rectal bleeding etcetera. As another example, to appropriately manage the use of restraints, an online alert is presented defining the requirements for a behavioral health restraint when it is selected.
DC.2.1.2	Support for Patient Context-enabled Assessments	Offer prompts based on patient-specific data at the point of information capture.	When a clinician fills out an assessment, data entered is matched against data already in the system to identify potential linkages. For example, the system could scan the medication list and the knowledge base to see if any of the symptoms are side effects of medication already prescribed. Important but rare diagnoses could be brought to the doctor's attention, for instance ectopic pregnancy in a woman of child bearing age who has abdominal pain.

DC.2.1.3	Support for identification of potential problems and trends	Identify trends that may lead to significant problems, and provide prompts for consideration.	When personal health information is collected directly during a patient visit input by the patient, or acquired from an external source (lab results), it is important to be able to identify potential problems and trends that may be patient-specific, given the individual's personal health profile, or changes warranting further assessment. For example: significant trends (lab results, weight); a decrease in creatinine clearance for a patient on metformin, or an abnormal increase in INR for a patient on warfarin.
DC.2.1.4	Support for patient and family preferences	Support the integration of patient and family preferences into clinical decision support at all appropriate opportunities.	Decision support functions should permit consideration of patient/family preferences and concerns, such as with language, religion, culture, medication choice, invasive testing, and advance directives.
DC.2.2	Care plans, guidelines and protocols		
DC.2.2.1	Support for condition based care plans, guidelines, protocols		
DC.2.2.1.1	Support for standard care plans, guidelines, protocols	Support the use of appropriate standard care plans, guidelines and/or protocols for the management of specific conditions.	At the time of the clinical encounter, standard care protocols are presented. These may include site-specific considerations.
DC.2.2.1.2	Support for context-sensitive care plans, guidelines, protocols	Identify and present the appropriate care plans, guidelines and/or protocols for the management of specific conditions that are patient-specific.	At the time of the clinical encounter (problem identification), recommendations for tests, treatments, medications, immunizations, referrals and evaluations are presented based on evaluation of patient specific data, their health profile and any site-specific considerations. These may be modified on the basis of new clinical data at subsequent encounters.
DC.2.2.1.3	Capture variances from standard care plans, guidelines, protocols	Identify variances from patient-specific and standard care plans, guidelines, and protocols.	Variances from care plans, guidelines, or protocols are identified and tracked, with alerts, notifications and reports as clinically appropriate. This may include systematic deviations from protocols or variances on a case by case basis dictated by the patient's particular circumstances.
DC.2.2.1.4	Support management of patient groups or populations	Provide support for the management of populations of patients that share diagnoses, problems, demographic characteristics, and etcetera.	Populations or groups of patients that share diagnoses (such as diabetes or hypertension), problems, demographic characteristics, and medication orders are identified. The clinician may be notified of eligibility for a particular test, therapy, or follow-up; or results from audits of compliance of these populations with disease management protocols.
DC.2.2.1.5	Support for research protocols relative to individual patient care.	Provide support for the management of patients enrolled in research protocols and management of patients enrolled in research protocols.	The clinician is presented with protocol-based care for patients enrolled in research studies. See S.3.3.1 for support for enrollment of patients in research protocols.
DC.2.2.1.6	Support self-care	Provide the patient with decision support for self-management of a condition between patient-provider encounters.	Patients with specific conditions need to follow self-management plans that may include schedules for home monitoring, lab tests, and clinical check ups; recommendations about nutrition, physical activity, tobacco use, etcetera; and guidance or reminders about medications.

DC.2.3	Medication and immunization management		
DC.2.3.1	Support for medication and immunization ordering		
DC.2.3.1.1	Support for drug interaction checking	Identify drug interaction warnings at the point of medication ordering	The clinician is alerted to drug-drug, drug-allergy, and drug-food interactions at levels appropriate to the health care entity. These alerts may be customized to suit the user or group.
DC.2.3.1.2	Patient specific dosing and warnings	Identify and present appropriate dose recommendations based on patient-specific conditions and characteristics at the time of medication ordering.	The clinician is alerted to drug-condition interactions and patient specific contraindications and warnings e.g. elite athlete, pregnancy, breast-feeding or occupational risks. The preferences of the patient may also be presented e.g. reluctance to use an antibiotic. Additional patient parameters, including age, Ht, Wt, BSA, may also be incorporated.
DC.2.3.1.3	Medication recommendations	Recommend treatment and monitoring on the basis of cost, local formularies or therapeutic guidelines and protocols.	Offer alternative treatments on the basis of best practice (e.g. cost or adherence to guidelines), a generic brand, a different dosage, a different drug, or no drug (watchful waiting). Suggest lab order monitoring as appropriate. Support expedited entry of series of medications that are part of a treatment regimen, i.e. renal dialysis, Oncology, transplant medications, etcetera.
DC.2.3.2	Support for medication and immunization administration or supply	Alert providers in real-time to potential administration errors such as wrong patient, wrong drug, wrong dose, wrong route and wrong time in support of medication administration or pharmacy dispense/supply management and workflow.	To reduce medication errors at the time of administration of a medication, the patient is positively identified; checks on the drug, the dose, the route and the time are facilitated. Documentation is a by-product of this checking; administration details and additional patient information, such as injection site, vital signs, and pain assessments, are captured. In addition, access to online drug monograph information allows providers to check details about a drug and enhances patient education.
DC.2.4	Orders, referrals, results and care management		
DC.2.4.1	Support for non-medication ordering	Identify necessary order entry components for non-medication orders that make the order pertinent, relevant and resource-conservative at the time of provider order entry; flag any inappropriate orders based on patient profile.	Possible order entry components include, but are not limited to: missing results required for the order, suggested corollary orders, notification of duplicate orders, institution-specific order guidelines, guideline-based orders/order sets, order sets, order reference text, patient diagnosis specific recommendations pertaining to the order. Also, warnings for orders that may be inappropriate or contraindicated for specific patients (e.g. X-rays for pregnant women) are presented.

DC.2.4.2	Support for result interpretation	Evaluate results and notify provider of results within the context of the patient's clinical data.	Possible result interpretations include, but are not limited to: abnormal result evaluation/notification, trending of results (such as discrete lab values), evaluation of pertinent results at the time of provider order entry (such as evaluation of lab results at the time of ordering a radiology exam), evaluation of incoming results against active medication orders.
DC.2.4.3	Support for referrals		
DC.2.4.3.1	Support for the referral process based upon the specific patient's clinical data	Evaluate referrals within the context of a patient's clinical data.	When a healthcare referral is made, pertinent health information, including pertinent results, demographic and insurance data elements (or lack thereof) are presented to the provider. Protocols for appropriate workup prior to referral may be presented.
DC.2.4.3.2	Support for referral recommendations	Evaluate patient data and recommend that a patient be referred based on the specific patient's clinical data.	Entry of specific patient conditions may lead to recommendations for referral e.g. for smoking cessation counseling if the patient is prescribed a medication to support cessation.
DC.2.4.4	Support for Care Delivery		
DC.2.4.4.1	Support for safe blood administration	Alert provider in real-time to potential blood administration errors.	To reduce blood administration errors at the time of administration of blood products, the patient is positively identified and checks on the blood product, the amount, the route and the time are facilitated. Documentation is a by-product of this checking.
DC.2.4.4.2	Support for accurate specimen collection	Alert providers in real-time to ensure specimen collection is supported.	To ensure the accuracy of specimen collection, when a provider obtains specimens from a patient, the clinician can match each specimen collection identifier and the patient's ID bracelet. The provider is notified in real-time of potential collection errors such as wrong patient, wrong specimen type, wrong means of collection, wrong site, and wrong date and time. Documentation of the collection is a by-product of this checking.
DC.2.5	Support for Health Maintenance: Preventive Care and Wellness		
DC.2.5.1	Present alerts for preventive services and wellness	At the point of clinical decision making, identify patient specific suggestions/reminders, screening tests/exams, and other preventive services in support of routine preventive and wellness patient care standards.	At the time of an encounter, the provider or patient is presented with due or overdue activities based on protocols for preventive care and wellness. Examples include but are not limited to, routine immunizations, adult and well baby care, age and sex appropriate screening exams, such as PAP smears.

DC.2.5.2	Notifications and reminders for preventive services and wellness	Between healthcare encounters, notify the patient and/or appropriate provider of those preventive services, tests, or behavioral actions that are due or overdue.	The provider can generate notifications to patients regarding activities that are due or overdue and these communications can be captured. Examples include but are not limited to time sensitive patient and provider notification of: follow-up appointments, laboratory tests, immunizations or examinations. The notifications can be customized in terms of timing, repetitions and administration reports. E.g. a Pap test reminder might be sent to the patient a 2 months prior to the test being due, repeated at 3 month intervals, and then reported to the administrator or clinician when 9 months overdue.
DC.2.6	Support for population health		
DC.2.6.1	Support for clinical health state monitoring within a population.	Support clinical health state monitoring of aggregate patient data for use in identifying health risks from the environment and/or population.	Standardized surveillance performance measures that are based on known patterns of disease presentation can be identified by aggregating data from multiple input mechanisms. For example, elements include, but are not limited to patient demographics, resource utilization, presenting symptoms, acute treatment regimens, laboratory and imaging study orders and results and genomic and proteomic data elements. Identification of known patterns of existing diseases involves aggregation and analysis of these data elements by existing relationships. However, the identification of new patterns of disease requires more sophisticated pattern recognition analysis. Early recognition of new patterns requires data points available early in the disease presentation. Demographics, ordering patterns and resource use (e.g., ventilator or intensive care utilization pattern changes) are often available earlier in the presentation of non-predictable diseases. Consumer-generated information is also valuable with respect to surveillance efforts.
DC.2.6.2	Support for notification and response	Upon notification by an external, authoritative source of a health risk within the cared for population, alert relevant providers regarding specific potentially at-risk patients with the appropriate level of notification.	Upon receipt of notice of a health risk within a cared-for population from public health authorities or other external authoritative sources, identify and notify individual care providers or care managers that a risk has been identified and requires attention including suggestions on the appropriate course of action. This process gives a care provider the ability to influence how patients are notified, if necessary.
DC.2.6.3	Support for monitoring response to notifications regarding an individual patient's health, including appropriate follow-up notifications	In the event of a health risk alert and subsequent notification related to a specific patient, monitor if expected actions have been taken, and execute follow-up notification if they have not.	Identifies that expected follow-up for a specific patient event (e.g., follow up to error alerts or absence of an expected lab result) has not occurred and communicate the omission to appropriate care providers in the chain of authority. Of great importance to the notification process is the ability to match a care provider's clinical privileges with the clinical requirements of the notification.
DC.2.7	Support for knowledge access		

DC.2.7.1	Access clinical guidance	Provide relevant evidence-based information and knowledge to the point of care for use in clinical decisions and care planning.	Examples include but are not limited to: evidence on treatment of conditions and wellness, as well as context-specific links to other knowledge resources. For example, when a condition is diagnosed provider is directed to relevant online evidence for management.
DC.2.7.2	Patient knowledge access	Enable the accessibility of reliable information about wellness, disease management, treatments, and related information that is relevant for a specific patient.	An individual will be able to find reliable information to answer a health question, follow up from a clinical visit, identify treatment options, or other health information needs. The information may be linked directly from entries in the health record, or may be accessed through other means such as key word searching.
DC.3	**Operations Management and Communication**		
DC.3.1	Clinical workflow tasking	Schedule and manage tasks with appropriate timeliness.	Since the electronic health record will replace the paper chart, tasks that were based on the paper artifact must be effectively managed in the electronic environment. Functions must exist in the EHRS that support electronically any workflow that previously depended on the existence of a physical artifact (such as the paper chart, a phone message slip) in a paper based system. Tasks differ from other more generic communication among participants in the care process because they are a call to action and target completion of a specific workflow in the context of a patient's health record (including a specific component of the record). Tasks also require disposition (final resolution). The initiator may optionally require a response. For example, in a paper based system, physically placing charts in piles for review creates a physical queue of tasks related to those charts. This queue of tasks (for example, a set of patient phone calls to be returned) must be supported electronically so that the list (of patients to be called) is visible to the appropriate user or role for disposition. Tasks are time-limited (or finite). The state transition (e.g. created, performed and resolved) may be managed by the user explicitly or automatically based on rules. For example, if a user has a task to signoff on a test result, that task should automatically be marked complete by the EHR when the test result linked to the task is signed in the system. Patients will become more involved in the care process by receiving tasks related to their care. Examples of patient related tasks include acknowledgement of receipt of a test result forwarded from the provider, or a request to schedule an appointment for a pap smear (based on age and frequency criteria) generated automatically by the EHRS on behalf of the provider.

DC.3.1.1	Clinical task assignment and routing	Assignment, delegation and/or transmission of tasks to the appropriate parties.	Tasks are at all times assigned to at least one user or role for disposition. Whether the task is assignable and to whom the task can be assigned will be determined by the specific needs of practitioners in a care setting. Task-assignment lists help users prioritize and complete assigned tasks. For example, after receiving a phone call from a patient, the triage nurse routes or assigns a task to return the patient's call to the physician who is on call. Task creation and assignment may be automated, where appropriate. An example of a system-triggered task is when lab results are received electronically; a task to review the result is automatically generated and assigned to a clinician. Task assignment ensures that all tasks are disposed of by the appropriate person or role and allows efficient interaction of entities in the care process.
DC.3.1.2	Clinical task linking	Linkage of tasks to patients and/or a relevant part of the electronic health record.	Clinical tasks are linked to a patient or to a component of a patient's medical record. An example of a well defined task is "Dr. Jones must review Mr. Smith's blood work results." Efficient workflow is facilitated by navigating to the appropriate area of the record to ensure that the appropriate test result for the correct patient is reviewed. Other examples of tasks might involve fulfillment of orders or responding to patient phone calls.
DC.3.1.3	Clinical task tracking	Track tasks to guarantee that each task is carried out and completed appropriately.	In order to reduce the risk of errors during the care process due to missed tasks, the provider is able to view and track un-disposed tasks, current work lists, the status of each task, unassigned tasks or other tasks where a risk of omission exists. For example, a provider is able to create a report to show test results that have not been reviewed by the ordering provider based on an interval appropriate to the care setting.
DC.3.1.3.1	Clinical task timeliness tracking	Track and/or report on timeliness of task completion.	Capability to track and review reports on the timeliness of certain tasks in accordance with relevant law and accreditation standards.

DC.3.2	Support clinical communication		Healthcare requires secure communications among various participants: patients, doctors, nurses, chronic disease care managers, pharmacies, laboratories, payers, consultants, and etcetera. An effective EHRS supports communication across all relevant participants, reduces the overhead and costs of healthcare-related communications, and provides automatic tracking and reporting. The list of communication participants is determined by the care setting and may change over time. Because of concerns about scalability of the specification over time, communication participants for all care settings or across care settings are not enumerated here because it would limit the possibilities available to each care setting and implementation. However, communication between providers and between patients and providers will be supported in all appropriate care settings and across care settings. Implementation of the EHRS enables new and more effective channels of communication, significantly improving efficiency and patient care. The communication functions of the EHRS will eventually change the way participants collaborate and distribute the work of patient care.
DC.3.2.1	Inter-provider communication	Support secure electronic communication (inbound and outbound) between providers to trigger or respond to pertinent actions in the care process (including referral), document non-electronic communication (such as phone calls, correspondence or other encounters) and generate paper message artifacts where appropriate.	Communication among providers involved in the care process can range from real time communication (for example, fulfillment of an injection while the patient is in the exam room), to asynchronous communication (for example, consult reports between physicians). Some forms of inter-practitioner communication will be paper based and the EHRS must be able to produce appropriate documents.
DC.3.2.2	Pharmacy communication	Provide features to enable secure bidirectional communication of information electronically between practitioners and pharmacies or between practitioner and intended recipient of pharmacy orders.	When a medication is prescribed, routed to the pharmacy or another intended recipient of pharmacy orders. This information is used to avoid transcription errors and facilitate detection of potential adverse reactions. Upon filling the prescription, information is sent back to the practitioner to indicate that the patient received the medication. If there is a question from the pharmacy, that communication can be presented to the provider with their other tasks.
DC.3.2.3	Provider and patient or family communication	Trigger or respond to electronic communication (inbound and outbound) between providers and patients or patient representatives with pertinent actions in the care process.	The clinician is able to communicate with patients and others, capturing the nature and content of electronic communication, or the time and details of other communication. For example: when test results arrive, the clinician may wish to email the patient that test result was normal (details of this communication are captured); a patient may wish to request a refill of medication by emailing the physician; patients with asthma may wish to communicate their peak flow logs/diaries to their provider; or a hospital may wish to communicate with selected patients about a new smoking cessation program.

DC.3.2.4	Patient, family and care giver education	Identify and make available electronically or in print any educational or support resources for patients, families, and caregivers that are most pertinent for a given health concern, condition, or diagnosis and which are appropriate for the person (s).	The provider or patient is presented with a library of educational materials and where appropriate, given the opportunity to document patient/caregiver comprehension. The materials can be printed or electronically communicated to the patient.
DC.3.2.5	Communication with medical devices	Support communication and presentation of data captured from medical devices.	Communication with medical devices is supported as appropriate to the care setting. Examples include: vital signs/pulse-oximeter, anesthesia machines, home diagnostic devices for chronic disease management, laboratory machines, bar coded artifacts (medicine, immunizations, demographics, history, and identification).

Supportive EHR-S Functions

ID	Name	Statement	Description
S.1	**Clinical Support**		
S.1.1	Registry Notification	Enable the automated transfer of formatted demographic and clinical information to and from local disease specific registries (and other notifiable registries) for patient monitoring and subsequent epidemiological analysis.	The user can export personal health information to disease specific registries, other notifiable registries like immunization registries, and add new registries through the addition of standard data transfer protocols or messages.
S.1.2	Donor management support	Provide capability to capture or receive, and share needed information on potential organ and blood donors and recipients.	The user is able to capture or receive information on potential organ and blood donors and recipients. The user can make this information available to internal and external donor matching agencies.
S.1.3	Provider directory	Provide a current directory of practitioner, team, department, organization, and etcetera, information in accordance with relevant laws, regulations, and conventions.	Maintain or access current directory of provider information in accordance with relevant laws, regulations, and conventions, including full name, address or physical location, and a 24x7 telecommunications address (e.g. phone or pager access number) for the purposes of the following functions
S.1.3.1	Provider demographics	Provide a current directory of practitioners that, in addition to demographic information, contains data needed to determine levels of access required by the EHR security system.	Provider demographics may include any credentials, certifications, or any other information that may be used to verify that a provider is permitted to perform certain services.
S.1.3.2	Provider's location within facility	Provide provider location or contact information on a facility's premises.	
S.1.3.3	Provider's on call location	Provide provider location or contact information when on call.	
S.1.3.4	Provider's general location	Provide locations or contact information for the provider in order to direct patients or queries.	
S.1.4	Patient directory	Provide a current directory of patient information in accordance with relevant privacy and other applicable laws, regulations, and conventions.	Provide a current directory of patient information in accordance with relevant privacy and other applicable laws, regulations, and conventions, including, when available, full name, address or physical location, alternate contact person, primary phone number, and relevant health status information for the purposes of the following functions.
S.1.4.1	Patient demographics	Support interactions with other systems, applications, and modules to enable the maintenance of updated demographic information in accordance with realm-specific recordkeeping requirements.	The minimum demographic data set must include the data required by realm-specific laws governing health care transactions and reporting. This may also include data input of death status information.
S.1.4.2	Patient's location within a facility	Provide the patient's location information within a facility's premises.	Example: The patient census in a hospital setting
S.1.4.3	Patient's residence for the provision and	Provide the patient's residence information solely for purposes related	

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	administration of services	to the provision and administration of services to the patient, patient transport, and as required for public health reporting.	
S.1.4.4	Optimize patient bed assignment	Support interactions with other systems, applications, and modules to ensure that the patient's bed assignments within the facility optimize care and minimize risks e.g. of exposure to contagious patients.	
S.1.5	De-identified data request management	Provide patient data in a manner that meets local requirements for de-identification.	When an internal or external party requests patient data and that party requests de-identified data (or is not entitled to identify patient information, either by law or custom), the user can export the data in a fashion that meets local requirements for de-identification. An audit trail of these requests and exports is maintained. For internal clinical audit, a re-identification key may be added to the data.
S.1.6	Scheduling	Support interactions with other systems, applications, and modules to provide the necessary data to a scheduling system for optimal efficiency in the scheduling of patient care, for either the patient or a resource/device.	The system user can schedule events as required. Relevant clinical or demographic information can be linked to the task.
S.1.7	Healthcare resource availability	Support interactions with other systems, applications, and modules to enable the distribution of local healthcare resource information in times of local or national emergencies.	In times of identified local or national emergencies and upon request from authorized bodies, provide current status of healthcare resources including, but not limited to, available beds, providers, support personal, ancillary care areas and devices, operating theaters, medical supplies, vaccines, and pharmaceuticals. The intent is for the authorized body to distribute either resources or patient load to maximize efficient healthcare delivery.
S.2	**Measurement, Analysis, Research and Reports**		
S.2.1	Measurement, monitoring, and analysis	Support measurement and monitoring of care for relevant purposes.	
S.2.1.1	Outcome Measures and Analysis	Support the capture and reporting of information for the analysis of outcomes of care provided to populations, in facilities, by providers, and in communities.	
S.2.1.2	Performance and accountability measures	Support the capture and reporting of quality, performance, and accountability measures to which providers/facilities/delivery systems/communities are held	

ID	Name	Statement	Description
		accountable including measures related to process, outcomes, and/or costs of care, may be used in 'pay for performance' monitoring and adherence to best practice guidelines.	
S.2.2	Report generation	Provide report generation features for the generation of standard and ad hoc reports.	A user can create standard and ad hoc reports for clinical, administrative, and financial decision-making, and for patient use - including structured data and/or unstructured text from the patient's health record. Reports may be linked with financial and other external data sources (i.e. data external to the entity). Such reports may include patient-level reports, provider/facility/delivery system-level reports, population-level reports, and reports to public health agencies. Examples of patient-level reports include: administratively required patient assessment forms, admission/transfer/discharge reports, operative and procedure reports, consultation reports, and drug profiles. Examples of population-level reports include: reports on the effectiveness of clinical pathways and other evidence-based practices, tracking completeness of clinical documentation, etcetera. Examples of reports to public health agencies include: vital statistics, reportable diseases, discharge summaries, immunization data including adverse outcomes, cancer data, and other such data necessary to maintain the publics' health (including suspicion of newly emerging infectious disease and non-natural events).
S.2.2.1	Health record output	Allow users to define the records and/or reports that are considered the formal health record for disclosure purposes, and provide a mechanism for both chronological and specified record element output.	Provide hardcopy and electronic output that can fully chronicles the healthcare process, supports selection of specific sections of the health record, and allows healthcare organizations to define the report and/or documents that will comprise the formal health record for disclosure purposes.
S.3	**Administrative and Financial**		
S.3.1	Encounter/Episode of care management	Manage and document the health care needed and delivered during an encounter/episode of care.	Using data standards and technologies that support interoperability, encounter management promotes patient-centered/oriented care and enables real

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			time, immediate point of service, point of care by facilitating efficient work flow and operations performance to ensure the integrity of: (1) the health record, (2) public health, financial and administrative reporting, and (3) the healthcare delivery process. This support is necessary for direct care functionality that relies on providing user interaction and workflows, which are configured according to clinical protocols and business rules based on encounter specific values such as care setting, encounter type (inpatient, outpatient, home health, etcetera), provider type, patient's EHR, health status, demographics, and the initial purpose of the encounter.
S.3.1.1	Specialized views	Present specialized views based on the encounter-specific values, clinical protocols and business rules	The system user is presented with a presentation view and system interaction appropriate to the context with capture of encounter-specific values, clinical protocols and business rules. This "user view" may be configurable by the user or system technicians. As an example, a mobile home health care worker using wireless laptop at the patient's home would be presented with a home health care specific workflow synchronized to the current patient's care plan and tailored to support the interventions appropriate for this patient, including chronic disease management protocols.
S.3.1.2	Encounter specific functionality	Provide assistance in assembling appropriate data, supporting data collection and processing output from a specific encounter.	Workflows, based on the encounter management settings, will assist in determining the appropriate data collection, import, export, extraction, linkages and transformation. As an example, a pediatrician is presented with diagnostic and procedure codes specific to pediatrics. Business rules enable automatic collection of necessary data from the patient's health record and patient registry. As the provider enters data, workflow processes are triggered to populate appropriate transactions and documents. For example, data entry might populate an eligibility verification transaction or query the immunization registry.

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S.3.1.3	Automatic generation of administrative and financial data from clinical record	Provide patients clinical data to support administrative and financial reporting.	A user can generate a bill based on health record data. Maximizing the extent to which administrative and financial data can be derived or developed from clinical data will lessen provider reporting burdens and the time it takes to complete administrative and financial processes such as claim reimbursement. This may be implemented by mapping of clinical terminologies in use to administrative and financial terminologies.
S.3.1.4	Support remote healthcare services	Support remote health care services such as telehealth and remote device monitoring by integrating records and data collected by these means into the patient's EHR for care management, billing and public health reporting purposes.	Enables remote treatment of patients using monitoring devices, and two way communications between provider and patient or provider and provider. - Promotes patient empowerment, self-determination and ability to maintain health status in the community. Promotes personal health, wellness and preventive care. For example, a diabetic pregnant Mom can self-monitor her condition from her home and use web TV to report to her provider. The same TV-internet connectivity allows her to get dietary and other health promoting information to assist her with managing her high-risk pregnancy.
S.3.2	Information access for supplemental use	Support extraction, transformation and linkage of information from structured data and unstructured text in the patient's health record for care management, financial, administrative, and public health purposes.	Using data standards and technologies that support interoperability, information access functionalities serve primary and secondary record use and reporting with continuous record availability and access that ensure the integrity of (1) the health record, (2) public health, financial and administrative reporting, and (3) the healthcare delivery process.
S.3.2.1	Rules-driven clinical coding assistance	Make available all pertinent patient information needed to support coding of diagnoses, procedures and outcomes.	The user is assisted in coding information for clinical reporting reasons. For example, a professional coder may have to code the principal diagnosis in the current, applicable ICD as a basis for hospital funding. All diagnoses and procedures during the episode may be presented to the coder, as well as the applicable ICD hierarchy containing these codes.
S.3.2.2	Rules-driven financial and administrative coding assistance	Provide financial and administrative coding assistance based on the structured data and unstructured text available in the encounter documentation.	The user is assisted in coding information for billing or administrative reasons. For example, the HIPAA 837 Professional claim requires the date of the last menstrual cycle for claims involving pregnancy. To support the generation of this transaction, the clinician would need to be prompted to enter this date when the patient is first

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			determined to be pregnant, then making this information available for the billing process.
S.3.2.3	Integrate cost/financial information	Support interactions with other systems, applications, and modules to enable the use of cost management information required to guide users and workflows	The provider is alerted or presented with the most cost-effective services, referrals, devices and etcetera, to recommend to the patient. This may be tailored to the patient's health insurance/plan coverage rules. Medications may be presented in order of cost, or the cost of specific interventions may be presented at the time of ordering.
S.3.3	Administrative transaction processing	Support the creation (including using external data sources, if necessary), electronic interchange, and processing of transactions listed below that may be necessary for encounter management during an episode of care	Support the creation (including using external data sources, if necessary), electronic interchange, and processing of transactions listed below that may be necessary for encounter management during an episode of care. > The EHR system shall capture the patient health-related information needed for administrative and financial purposes including reimbursement. >Captures the episode and encounter information to pass to administrative or financial processes (e.g. triggers transmissions of charge transactions as by-product of on-line interaction including order entry, order statusing, result entry, documentation entry, medication administration charting.) > Automatically retrieves information needed to verify coverage and medical necessity. > As a byproduct of care delivery and documentation: captures and presents all patient information needed to support coding. Ideally performs coding based on documentation. > Clinically automated revenue cycle - examples of reduced denials and error rates in claims. > Clinical information needed for billing is available on the date of service. >Physician and clinical teams do not perform additional data entry / tasks exclusively to support administrative or financial processes.
S.3.3.1	Enrollment of patients	Support interactions with other	Expedites determination of health

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		systems, applications, and modules to enable enrollment of uninsured patients into subsidized and unsubsidized health plans, and enrollment of patients who are eligible on the basis of health and/of financial status in social service and other programs, including clinical trials.	insurance coverage, thereby increasing patient access to care. The provider may be alerted that uninsured patients may be eligible for subsidized health insurance or other health programs because they meet eligibility criteria based on demographics and/or health status. For example: a provider is notified that the uninsured parents of a child enrolled in S-CHIP may now be eligible for a new subsidized health insurance program; a provider of a pregnant patient who has recently immigrated is presented with information about eligibility for subsidy. Links may be provided to online enrollment forms. When enrollment is determined, the health coverage information needed for processing administrative and financial documentation, reports or transactions is captured.
S.3.3.2	Eligibility verification and determination of coverage	Support interactions with other systems, applications, and modules to enable eligibility verification for health insurance and special programs, including verification of benefits and pre-determination of coverage.	Automatically retrieves information needed to support verification of coverage at the appropriate juncture in the encounter workflow. Improves patient access to covered care and reduces claim denials. When eligibility is verified, the EHRS would capture eligibility information needed for processing administrative and financial documentation, reports or transactions - updating or flagging any inconsistent data. In addition to health insurance eligibility, this function would support verification of registration in programs and registries, such as chronic care case management and immunization registries. An EHRS would likely verify health insurance eligibility prior to the encounter, but would verify registration in case management or immunization registries during the encounter.
S.3.3.3	Service authorizations	Support interactions with other systems, applications, and modules to enable the creation of requests, responses and appeals related to service authorization, including prior authorizations, referrals, and pre-certification.	Automatically retrieves information needed to support verification of medical necessity and prior authorization of services at the appropriate juncture in the encounter workflow. Improves timeliness of patient care and reduces claim denials.
S.3.3.4	Support of service requests and claims	Support interactions with other systems, applications, and modules to support the creation of health care attachments for submitting additional clinical information in support of service requests and claims.	Automatically retrieves structured data, including lab, imaging and device monitoring data, and unstructured text based on rules or requests for additional clinical information in support of service requests or claims at the appropriate juncture in the encounter workflow

ID	Name	Statement	Description
S.3.3.5	Claims and encounter reports for reimbursement	Support interactions with other systems, applications, and modules to enable the creation of claims and encounter reports for reimbursement	Automatically retrieves information needed to support claims and encounter reporting at the appropriate juncture in the encounter workflow.
S.3.3.6	Health service reports at the conclusion of an episode of care.	Support the creation of health service reports at the conclusion of an episode of care. Support the creation of health service reports to authorized health entities, for example public health, such as notifiable condition reports, immunization, cancer registry and discharge data that a provider may be required to generate at the conclusion of an episode of care.	Effective use of this function means that clinicians do not perform additional data entry to support health management programs and reporting.
S.3.4	Manage Practitioner/Patient relationships	Identify relationships among providers treating a single patient, and provide the ability to manage patient lists assigned to a particular provider.	This function addresses the ability to access and update current information about the relationships between caregivers and the subjects of care. This information should be able to flow seamlessly between the different components of the EHRS, and between the EHRS and other systems. Business rules may be reflected in the presentation of, and the access to this information. The relationship among providers treating a single patient will include any necessary chain of authority/responsibility. Example: In a care setting with multiple providers, where the patient can only see certain kinds of providers (or an individual provider); allow the selection of only the appropriate providers. Example: The user is presented with a list of people assigned to a given practitioner and may alter the assignment as required - to a group, to another individual or by sharing the assignment.
S.3.5	Subject to Subject relationship	Capture relationships between patients and others to facilitate appropriate access to their health record on this basis (e.g. parent of a child) if appropriate.	A user may assign the relationship of parent to a person who is their offspring. This relationship may facilitate access to their health record as parent of a young child.
S.3.5.1	Related by genealogy	Provide information of Related by genealogy (blood relatives)	
S.3.5.2	Related by insurance	Support interactions with other systems, applications, and modules to provide information of Related by insurance (domestic partner, spouse, and guarantor).	
S.3.5.3	Related by living situation	Provide information of Related by living situation (in same household)	
S.3.5.4	Related by other means	Provide information of Related by other means (e.g. epidemiologic	

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		exposure or other person authorized to see records, Living Will cases)	
S.3.6	Acuity and Severity	Provide the data necessary for the capability to support and manage patient acuity/severity of illness/risk adjustment	
S.3.7	Maintenance of supportive functions	Update EHR supportive content on an automated basis.	
S.3.7.1	Clinical decision support system guidelines updates	Receive and validate formatted inbound communications to facilitate updating of clinical decision support system guidelines and associated reference material	
S.3.7.2	Account for patient education material updates	Receive and validate formatted inbound communications to facilitate updating of patient education material	
S.3.7.3	Patient reminder information updates	Receive and validate formatted inbound communications to facilitate updating of patient reminder information from external sources such as Cancer or Immunization Registries	
S.3.7.4	Public health related updates	Receive and validate formatted inbound communications to facilitate updating of public health reporting guidelines	

Information Infrastructure EHR-S Functions

ID	Name	Statement	Description
I.1	Security	Secure the access to an EHR-S and EHR information. Manage the sets of access control permissions granted within an EHR-S. Prevent unauthorized use of data, data loss, tampering and destruction.	To enforce security, all EHR-S applications must adhere to the rules established to control access and protect the privacy of EHR information. Security measures assist in preventing unauthorized use of data and protect against loss, tampering and destruction.
I.1.1	Entity Authentication	Authenticate EHR-S users and/or entities before allowing access to an EHR-S.	Both users and application are subject to authentication. The EHR-S must provide mechanisms for users and applications to be authenticated. Users will have to be authenticated when they attempt to use the application, the applications must authenticate themselves before accessing EHR information managed by other applications or remote EHR-S'. In order for authentication to be established a Chain of Trust agreement is assumed to be in place. Examples of entity authentication include: > Username/ password; > Digital certificate; > Secure token; > Biometrics
I.1.2	Entity Authorization.	Manage the sets of access-control permissions granted to entities that use an EHR-S (EHR-S Users). Enable EHR-S security administrators to grant authorizations to users, for roles, and within contexts. A combination of the authorization levels may be applied to control access to EHR-S functions or data within an EHR-S, including at the application or the operating system level.	Entities that use an EHR-S (EHR-S Users) are authorized to use the components of an EHR-S according to identity, role, work-assignment, present condition and/or location in accordance with an entity's scope of practice within a legal jurisdiction. > User based authorization refers to the permissions granted or denied based on the identity of an individual. An example of User based authorization is a patient defined denial of access to all or part of a record to a particular party for reasons such as privacy. Another user based authorization is for a telemonitor device or robotic access to an EHR-S for prescribed directions and other input. > Role based authorization refers to the responsibility or function performed in a particular operation or process. Example roles include: an application or device (telemonitor or robotic); or a nurse, dietician, administrator, legal guardian, and auditor. > Context-based Authorization is defined by ISO as security-relevant properties of

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			the context in which an access request occurs, explicitly time, location, route of access, and quality of authentication. For example, an EHR-S might only allow supervising providers' context authorization to attest to entries proposed by residents under their supervision. In addition to the standard, context authorization for an EHR-S is extended to satisfy special circumstances such as, assignment, consents, or other healthcare-related factors. A context-based example might be a right granted for a limited period to view those, and only those, EHR records connected to a specific topic of investigation.
I.1.3	Entity Access Control	Verify and enforce access control to all EHR-S components, EHR information and functions for end-users, applications, sites, etc., to prevent unauthorized use of a resource, including the prevention or use of a resource in an unauthorized manner.	This is a fundamental function of an EHR-S. To ensure access is controlled, an EHR-S must perform an identity lookup of users or application for any operation that requires it (authentication, authorization, secure routing, querying, etc.) and enforce the system and information access rules that have been defined.
I.1.3.1	Patient Access Management	Enable a healthcare professional to manage a patient's access to the patient's personal health information. Patient access-management includes allowing a patient access to the patient's information and restricting access by the patient or guardian to information that is potentially harmful to the patient.	A healthcare professional will be able to manage a patient's ability to view his/her EHR, and to alert other providers accessing the EHR about any constraints on patient access placed by this provider. Typically, a patient has the right to view his/her EHR. However, a healthcare provider may sometimes need to prevent a patient (or guardian) from viewing parts of the record. For example, a patient receiving psychiatric care might harm himself (or others) if he reads the doctor's evaluation of his condition. Furthermore, reading the doctor's therapy plan might actually cause the plan to fail.
I.1.4	Non-repudiation	Limit an EHR-S user's ability to deny (repudiate) an electronic data exchange originated, received or authorized by that user.	Non-repudiation ensures that an entered or a transferred message has been entered, sent, or received by the parties claiming to have entered, sent or received the message. Non-repudiation is a way to guarantee that the sender of a message cannot later deny having sent the message and that the recipient cannot deny having received the message. Non-repudiation may be achieved through the use of: > Digital signature, which serves as a

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			unique identifier for an individual (much like a written signature). > Confirmation service, which utilizes a message transfer agent to create a digital receipt (providing confirmation that a message was sent and/or received) and > Timestamp, which proves that a document existed at a certain date and time
I.1.5	Secure Data Exchange	Secure all modes of EHR data exchange.	Whenever an exchange of EHR information occurs, it requires appropriate security and privacy considerations, including data obfuscation as well as both destination and source authentication when necessary. For example, it may be necessary to encrypt data sent to remote or external destinations. This function requires that there is an overall coordination regarding what information is exchanged between EHR-S entities and how that exchange is expected to occur. The policies applied at different locations must be consistent or compatible with each other in order to ensure that the information is protected when it crosses entity boundaries within an EHRS or external to an EHRS.
I.1.6	Secure Data Routing	Route electronically exchanged EHR data only to/from known, registered, and authenticated destinations/sources (according to applicable healthcare-specific rules and relevant standards).	An EHR-S needs to ensure that it is exchanging EHR information with the entities (applications, institutions, directories) it expects. This function depends on entity authorization and authentication to be available in the system. For example, a physician practice management application in an EHR-S might send claim attachment information to an external entity. To accomplish this, the application must use a secure routing method, which ensures that both the sender and receiving sides are authorized to engage in the information exchange.
I.1.7	Information Attestation	Manage electronic attestation of information including the retention of the signature of attestation (or certificate of authenticity) associated with incoming or outgoing information.	The purpose of attestation is to show authorship and assign responsibility for an act, event, condition, opinion, or diagnosis. Every entry in the health record must be identified with the author and should not be made or signed by someone other than the author. (Note: A transcriptionist may transcribe an author's notes and a senior clinician may attest to the accuracy of another's statement of events.) Attestation is

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			required for (paper or electronic) entries such as narrative or progress notes, assessments, flow sheets, and orders. Digital signatures may be used to implement document attestation. For an incoming document, the record of attestation is retained if included. Attestation functionality must meet applicable legal, regulatory and other applicable standards or requirements.
I.1.8	Enforcement of Confidentiality	Enforce the applicable jurisdiction's patient privacy rules as they apply to various parts of an EHR-S through the implementation of security mechanisms.	A patient's privacy may be adversely affected when EHRs are not held in confidence. Privacy rule enforcement decreases unauthorized access and promotes the level of EHR confidentiality.
I.2	Health record information and management	Manage EHR information across EHR-S applications by ensuring that clinical information entered by providers is a valid representation of clinical notes; and is accurate and complete according to clinical rules and tracking amendments to clinical document. Ensure that information entered by or on behalf of the patient is accurately represented.	Since EHR information will typically be available on a variety of EHR-S applications, an EHR-S must provide the ability to access, manage and verify accuracy and completeness of EHR information, and provide the ability to audit the use of and access to EHR information.
I.2.1	Data Retention, Availability and Destruction	Retain, ensure availability, and destroy health record information according to organizational standards. This includes: > Retaining all EHR-S data and clinical documents for the time period designated by policy or legal requirement; >Retaining inbound documents as originally received (unaltered); >Ensuring availability of information for the legally prescribed period of time; and >Providing the ability to destroy EHR data/records in a systematic way according to policy and after the legally prescribed retention period.	Discrete and structured EHR-S data, records and reports must be: > Made available to users in a timely fashion; > Stored and retrieved in a semantically intelligent and useful manner (for example, chronologically, retrospectively per a given disease or event, or in accordance with business requirements, local policies, or legal requirements); > Retained for a legally-proscribed period of time; and >Destroyed in a systematic manner in relation to the applicable retention period. An EHR-S must also allow an organization to identify data/records to be destroyed, and to review and approve destruction before it occurs.
I.2.2	Audit trail	Provide audit trail capabilities for resource access and usage indicating	Audit functionality extends to security audits, data audits, audits of data

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		the author, the modification (where pertinent), and the date and time at which a record was created, modified, viewed, extracted, or deleted. Audit trails extend to information exchange and to audit of consent status management (to support DC.1.5.1) and to entity authentication attempts. Audit functionality includes the ability to generate audit reports and to interactively view change history for individual health records or for an EHR-S.	exchange, and the ability to generate audit reports. Audit trail settings should be configurable to meet the needs of local policies. Examples of audited areas include: > Security audit, which logs access attempts and resource usage including user login, file access, other various activities, and whether any actual or attempted security violations occurred; > Data audit, which records who, when, and by which system an EHR record was created, updated, translated, viewed, extracted, or (if local policy permits) deleted. Audit-data may refer to system setup data or to clinical and patient management data; and > Information exchange audit, record data exchanged between EHR-S applications (for example, sending application; the nature, history, and content of the information exchanged); and information about data transformations (for example, vocabulary translations, reception event details, etc.). > Audit reports should be flexible and address various users' needs. For example, a legal authority may want to know how many patients a given healthcare provider treated while the provider's license was suspended. Similarly, in some cases a report detailing all those who modified or viewed a certain patient record may be needed. > Security audit trails and data audit trails are used to verify enforcement of business, data integrity, security, and access-control rules. There is a requirement for system audit trails for the following events: > Loading new versions of, or changes to, the clinical system; > Loading new versions of codes and knowledge bases;

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			> Changing the date and time where the clinical system allows this to be done; > Taking and restoring of backup; Archiving any data; > Re-activating of an archived patient record; >Entry to and exiting from the clinical system; > Remote access connections including those for system support and maintenance activities
I.2.3	Synchronization	Maintain synchronization involving: >Interaction with entity directories; >Linkage of received data with existing entity records; >Location of each health record component; and >Communication of changes between key systems.	An EHR-S may consist of a set of components or applications; each application manages a subset of the health information. Therefore it is important that, through various interoperability mechanisms, an EHR-S maintains all the relevant information regarding the health record in synchrony. For example, if a physician orders an MRI, a set of diagnostic images and a radiology report will be created. The patient demographics, the order for MRI, the diagnostic images associated with the order, and the report associated with the study must all be synchronized in order for the clinicians to view the complete record.
I.2.4	Extraction of health record information	Manage data extraction in accordance with analysis and reporting requirements. The extracted data may require use of more than one application and it may be pre-processed (for example, by being de-identified) before transmission. Data extractions may be used to exchange data and provide reports for primary and ancillary purposes.	An EHR-S enables an authorized user, such as a clinician, to access and aggregate the distributed information, which corresponds to the health record or records that are needed for viewing, reporting, disclosure, etc. An EHR-S must support data extraction operations across the complete data set that constitutes the health record of an individual and provide an output that fully chronicles the healthcare process. Data extractions are used as input to continuity of care records. In addition, data extractions can be used for administrative, financial, research, quality analysis, and public health purposes.
I.3	Unique identity, registry, and directory services	Enable secure use of registry services and directories to uniquely identify and supply links for retrieval and to identify the location of subjects of care: patients and providers for health care purposes;	Unique identity, registry, and directory service functions are critical to successfully managing the security, interoperability, and the consistency of the health record data across an EHR-S.

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		payers, health plans, sponsors, employers and public health agencies for administrative and financial purposes; and health care resources and devices for resource management purposes.	
I.3.1	Distributed registry access	Enable system communication with registry services through standardized interfaces and extend to services provided externally to an EHR-S.	An EHR-S relies on a set of infrastructure services, directories, and registries, which may be organized hierarchically or federated, that support communication between EHR-S'. For example, a patient treated by a primary care physician for a chronic condition may become ill while out of town. The new provider's EHR-S interrogates a local, regional, or national registry to find the patient's previous records. From the primary care record, a remote EHR-S retrieves relevant information in conformance with applicable patient privacy and confidentiality rules. An example of local registry usage is an EHR-S application sending a query message to the Hospital Information System to retrieve a patient's demographic data.
I.4	Health Informatics and Terminology Standards	Ensure consistent terminologies, data correctness, and interoperability in accordance with realm specific requirements by complying with standards for health care transactions, vocabularies, code sets, as well as artifacts such as: templates, system interfaces, decision support syntax and algorithms, and clinical document architecture. Support reference to standard and local terminologies and their versions in a manner that ensures comparable and consistent use of vocabulary, such as the Common Terminology Services specification.	Examples that an EHR-S needs to support are a consistent set of terminologies such as: LOINC, SNOMED, applicable ICD, CPT and messaging standards such as X12 and HL7. Vocabularies may be provided through a terminology service internal or external to an EHR-S.
I.4.1	Maintenance and versioning of health informatics and terminology standards.	Enable version control according to customized policies to ensure maintenance of utilized standards.	Version control allows for multiple sets or versions of the same terminology to exist and be distinctly recognized over time. Terminology versioning supports retrospective analysis and research as well as interoperability with systems that comply with different releases of the standard. Similar functionality must exist for messaging and other informatics based standards. It should be possible to retire deprecated versions when applicable business cycles are completed while maintaining obsolescent code sets for possible claims adjustment

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			throughout the claim's lifecycle.
I.4.2	Mapping local terminology, codes, and formats	Map or translate local terminology, codes and formats to standard terminology, codes, and formats to comply with health informatics standards.	An EHR-S, which uses local terminology, must be capable of mapping and/or converting the local terminology into a standard terminology. For example, a local term or code for "Ionized Calcium" must be mapped to an equivalent, standardized (LOINC) term or code when archiving or exchanging artifacts.
I.5	Standards-based Interoperability	Provide automated health delivery processes and seamless exchange of key clinical and administrative information through standards-based solutions.	Interoperability standards enable an EHR-S to operate as a set of applications.
I.5.1	Interchange Standards	Support the ability to operate seamlessly with complementary systems by adherence to key interoperability standards. Systems may refer to other EHR-S', applications within an EHR-S, or other authorized entities that interact with an EHR-S.	An EHR-S must adhere to standards for connectivity, information structures, and semantics ("interoperability standards"). An EHR-S, which may exist locally or remotely, must support seamless operations between complementary systems. An EHR-S must support realm specific interoperability standards such as: HL7 Messages, Clinical Document Architecture (CDA), X12N healthcare transactions, and Digital Imaging and Communication in Medicine (DICOM). An EHR-S must be capable of common semantic representations to support information exchange. An EHR-S may use different standardized or local vocabularies in accordance with realm specific requirements. In order to reconcile the semantic differences across vocabularies, an EHR-S must adhere to standard vocabulary or leverage vocabulary lookup and mapping capabilities that are included in the Health Informatics and Terminology Standards. An EHR-S must support multiple interaction modes to respond to differing levels of immediacy and types of exchange. For example, messaging is effective for many near-real time, asynchronous data exchange scenarios but may not be appropriate if the end-user is requesting an immediate response from a remote application.

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			In addition, in the case where store-and-forward, message-oriented interoperability is used; the applications may need to support the appropriate interaction mode. For example: Unsolicited Event Notifications, Query/Response, Query for display, Unsolicited summary, structured/discrete, and unstructured clinical documents.
I.5.2	Standards-based Application Integration	Provide integration with complementary systems and infrastructure services (directory, vocabulary, etc.) using standard-based application programming interfaces (for example, CCOW).	Similar to standard-based messaging, standard-based application integration requires that an EHR-S use standardized programming interfaces, where applicable. For example, CCOW may be used for visual integration and WfMC for workflow integration.
I.5.3	Interchange Agreements	Support interaction with entity directories to determine the recipients' address profile and data exchange requirements, and use these rules of interaction when exchanging information with partners.	An EHR-S uses the entity registries to determine the security, addressing, and reliability requirements between partners. An EHR-S uses this information to define how data will be exchanged between the sender and the receiver.
I.6	Business Rules Management	Manage the ability to create, update, delete, and version business rules including institutional preferences. Apply business rules from necessary points within an EHR-S to control system behavior. An EHR-S audits changes made to business rules, as well as compliance to and overrides of applied business rules.	An EHR-S business rule implementation functions include: decision support, diagnostic support, workflow control, access privileges, as well as system and user defaults and preferences. An EHR-S supports the ability of providers and institutions to customize decision support components such as triggers, rules, or algorithms, as well as the wording of alerts and advice to meet realm specific requirements and preferences. Examples of applied business rules include: > Suggesting diagnosis based on the combination of symptoms (flu-like symptoms combined with widened mediastinum suggesting anthrax); > Classifying a pregnant patient as high risk due to factors such as age, health status, and prior pregnancy outcomes; > Sending an update to an immunization registry when a vaccination is administered; > Limiting access to mental health

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			information to a patient's psychiatrist/psychologist; > Establishing system level defaults such as for vocabulary data sets to be implemented.; and > Establishing user level preferences such as allowing the use of health information for research purposes.
I.7	Workflow Management	Support workflow management functions including both the management and set up of work queues, personnel, and system interfaces as well as the implementation functions that use workflow-related business rules to direct the flow of work assignments.	Workflow management functions that an EHR-S supports include: > Distribution of information to and from internal and external parties; > Support for task-management as well as parallel and serial task distribution; > Support for notification and task routing based on system triggers; and > Support for task assignments, escalations and redirection in accordance with business rules. Workflow definitions and management may be implemented by a designated application or distributed across an EHR-S.

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