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1.0 Introduction

1.1 What is HL7?

Established in 1987, Health Level Seven (HL7) is an ANSI accredited, not-for-profit standards-development organization, whose mission is to provide standards for the exchange, integration, sharing, and retrieval of electronic health information; support clinical practice; and support the management, delivery and evaluation of health services. HL7 is accredited by the American National Standards Institute (ANSI). ANSI accreditation, coupled with HL7’s own procedures, dictates that any standard published by HL7 and submitted to ANSI for approval, be developed and ratified by a process that adheres to ANSI’s procedures for open consensus (http://www.ANSI.org). Balance of interest requirement by attaining near equal participation in the voting process by the various constituencies that are materially affected by the standard (e.g., vendors, providers, government agencies, consultants, non-profit organizations). This balance of interest goal ensures that a particular constituency is neither refused participation nor is it allowed to dominate the development and ratification of a proposed standard.

1.2 What are Electronic Health Record Systems?

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).

In developing this ballot, HL7 relied on three well-accepted definitions: two provided by the U.S. Institute of Medicine and one developed by the European Committee for Standardization/ Comité Européen de Normalisation (CEN). This ballot leverages these existing EHR-S definitions and does not attempt to create a redundant definition of an ERH-S.

Existing EHR System Definitions

The Institute of Medicine’s 1991 report, Computerized Patient Record, defined an 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.”
1.3 What is the Ballot's Background?

HL7 Electronic Health Records Special Interest Group (EHR SIG) was established in the spring of 2002. In the spring of 2003, efforts began to develop a standardized functional specification for Electronic Health Records Systems (EHR-S). The EHR SIG is primarily intended to serve as a body which promotes the uptake of Electronic Health Record (EHR) implementation by standardizing the functions that may be present, based on user selection, in an EHR-S.

The Department of Health and Human Services, the Veterans Health Administration, the Health Information Management Systems Society and the Robert Wood Johnson Foundation, in a public-private partnership, approached HL7 to accelerate their existing work to develop a consensus standard to define the functions of an EHR-S. HL7, through its 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 initial ballot period in 2003, the HL7 EHR SIG has now produced a clearer, more simplified list of functions, while delegating specifications on how functions may be used within individual care settings and the priorities of time when functions should be available for use to country-specific realms. This EHR-S Model does not offer country-specific care settings or priority content for balloting. However, the U.S. realm has submitted reference examples. (For the care setting examples, see the accompanying White Paper.)

The primary objective of this HL7 EHR System Functional Model is to define a standardized model of the functions that may be present in EHR Systems. Accordingly, it is essential from the outset to make a clear distinction between the EHR as an entity in its own right and systems that operate on the EHR – i.e., EHR Systems. The basis and foundation for the HL7 definition of an EHR System is described in section 4.1.

1.4 How were the Functions Identified and Developed?

To achieve healthcare community consensus at the outset, the functions are described at a conceptual level, providing a robust foundation for a more detailed work. Functions were included if considered essential in at least one care setting. Written in user-oriented language, the document is intended for a broad readership. Periodic updating of this document will occur during the DSTU period based on healthcare community requests.

Functional Granularity is a term used to describe the level of abstraction at which a function is represented. Functions that are commonly grouped together in practice or by major systems have been consolidated where appropriate; functions requiring extra or separate language or involving different workflows have been kept separate where appropriate. Decision Support is maintained as a separate section, but mapped to other key sections, to indicate the “smart” function behind an action. All of the functions could be expanded into more granular elements but a balance between a usable document and an unwieldy list of functions has been agreed upon. The goal of determining an appropriate level of functional granularity at this time is to present functions that can be easily selected and used by readers of this ballot, but that are not so abstract that readers would need to create a large number of additional functions within each function.

Although the determination of functional granularity is a relatively subjective task, systematic evaluation of each function by diverse groups of industry professionals have resulted in a level of granularity appropriate for this EHR-S Model. Every attempt has been made to provide supporting information in the Functional Descriptions to illustrate the more granular aspects of functions that may have been consolidated for usability purposes.

Keeping with the intent of this EHR-S Model to be independent with regard to technology or implementation strategy, no specific technology has been included in the functions, but may be used in the examples to illustrate the functions. Inclusion of specific technologies in the examples does not endorse or support the use of those technologies as implementation strategies.

Drafts of the EHR-S Model and of specific functions have been widely reviewed by healthcare providers, vendors, and other stakeholders. This ballot reflects input from all these reviewers.
1.5 What is the Ballot Package?

The HL7 ballot package for the EHR System Functional Model and Standard DSTU includes content that is either Reference or “Normative” – see the following table for description of these terms.

**Document Status**

<table>
<thead>
<tr>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference</td>
<td>Content that contains information that clarifies concepts or otherwise provides additional information to aid understanding and comprehension. Reference material is not balloted. Readers may comment, identify typographical errors, or provide suggestions for improving the document, but such comments do not materially affect a ballot. Please Note - Reference material is not part of the DSTU and is not to be voted on.</td>
</tr>
<tr>
<td>Normative – to be voted on</td>
<td>Content that is part of the EHR-S Model ballot package for which HL7 committee members and interested industry participants shall cast a ballot following the HL7 procedures for Balloting Normative Documents. This HL7 proposed DSTU document will be subject to a successful committee vote and then be submitted to ANSI as a formal notice of HL7’s intent to publish a formal standard in this area.</td>
</tr>
</tbody>
</table>

The Ballot Package includes the following materials.

<table>
<thead>
<tr>
<th>Document title</th>
<th>Description</th>
<th>Target file name</th>
<th>Status of Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>The entire ballot package</td>
<td><strong>The entire ballot package</strong></td>
<td>HL7_EHR-S_Functional_Model_DS_TU_ballot.zip</td>
<td><strong>Normative</strong> - To be voted on - and - <strong>Reference</strong></td>
</tr>
<tr>
<td>HL7 EHR System Functional Model and Standard, Draft Standard for Trial Use, Standard Overview</td>
<td>Overview and background on the proposed EHR-S Model and Standard.</td>
<td>HL7_EHR-S_Functional_Model_DS_TU_Overview</td>
<td><strong>Normative content:</strong> 1. Section 2 2. Section 3 - and - <strong>Reference content:</strong> 1. Section 1 2. Section 4</td>
</tr>
<tr>
<td>HL7 EHR System Functional Model and Standard, Draft Standard for Trial Use, Functional Outline</td>
<td>The Functional Outline composed of Direct Care, Supportive, and Information Infrastructure functions and related descriptive elements.</td>
<td>HL7_EHR-S_Functional_Model</td>
<td><strong>Normative content:</strong> 1. Function Name 2. Function Description - and - <strong>Reference</strong></td>
</tr>
<tr>
<td>HL7 EHR System Functional Model and Standard, Draft Standard for Trial Use, Ballot</td>
<td>The EHR-S Functional Model and Standard ballot spreadsheet is used to record votes and line-item comments for both all sections of the document.</td>
<td>HL7_EHR-S_Functional_Model_DS_TU_Ballot.xls</td>
<td>Where votes for Normative and comments for Reference material are recorded for return to HL7 and subsequent reconciliation.</td>
</tr>
</tbody>
</table>
2.0 Purpose (Normative – To be Voted on)

The HL7 EHR System Functional Model and Standard DSTU provides a reference list 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, through the creation of Profiles, enables a standardized description and common understanding of functions sought or available in a given setting (e.g. intensive care, cardiology office practice in one country or primary care in another country).

For brevity, this proposed DSTU will be referred to within this document as the “EHR-S Model” where the meaning is unambiguous. A DSTU is a draft standard that incorporates the input from users prior to the DSTU becoming a standard. (See Appendix B “What is a DSTU?”)

Notably, the EHR-S Model does not address whether the EHR-S is a system-of-systems or a single system providing the functions required by the users. This standard makes no distinction regarding implementation - the EHR-S described in a profile may be a single system or a system of systems. Further, the functions make no statement about which technology is used, nor about the content of the electronic health record. The specifics of ‘how’ EHR systems are developed or implemented is not considered to be within the scope of this proposed DSTU now or in the future. This EHR-S Model does not address or endorse implementations or technology, nor does it include the data content of the electronic health record.
This proposed DSTU is not:

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

Additionally, the EHR-S Model is not sufficient to provide a longitudinal health record; however, it will contribute to its development. The information exchange enabled by the EHR-S supports the population of clinical documents, event summaries, minimum data sets, claims attachments, and, in the future, will enable a longitudinal health record.

Similarly, the EHR-S Model supports research needs by ensuring that the data available to researchers follow the required protocols for privacy, confidentiality, and security. The diversity of research needs precludes the specific listing of functions that are potentially useful for research.

### 3.0 Overview and Definition of the Model (Normative – To be Voted on)

The EHR-S Functional Model, see diagram, is composed of a functional outline (which is divided into three sections, direct care, supportive and information infrastructure) and profiles, which overlay the outlined functions, and assigned priorities for the functions in the profile. While the functional outline should contain all reasonably anticipated EHR-S functions, it is not itself intended as a list of all functions to be found in a specific EHR-S. Profiles can be used to constrain the functions to an intended use. The proposed DSTU defines the Functional Outline and the general use of profiles and priorities (See 4. Anticipated Uses). The proposed DSTU does not define any specific profiles (but profiles are offered as examples in the ballot reference material).

The EHR-S functional outline of the EHR-S Model is divided into three sections: Direct Care, Supportive and Information Infrastructure functions. Within the three main sections are thirteen subsections (see the graphic below). There are over 125 individual functions in the EHR-S DSTU, each including a Function Name and Function Statement (normative - to be voted on) as well as other associated information such as description, rationale for inclusion and citation (reference - comments are welcome). It is important to note that the numbering of the functions indicates parent-child relationships and that in many cases the parent is fully expressed by the children. In the aggregate, the functional model is intended to include the superset of
functions from which a subset can be generated by the user to illustrate what they need within their EHR-S. Only a subset of this inclusive set of functions will apply to any particular EHR-S.

### 3.1 EHR-S Functional Outline: The Functions and Their Use

The EHR-S Functional Outline provides a list of functions characterized using a superset of Functions (described below in 3.5) and organized into discrete sections and sub-sections. Functions describe the behavior of a system in user-oriented language so as to be recognizable to the key stakeholders of an EHR-S.

When adopted, the EHR-S Model will promote a common understanding of individual EHR-S functions. This will serve the following purposes:

- Be a communication link between EHR-S functions and end user defined benefits such as patient safety, quality outcomes and cost efficiencies.
- Promote a common understanding, and eventually, conformance measures of EHR functions upon which developers, vendors, users and other interested parties can plan and evaluate EHR-S functions.
- Provide the necessary framework to drive the requirements and applications of next level standards, such as EHR content, coding, information models, constructs and interoperability.
- Establish a standards-based method by which each realm (country) can apply these EHR functions to its individually defined care settings and priorities.
- Inform those concerned with secondary use and national infrastructure what functions can be expected among provider EHR-S’s.
3.2 Sections of the EHR-S Functional Outline

The EHR-S Model is divided into three broad categories, three sections/chapters of functions – Direct Care, Supportive, and Information Infrastructure.

Direct Care EHR-S Functions

Definition

Direct Care EHR-S functions are the subset of EHR-S functions that enable hands-on delivery of healthcare and offer clinical-decision support.

Example

For example, when a child presents with symptoms of common cold, a Direct Care EHR-S function will enable the doctor to record that event. Additionally, Clinical decision-support functions within the Direct Care EHR-S section will alert the provider that a vaccination is due and will offer contraindication alerts for the medication given to the child who has symptoms of a cold.

Actors

The principal users of these functions are expected to be authorized healthcare providers; the patient and/or subject of care will have access to certain functions to view, update or make corrections to their Electronic Health Record. The provider will receive appropriate decision support, as well as support from the EHR-S to enable effective electronic communication between providers, and between the provider and the patient/parent/caregiver.

Supportive EHR-S Functions

Definition

Supportive EHR-S functions are the subset of EHR-S functions that assist with the administrative and financial requirements associated with the delivery of healthcare. Supportive EHR-S functions also provide input to systems that perform medical research, promote public health, and seek to improve the quality of healthcare delivered.

Example

For example, when the above child is being scheduled for an appointment, Supportive EHR-S functions will automatically verify insurance eligibility (electronically). During the encounter, Supportive EHR-S functions will electronically query local immunization registries (to insure that the child is currently registered), and will determine the child’s immunization status. After treatment, Supportive EHR-S functions will report any immunization to an immunization registry and will provide any encounter data required by financial and administrative systems.

Actors

The Support Staff are the principal users of these functions but, under certain circumstances, the Healthcare Providers might be expected to perform certain administrative functions.
**Information Infrastructure EHR-S Functions**

**Definition**

*Information Infrastructure EHR-S functions* are the subset of EHR-S functions that:

a. Provide a framework for the proper operation of the Direct-care and Supportive EHR-S functions, and

b. Offer EHR-S technical capabilities that are essential, yet transparent, to the user.

**Example**

For example, *Direct Care* and *Supportive EHR-S functions* must operate in a secure environment. Therefore, *Information Infrastructure functions* will provide a secure electronic environment for the immunization registration query mentioned above and will report the child’s immunization event in a secure manner. *Information Infrastructure functions* will also transparently provide other essential services, such as the archival and backup of the child’s record and an audit trail of all accesses to the child’s record. (NOTE: These *Information Infrastructure functions* make an implicit assumption that a base technical environment exists. As part of future conformance activities, many of these functions may be mapped to existing technical standards. These functions are not intended to imply or endorse the implementation of any specific technical standard, nor imply a need for new technical standards.)

**Actors**

These functions are expected to be performed transparently by EHR-S applications on behalf of EHR-S end-users. The System Administrator is expected to be involved in all operations related to configuring and managing the EHR-S operation.

### 3.3 Components of EHR-S Functional Outline

Each function in the HL7 EHR-S Functional Model is identified and described using a set of elements or components as detailed below.

**HL7 EHR-S Functional Model and Standard**

<table>
<thead>
<tr>
<th>ID</th>
<th>Function Name</th>
<th>Function Statement</th>
<th>Function Description</th>
<th>Rationale</th>
<th>See Also</th>
<th>Citation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normative To be voted on</td>
<td>Normative To be voted on</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**ID**

This is the unique outline identification of a function in the outline. The Direct Care functions will be identified by DC followed by a number. Supportive functions will be identified by an ‘S’ followed by a number. Information Infrastructure functions will be identified by an ‘I’ followed by a number. Numbering for all sections begins at 1.0.

Example DC.1.1.3.2
Function Name – See EHR-S Functional Outline for Normative Content

The name of the Function.

Example: Manage Medication List

Function Statement – See EHR-S Functional Outline for Normative Content

Brief statement of the purpose of this function.

Example: Create and maintain patient-specific medication lists.

Description – for reference

Detailed description of the function, including examples if needed. This detailed description will, in the future, be associated with clear criteria for conformance.

Example:

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 is accessible. Medication lists are not limited to medication orders recorded by providers, but may include patient-reported medications.

Rationale – for reference

This element is intended to clarify the rationale for including the function in the EHR-S Functional Model. The rationale must reference one or more of the following:

1. Support delivery of effective healthcare
2. Improve patient safety
3. Facilitate management of chronic conditions
4. Improve efficiency
5. Facilitate self-health management
6. Ensure privacy, confidentiality

See Also – for reference

This element is intended to identify relationships between functions. Future work will involve greater specificity of the relationship between the functions including dependency and precursor/successor associations.

Citation – for reference

This element is used for quoting of an authoritative source for substantiation for the rationale for including this function in the EHR-S Model.
3.4 EHR –S Model: Profiles

Profiles are subsets of the functional outline which apply to a particular EHR-S or express the requirements for a particular group. The reference material available with this proposed DSTU describes the development of a number of profiles.

4.0 Anticipated Uses

4.1 Anticipated Development Approach: Profiles

HL7 is an international community and supports the development of Profiles which are country (HL7 realm) specific specifications within a standard. In future iterations of this EHR-S standard it is anticipated that there will be realm specific profiles (subsets of functions) that have been found essential now or in the future for specific functional areas (e.g., order entry) or care setting (e.g., a hospital ward). Included in the ballot package are sample profiles developed by the EHR Collaborative (http://www.ehrcollaborative.org) within the U.S. realm. These example profiles are included as reference documents.

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

Profiles are the expression of usable subsets of functions from this EHR-S Model. In this EHR-S Model the reader will see a long list of Function Names and Function Statements on which they will be asked to vote affirmative or negative. This vote indicates that the Function Name and Function Statement is a reasonable representation of a function that may be needed for a clinical environment. The vote is not an affirmation that the list of functions should be used in its entirety. The list of functions is not considered to be in a usable form until a Profile is generated.

The act of creating a profile supports a business case for EHR-S use by selecting an applicable subset of functions from the EHR-S Model list of functions. For example, a profile may be created by a purchaser, to indicate requirements; by a vendor, to indicate the capability of specific products; or by any person/entity wishing to stipulate a desired subset of functions for a particular purpose, including a care setting within a specific realm. Once an applicable subset of functions has been selected, the person/entity creating the profile gives each function a priority of essential now, essential future or optional. Functions that are not selected can be annotated with Not Applicable to reflect that it was considered and rejected, or those functions just left off the final profile document. (See White Paper included in the Ballot Package.)

4.2 Anticipated Stakeholder Use: U.S. Department of Health and Human Services

Below is a statement for the anticipated use of the EHR-S Model by the U.S. Department of Health and Human Services, one of the industry stakeholders that actively supported the HL7 efforts:

"The Department of Health and Human Services (HHS) is one of several sponsors of the HL7 effort to define a draft standard for electronic health records (EHRs) system functions. HHS is grateful for the efforts by the HL7 in this arena. We believe that substantial benefits to the healthcare system would ensue if HL7 were able to identify and define as a draft standard for trial use (DSTU) the EHR system functions in an international ballot and achieve a successful voting outcome. HHS understands and appreciates that as a DSTU the EHR model and functions are draft and will continue to evolve.

We understand that healthcare providers, vendors, and others with an interest in EHRs have requested that HHS, other parts of the U.S. government, and other governments around the world indicate how we will promote the adoption of the EHR Functional Model and Standard. As HHS designs and implements programs and policies that promote the use of EHRs, HHS will consider the EHR functions that are successfully balloted by the HL7 along with other
HL7 EHR-S Functional Model Overview

sources of information. For example, HHS does not anticipate incorporating all of the functions embedded in the current ballot as we design programs and policies. Rather, HHS will determine, for each program and policy decision related to EHRs, which, if any, of the EHR functions specified in this ballot, related reference material, and other sources of information should be considered as the programs and policies are designed and implemented."
Appendix A

Ballot Process

As stated above, the EHR-S Functional Model is being balloted as a DSTU. As a proposed DSTU, it requires a successful ballot at the committee level, which will include the voting of interested industry participants registered for the ballot. For an overview of the HL7 ballot process see Appendix C. This section describes the ballot process for the EHR-S Model.

It is important to note that you will have the option to vote on specific Normative sections of the standard document you are reading; on all three sections of the EHR-S model; or to vote on any one or two sections of the model. Though the entire EHR-S Model has been presented for your review and comment, for this proposed DSTU we are using the “Chapter” voting rules of HL7. This means that the voting, reconciliation and approval process for this proposed DSTU will be for the Normative sections of this document, and for each of the three individual sections of the model, the list of functions - Direct Care, Supportive and Information Infrastructure.

Preparation to Vote

Readers (especially those unfamiliar with this EHR-S Model) will find it helpful to read the Reference Material of the ballot package before voting on the ballot. Within the Reference Material readers can find a care setting profile that is similar to their care environment to illustrate the use of the proposed DSTU prior to voting. Readers may also wish to focus on the specific section/chapter of the Functional Model that is more relevant for their every day work. Three scenarios (see Appendix D) may help readers from different professional backgrounds or organizations envision how they would study, comment on, and ultimately use the EHR-S Model DSTU.

As stated above, each balloter may vote on the normative text in the standard (as identified), on individual functions, and on each of the three sections/chapters – see details below. A balloter may also offer comments (editorial or substantive) on any individual function(s), on this EHR-S standard and introduction to the model, on the EHR-S White Paper, on the Care Setting Profiles. A survey is also included for feedback on the EHR-S Model overall, sections, sub-sections, white paper and the varied reference material included in the ballot package.

It is anticipated that the largest amount of input will be on the level of functional granularity. The individual balloter is requested to be flexible in how granular their particular functions of interest are represented in this ballot. Not all requests for inclusion of specific functions as individual line items can be accommodated. This was attempted in the proposed DSTU’s first ballot and was rejected by the balloters. Instead, when looking for a specific function, determine which existing higher level function it might be a component of and suggest wording changes to that existing function’s Functional Description or Example columns to encompass the particular function of interest.

Ballot voting and comment options

HL7 provides an online interface that allows voters to submit their overall vote for each of the proposed four chapters of the proposed DSTU (the standard and three sections of the model) and related summary comments. However, to register detail votes on functions of the EHR-S Model, you will need to complete and submit, by the voting deadline, the “EHR-S Ballot Spreadsheet.” Use this MS Excel spreadsheet file included in the ballot package to register the details of your vote.

On both the HL7 online interface and the Ballot Spreadsheet, you will be expected to provide a vote on the four chapters: the standard, Direct Care, Supportive, and Information Infrastructure. You will have three options: Affirmative, Negative, or Abstain. If you vote Negative, you must complete the Spreadsheet to document your
specific areas of concern and to detail your recommended or desired changes – without supporting detail for a negative; it will be automatically determined as “non-persuasive”.

In the Ballot Spreadsheet, you will have the opportunity to vote and comment:

- On the normative parts of this Standard Overview.
- On the normative parts of each of the three sections of the Standard Model.
- On the name and statement element of any one function, or your selection of functions.

However, if you have voted “affirmative” for the Standard Overview or one of the three sections of the Standard Model, you will NOT be able to vote negative on any respective text or individual function of that related chapter. (Of course, you are free to go back and change your overall section/chapter vote, and then you will be able to cast a negative vote on the text or individual function.)

At the detail level, you will have five voting options, two voting options for negative votes and three options for affirmative votes, see the descriptions below:

Types of Negative Votes (available to those voting “Overall Negative”):

*(Neg-Mj)* Negative-Major vote (with corresponding comment). Use Neg-Mj if the material seems to be non-functional or seriously incomplete, or requires a major correction before final publication. (Note: All Neg-Mj votes will be formally resolved by the HL7 EHR SIG.)

*(Neg-Mi)* Negative-Minor vote (with corresponding comment). Use Neg-Mi if your comment on the material needs to be resolved by the HL7 EHR SIG committee, but when the matter does not warrant a Neg-Mj vote.

Types of Affirmative Votes (available to all voters):

*(A-S)* Affirmative vote (with corresponding Suggestion or Comment–). Use A-S to suggest, for example, the inclusion of additional background information or a justification for a particular solution.

*(A-T)* Affirmative vote (with corresponding Typographical error identified). Use A-T if the material contains a typographical error such as a misspelled word.

*(A-C)* Affirmative vote (with corresponding Comment) – lower priority comment.

The Ballot Spreadsheet also provides worksheet tabs in which you can provide comments for the other reference element of functions. These comments may be included as part of the review and reconciliation effort for your vote on a particular function, but are not required as part of the HL7 ballot process. The EHR SIG also welcomes your input and feedback on the other reference material included in the ballot package. There will be a tab in the Ballot Spreadsheet to capture your comments and feedback on the reference material (e.g. white paper, care setting profiles). For the survey and comments tabs, the balloter options will be the following: 1) Complete or General Agreement 2) Minor Concerns or Issue, 3) Major Issue, 4) No Comment.

What Your Vote Means

It is anticipated that there will be several hundred ballots for the EHR-S Model. For the review process to be effective, we encourage you to limit your negative votes to normative text in the standard, and functions in the model - changes that you feel strongly about, a change that you feel is critical for the EHR-S Model to be valuable or successful for the healthcare industry. Why? A negative vote on any individual function, by HL7 ballot rules, must be considered as a negative vote on the entire EHR-S section/chapter. In addition, all substantive document changes in response to negative votes must be considered and reconciled by the entire EHR Special Interest Group. Whereas, in general, the comments can be reviewed and addressed (outside of substantive document changes) by the work group responsible for the affected section/chapter. When you do
feel obliged to cast a negative vote, balloters are encouraged to clearly indicate whether any negative vote is “major” or “minor.” This will assist in the EHR SIG efforts to prioritize the reconciliation process described below.

The ballot votes/comments are reconciled

The co-chairs or other designated individuals (the reconciliation team) review the votes and comments and organize the comments to facilitate the work of the SIG members involved in determining the disposition of the ballot comments. Dispositions take one of three forms:

- **a) not related** (out of scope),
- **b) not persuasive** (the reviewers do not agree with the suggestion/comment) or
- **c) persuasive** (the reviewers agree with the suggestion/comment and suggest that some or all of it be incorporated into the ballot document).

The reconciliation team will notify the members of ballot pool of the time and place where the ballot comments will be discussed and will distribute the ballot comments to the EHR SIG in advance of this meeting. Reconciliation of the initial EHR-S ballot will begin at the upcoming HL7 EHR SIG meeting, which convenes May 3-5 in San Antonio, Texas. Should the group not complete reconciliation by May 5, 2004, the reconciliation will continue by conference call and/or special meeting(s).

Negative voters are advised of the disposition of their negative votes/comments - Once the ballot comments have been assigned a disposition, the negative voters are notified via e-mail of the disposition of their negative votes. The negative voter may then take one of three actions:

- **a) withdraw** the negative vote (agree that the ballot comments are out of scope or non persuasive and agree to withdraw the negative vote. Agree with the proposed resolution if the vote was considered persuasive. Withdrawn negative votes are then considered affirmative votes);
- **b) retract** the negative vote (a retraction typically occurs when a ballot was submitted in error and the voter does not want the vote to be included in the final ballot tally); or
- **c) maintain** a negative vote (these votes are considered outstanding negatives). Negative voters will be informed of the disposition of their vote/comments as appropriate throughout the reconciliation process. Appeals shall be handled in a manner consistent with Section 15.10 of the Bylaws.

Substantive Changes and Re-Ballots

In response to persuasive votes and comments, functions in the EHR-S Model may be added, deleted or changed. Also, text in the normative sections of the EHR-S Standard Overview may be modified in response to votes and comments. In the event that a substantive change is made, the affected function or chapter may be re-balloted. As long as the EHR-S section in question has passed the ballot with 2/3 of the ballots as affirmative, then the re-ballot of substantive changes can and will be limited to just the functions that were the result of substantive changes. Per HL7, “a substantive change in a proposed American National Standard is one that directly and materially affects the use of the standard.”

Changes to the EHR-S Model will not be deemed substantive if they involve grammar, typos, errors, eliminating function overlap, or non-destructive roll-ups and roll-downs (meaning, as an example, use of existing detail from the description to create more granular functions). Changes to reference elements of the model or reference material based on comments will also not be considered substantive. Below is the list of changes that would be considered substantive:

- Addition of a new function.
- Removal of a function that is not 'rolled up' into a parent function.
- Changing the **Function Name** so that it represents a different function.
- Changing the **Function Statement** so that it represents a different function.
- Changing the **Function Statement** such that a balloter would feel that the change impacts the material use for that function or related section.
Appendix B: What is a DSTU?

Definition from HL7 Policy and Procedure Manual:

POL 14.00.01 Draft Standard for Trial Use

In order to provide timely compliance with regulatory or other governmental mandate and/or timely response to industry or market demand, the Board of Directors is empowered to adopt and publish a Draft Standard for Trial Use (DSTU). The issuance of a DSTU shall be an extraordinary event and shall only proceed with the understanding that the draft standard will, following a suitable period for evaluation and comment, be expeditiously incorporated into a fully balloted and accredited version of the standard. Where the evaluation and comment period results in a need for substantive changes to the draft standard, the relevant accredited version of the standard may embody such changes or a revised DSTU may be published for further evaluation. In either case, given the need for substantive changes, the accredited version of the standard or the subsequent revised DSTU is not bound to maintain compatibility with the initial DSTU. Under such circumstances it is the obligation of the author(s), given that the intent of a draft standard is to improve the viability of the accredited standard, to select enhancement over compatibility. Conversely, recognizing the commitment and investment involved in implementing a DSTU for evaluation and comment, a DSTU implementation shall be accepted as viable for up to two years after its publication or for up to six months after the publication of a subsequent revised DSTU or the first accredited version of the standard that embodies the draft standard, whichever is longer.
Appendix C  The Basics of Health Level Seven Balloting (and an introduction to DSTU Balloting.)

What is Health Level Seven?
Established in 1987, Health Level Seven is an ANSI accredited, not-for-profit standards developing organization, whose mission is:

To provide a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. Specifically, to create flexible, cost effective standards, guidelines, and methodologies to enable healthcare information system interoperability and sharing of electronic health records.

These efforts enable effective, efficient communication between the constituents of the healthcare community as represented by our membership, which consists of an international community of healthcare organizations, vendors, healthcare information systems developers, consultants, systems integrators, and related public and private health services agencies.

The mission of HL7 encompasses the complete 'life cycle' of a standards specification - development, adoption, market recognition, utilization and adherence. The HL7 specifications are unified by shared reference models of the healthcare and technical domains.

For additional information about how HL7 is governed and organized, please refer to: http://www.hl7.org/about/hl7about.htm#WhatisHL7

Why Does HL7 Ballot its Standards and Documents?

Health Level Seven is accredited by the American National Standards Institute (ANSI). Such accreditation, coupled with HL7’s own procedures, dictates that any standard that is published by HL7 and submitted to ANSI for approval be developed and ratified by a process that adheres to ANSI’s procedures for open consensus (www.ANSI.org). Two of the most important components of these procedures are openness and balance of interest. Openness means that anyone who is materially affected by the proposed standard must be allowed to participate in its development and/or the process by which it is ratified (voting). Membership within HL7 cannot be a criterion for this participation, although ANSI allows standards developing organizations to charge an administrative/participation fee to non-members who wish to participate. Individuals who are not members of HL7 but wish to be involved in the balloting process can register at: http://www.hl7.org/ehr

Balance of interest is a requirement that HL7 strive for near equal participation in the voting process by the various constituencies that are materially affected by the standard (e.g., vendors, providers, government agencies, consultants, non-profit organizations, etc.). This ensures that a particular constituency is neither banned from participating nor allowed to dominate the development and ratification of a proposed standard. I use the term “near equal” as it is impossible to ensure that the same number of vendors, providers, consultants, non-profit organizations, etc. will be interested in balloting any particular draft standard. The ANSI requirement is that no particular constituency account for more than 50% of the total number of voters who ratified a standard. HL7 is audited at least once every 5 year to ensure adherence to the ANSI procedures and its own established processes.

The HL7 Balloting Process

HL7’s balloting process is detailed in sections 14 and 15 of the HL7 bylaws and in the HL7 Policy and Procedures manual (both are available on the HL7 web site at http://www.hl7.org). Any document that will be published by HL7 and submitted to ANSI for approval is required, by the HL7 bylaws, to be successfully balloted at both the committee and membership levels (which is not the case for the proposed DSTU, see the next paragraph) While any one can register for a committee ballot, the original intent was that the domain experts (who are typically organized within HL7 by committees) vote on the document initially in a committee ballot. In other words, the domain experts were expected to do the major “clean up” before advancing the
document to the larger audience (the entire HL7 membership) for vote and comment. Once the document is successfully balloted at the committee level, it advances to a membership ballot.

The EHR-S Functional Model document will be balloted as a DSTU. As a DSTU, The EHR-S Model only requires a successful ballot at the committee level. This is because the EHR-S Model, as a proposed DSTU, is not being given to ANSI for approval – it is being provided as a formal notice to ANSI and the industry of the HL7 intent to prepare a formal EHR-S standard in the future.

After HL7 ballot approval, both ANSI and HL7 will widely announce the availability of the DSTU, encourage the affected community to download and review/use it and then comment on it. A DSTU will be labeled such for a given number of months. During that time, HL7 will collect any comments that the affected community wishes to submit on the DSTU. The EHR SIG co-chairs and special interest group members will consider the comments and incorporate those that are appropriate. The intention is that all the contention and suggestions can be worked out during the DSTU period and incorporated into another ballot draft, which can then advance quickly through the remaining processes required to become an approved standard.

A summary of the balloting process is outlined below – see Chapter 5 above for detailed information on the voting process for the EHR-S Model. Text in red denotes the timeline, if known, for EHR-S Model ballot.

**Committee Ballots**

The ballot is announced - The intent to ballot a draft standard is announced at least 30-days prior to the ballot open date. This gives interested parties advance notification of a ballot. Anyone interested in voting on the proposed standard is required to sign up for the ballot pool. HL7 provides online ballot pool registration and provides for paper registration for individuals who do not have access to the technology required for online registration. Ballot registration is free to HL7 members. For this EHR-S Model, non-members are charged a one-time administrative/participation fee of $100 to cover the costs (e.g., staff time and resources that may be necessary for non-member participants) associated with standards development/balloting – meaning current and future ballots for the EHR-S Functional Model DSTU are covered by the initial fee payment. Individuals can register for the ballot pool from the time the ballot is announced until the moment the ballot is closed. The 30-day advance notice for the EHR ballot was announced on February 13, 2004.

The ballot opens – HL7 announces to its membership, to all individuals who have signed up for the ballot pool, and to other appropriate individuals/communities that the ballot is open (see Chapter 5 above, for more detailed information HL7 voting options). The ballot open announcement includes the ballot open and close dates and the online location at which the ballot document can be downloaded. HL7 headquarters will send a paper copy of the ballot document to any individual who does not have access to the technology to download the documents from our web site. The EHR-S Model ballot is scheduled to open no earlier than March 15, 2004, and no later than March 25, 2004.

Ballot pool registrants submit their votes – HL7 provides an online interface that allows voters to submit their overall vote and related summary comments. The online interface automatically sends the votes, as they are submitted, to the co-chairs of the HL7 EHR special interest group (SIG) and to the appropriate HL7 staff members. The votes and related comments are stored in an online database and the tally of votes can be viewed online at any time. The online ballot facility requires individuals to be registered in the ballot pool prior to submitting a vote. The 30 days during which votes can be submitted can be calculated using the earliest/latest ballot open dates noted above.

The ballot closes – The ballot will close at midnight on the specified close date. The online ballot system will not accept votes after that time and any paper votes received in the office by any means (i.e., mail, fax) after the ballot close date will not be counted. Late votes will, however, be forwarded to the EHR SIG co-chairs to provide them an opportunity to review the comments. The EHR-S Model ballot will close no sooner than April 14, 2004, and no later than April 24, 2004.
The ballot votes/comments are reconciled - The co-chairs or other designated individuals (the reconciliation team) review the votes and comments and organize the comments so that those who are interested in determining the disposition of the ballot comments can do so in an organized fashion. Dispositions take one of three forms:

a) Not related (out of scope).
b) Not persuasive (the reviewers do not agree with the suggestion/comment).
c) Persuasive (the reviewers agree with the suggestion/comment and suggest that some or all of it be incorporated into the ballot document).

The reconciliation team will notify the members of ballot pool of the time and place where the ballot comments will be discussed and will distribute the ballot comments to the EHR SIG in advance of this meeting. The ballot group meets, assigns dispositions to the ballot comments and captures the outcome of those votes as evidence of the process and for further distribution (typically posted to our website). Reconciliation of the initial EHR-S ballot will begin at the upcoming HL7 EHR SIG meeting, which convenes the week of May 3-5 in San Antonio, Texas. Should the group not complete reconciliation during by May 5, 2004, the reconciliation will continue by conference call and/or special meetings(s), which will be announced in advance.

Negative voters are advised of the disposition of their negative votes/comments - Once the ballot comments have been assigned a disposition, the negative voters are notified, in writing (typically e-mail) of the disposition of their negative votes. The negative voter may then take one of three actions:

a) Withdraw their negative vote (they agree that their ballot comments are incorrect and agree to withdraw their negative vote. Withdrawn negative votes are then considered affirmative votes).
b) Retract their negative vote (a retraction typically occurs when a ballot was submitted in error and the voter does not want the vote to be included in the final ballot tally).
c) Maintain a negative vote (these votes are considered outstanding negatives).

Negative voters will be informed of the disposition of their vote/comments as appropriate throughout the reconciliation process.

A final ballot tally is performed - Once the negative voters have been given an opportunity to withdraw, retract or maintain their negative votes, the finally ballot vote is tallied. A document passes committee ballot when at least 60% of the ballot pool members return a vote and when 2/3 of the combined affirmative and negative votes are affirmative.

The draft standard is either re-balloted at the committee level or submitted to ANSI as a DSTU – If the document does not pass the committee ballot criteria noted above or if there is significant new or substantive material added, the document is re-balloted at the committee level. If the document passed at the committee level and, the document will be submitted to ANSI as a DSTU.

Draft Standard for Trial Use Period

ANSI and HL7 encourage review/use of the DSTU for the designated number of months – Once the DSTU is registered with ANSI, HL7 and ANSI will announce its availability and provide an online mechanism for collecting comments about the DSTU. Anyone wishing to submit comments will need to register with HL7 (free of charge) so that we have the appropriate contact information (i.e., e-mail and phone number) should we need clarification on the comments.

The comments are reviewed and incorporated as appropriate – The EHR co-chairs and special interest group will review the comments, incorporating those that are appropriate. If there are significant changes to the published DSTU and/or if substantive changes are introduced at this point, the document will be re-balloted at the committee level and, once ratified by 2/3 affirmative vote, advance to membership ballot.
Appendix D: Scenarios on Reading and Voting on Ballot Package

Readers may wish to focus on the specific section of the EHR-S Model ballot package that is more relevant for their every day work. For example, a clinician might read the Direct Care and Supportive sections very closely, while technical people might focus especially on the Information Infrastructure section. Within an organization, it might be helpful to delegate responsibility for scrutinizing the different sections among staff with different responsibilities and expertise.

Three vignettes are included here to help readers in different positions or organizations envision how they would study, comment on, and ultimately implement the DSTU Functional Outline.

Scenario 1 - GROUP PRACTICE.

Dr. Smith is part of a 50-person group practice. The practice currently has a clinical information system that provides billing, scheduling, and other administrative support. For several reasons, it will need to be upgraded or replaced within 2 years. It does not include electronic health records. Dr. Smith wants the practice to vote on the HL7 EHR-S Model ballot to be sure it would be helpful to them as they make their IT decisions. Dr. Smith and interested colleagues review the Ambulatory Care documents in the reference section to see how the example use setting and scenario illustrate the EHR functions related to their practice; they look at the example Ambulatory Care prioritization of the individual functions that a group of experts working with HL7 have suggested. With a good understanding of what the EHR functions would mean for their practice, Dr. Smith and several other providers then focus on the Direct Care and Supportive sections, while the technical support staff look at the Information Infrastructure section. They meet to discuss their conclusions. Overall, they are very favorable to the list of functions. They identify a few terminology issues and suggestions for revising them. They vote in the affirmative, offering their specific suggestions for improvement. They plan to use the list of functions in discussions with vendors about their next IT system, recognizing that some functions may not yet be available.

Scenario 2 - HOSPITAL.

Mr. Jones is the Chief Informatics Officer in a large hospital organization. Their IT system was installed two years ago and includes patient tracking and ordering components; it was upgraded for HIPAA compliance. It does not include clinical decision support, performance monitoring, or public health reporting. Mr. Jones asks the Chief Medical Officer to organize a review of the HL7 EHR-S Model while his team also reviews it. They both begin by looking at the Acute Care documents in the reference section to see how a group of experts working with HL7 have suggested the EHR-S might be used within a hospital. The example scenario and example prioritization of the individual functions is helpful. The CMO and several doctors and senior nurses review the Direct Care and Supportive sections of the EHR-S Model; the CIO and his team focus on the Information Infrastructure section but also look at the Direct Care and Supportive sections. A small team of providers and IT staff meet to discuss their conclusions. They decide to vote affirmative but suggest some specific revisions to some functions, to some sections of the Informative text, and to the Acute Care reference materials. They plan to use the list of functions in discussions with vendors about adding decision support, performance monitoring, and public health reporting to their existing system, recognizing that their budget will only allow very limited expansion in the near term.

Scenario 3 - IT VENDOR.

Ms. Green is the head of the clinical systems division of a large health IT company. Their product line includes both dedicated EHR systems and integrated systems that include an EHR. Their EHR and integrated systems have some decision support for medication ordering, but no performance monitoring/reporting functions. While most of their clients are larger provider organizations and hospitals, they are planning to expand into the small practice and home health markets with a simple, less expensive clinical system. In anticipation of HHS’s implementation of the Medicare Reform law, which provides financial incentives for providers who use IT to track patients, the company wants to add a range of functionality to its products that would meet or exceed the Medicare requirements. Ms. Green asks her staff to review the entire HL7 EHR-S Model package, beginning
with the care setting examples in the reference section. Based on the examples in the care setting section, they determine that they could add a relatively small number of functions to various products to be able to offer superior products for current and future clients. They review the list of functions in the ballot and find that a specific supportive function they already provide is not included. They vote negative, recommending the inclusion of the function, but anticipate discussing it with HL7. They see value in the EHR-S Model for their discussions with their clients about upgrades or new purchases.