



ANNOUNCEMENT OF FORMATION OF BALLOT POOLS FOR SEPTEMBER 2010 BALLOT CYCLE

July 23, 2010

Health Level Seven International® invites you to take part in the formation of ballot groups for the upcoming September 2010 ballot cycle. The candidate standards and other documents described in this announcement are expected to ballot prior to HL7's October 2010 Working Group Meeting (WGM). Comments received in response to these ballots will be addressed at that WGM running October 3-8, in Cambridge, Massachusetts, USA. Please note that while ballots are typically named for the month in which the corresponding WGM takes place, this ballot cycle will still be referred to as the September Ballot Cycle as that has now been the pattern for several years.

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Ballot Overview

Ballot Open/Close Dates

Most ballot pools in this document will open and close for voting on the following dates. Exceptions for a specific pool are listed with that pool.

Ballot Open Date: Monday, August 23, 2010

Ballot Close Date: Monday, September 27, 2010

Ballot Pool Enrollment Period

Ballot pool enrollment will be available from a date at least two weeks preceding the ballot pool opening date and will continue until one week before ballot pool close. While the exact dates are dependent upon individual pool ballot open and close dates, in general the signup period dates are as follows:

Ballot Pool Sign-Up Open Date: Monday, August 9, 2010 (no later than)

Ballot Pool Sign-Up Close Date: Sunday, September 20, 2010

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Please be aware that these dates may not be accurate for all ballot pools. To sign up, point your browser to <http://www.hl7.org/ctl.cfm?action=ballots.home>. **Important Note: Ballot pool signup will close one (1) week before the ballot close date.** This is also the final date non-members can sign up for Non-Member Participation in the ballot.

Ballot Listing

This section details the candidate/draft standards and other documents that HL7 intends to ballot before the upcoming September WGM. Please note that the following details about specific items are subject to review by the HL7 Technical Steering Committee:

- Approval of all projects initiating any ballot item
- Approval of titles for new candidate and draft standards and other documents
- Approval of new candidate Draft Standards for Trial Use
- Approval of ballot level for those items moving directly to Normative ballot

Any changes from the initial details in this announcement will be identified in the ballot announcement document released when the September 2010 ballot cycle opens.

In addition, please be aware that some of the listed ballot pools are closed to additional enrollment. Original consensus group ballots are subsequent ballots of material previously balloted at the normative level and are usually limited to the members of the original consensus group, as stipulated in the HL7 Governance and Operations Manual (GOM), section 14.03.04 - Consensus Group for Subsequent Normative Ballots of the Same Content. Accordingly, these ballot pools are closed to sign up on the HL7 Ballot Desktop. The affected pools are identified in this document. For complete details on original consensus group ballots, please refer to the indicated section of the HL7 GOM.

Standards Classifications

These items are based on or associated with the following standards classifications:

- Clinical Context Management Specification
- Clinical Document Architecture, Release 2
- Electronic Health Records
- Version 2 Messaging
- Version 3 Messaging
- Version 3 Specifications, Infrastructure and Foundation

A section is devoted to each of the standards classifications below.

Ballot Listings by Classification

Clinical Context Management Specification

The **Clinical Context Object Work Group** and the **Security Work Group** announce the formation of a ballot group for the following item:

[Ballot pending Technical Steering Division approval.]

- ***HL7 Clinical Context Management Specification Version 1.6 (1st Normative Ballot)***

Using a technique known as context management, the CCOW standard facilitates the integration of a clinical user's applications at the point of use. By allowing the

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synchronization and coordination of clinical applications so that they automatically follow the user's context, the CCOW standard servers as the basis for ensuring secure and consistent access to patient information from heterogeneous sources. The benefits include applications that are easier to use, the increased utilization of electronically available information, and an increase in patient safety. Further, CCOW support for secure context management provides a healthcare standards basis for addressing HIPAA requirements. Version 1.6 of the standard introduces language on the use of SAML Assertions for authenticating users into the CCOW context and for the subsequent re-use of saved SAML Assertion by authorized context participants. The use of SAML Assertions for authentication improves both user experience and allows for centrally managed control of user rights.

Unique Ballot ID: CCOW_CMS_V16_N1_2010SEP

Clinical Document Architecture, Release 2

The **Clinical Genomics** and **Structured Documents Work Groups** announce the formation of a ballot group for the following item:

[Ballot pending Technical Steering Division approval.]

- ***HL7 Implementation Guide for CDA Release 2: Genetic Testing Reports, Release 1 (1st DSTU Ballot)***

Genetic tests have recently become an important tool in clinical care based on the patient individual genetic makeup. They are also used in clinical trials and research. There is a need to define a universal CDA implementation guide that can accommodate various genetic testing reports. In addition, this IG will strive to serve both research and clinical environment as much as possible. Further refinements might be developed in the future to accommodate more specific needs. This version of the CDA Genetic Testing Report (GTR) Implementation Guide is developed through the OHT MDHT tool as a pilot, along with automatic publishing features.

Unique Ballot ID: CDAR2_IG_GENTESTRPT_R1_D1_2010SEP

The **Structured Documents Work Group** announces the formation of ballot groups for the following items:

[Ballot and alternate open date pending Technical Steering Division approval.]

Alternate Ballot open date: August 27, 2010

- ***HL7 Implementation Guide for CDA Release 2 - Level 3: Healthcare Associated Infection Reports, Release 6 - US Realm (1st DSTU Ballot)***

With cooperation from CDC and Healthcare Associated Infections (HAI) software vendors, this project will develop an implementation guide constraining CDA Release 2. The implementation guide will support electronic submission of HAI data to the National Healthcare Safety Network. This version of the HAI Reports IG sees the addition of templates supporting Antimicrobial Use and Resistance (AUR) Option and Hemovigilance Adverse Reaction (HAR) Report forms.

Unique Ballot ID: CDAR2L3_IG_HAIRPT_R6_D1_2010SEP

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[Ballot and alternate open date pending Technical Steering Division approval.]

Alternate Ballot open date: August 27, 2010

- ***HL7 Implementation Guide for CDA Release 2: Progress Note, Release 1 - US Realm (1st DSTU Ballot)***

This project will design a Progress Note in XML as a constraint on HL7 V3 CDA R2. A Progress Note documents a patient's clinical status during a hospitalization or outpatient visit. The project will review current Progress Note usage and will examine industry precedents and requirements. This project will follow the guidance of SDWG, domain work groups and the current approach to CDA templates in CCD and the Health Story implementation guides.

Unique Ballot ID: CDAR2_IG_PROGNOTE_R1_D1_2010SEP

[Ballot and alternate open date pending Technical Steering Division approval.]

Alternate Ballot open date: August 27, 2010

- ***HL7 Implementation Guide for CDA Release 2: greenCDA Modules for CCD, Release 1 (1st Informative Ballot)***

The full specification of CDA XML addresses universal requirements for exchange and management of structured clinical documents. The greenCDA concept is one method of working with an implementation-specific XML while maintaining the full utility of CDA, asserting as a primary principle that any simplification must also deliver valid, normative CDA (plain vanilla CDA). A greenCDA module is a documented schema corresponding to a CDA template or combination of templates together with a transform to normative CDA. This project will create a set of greenCDA modules for CCD.

Unique Ballot ID: CDAR2_IG_GREENMOD4CCD_R1_I1_2010SEP

Electronic Health Records

The **Electronic Health Records** and **Public Health and Emergency Response Work Groups** announce the formation of a ballot group for the following item:

[Ballot pending Technical Steering Division approval.]

- ***HL7 EHR-S Vital Records Functional Profile, Release 1 - US Realm (1st Informative Ballot)***

The HL7 EHR-S Vital Records Functional Profile specifies the functional requirements needed to facilitate EHR systems capturing vital records data at the point of contact or point of care and to enable interoperable electronic data exchanges among electronic health record systems, US vital records systems and potentially other public information systems for birth, death and fetal death events.

Unique Ballot ID: EHR_VRFP_R1_I1_2010SEP

The **Electronic Health Records** and **Pharmacy Work Groups** announce the formation of ballot groups for the following items:

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[Ballot pending Technical Steering Division approval.]

- ***HL7 EHR-System ePrescribing Functional Profile, Release 1 - US Realm (1st Informative Ballot)***

For several years, prescribers and pharmacies (pharmacists) have been communicating electronic prescription information using the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard. In July of 2004, sixteen participants from HL7 and NCPDP launched the NCPDP-HL7 Electronic Prescribing (eRx) Mapping Project. The purpose of this profile is to specify the functional requirements of electronic prescribing needed to support data exchange between prescribers, pharmacist and pharmacy providers and other health care entities needing medication-related information.

Unique Ballot ID: EHR_ERXFP_R1_I1_2010SEP

[Ballot pending Technical Steering Division approval.]

- ***HL7 EHR-System Pharmacist/Pharmacy Provider Functional Profile, Release 1 - US Realm (1st Informative Ballot)***

The Pharmacist/Pharmacy Provider Functional Profile will facilitate EHR systems' capture of medication and clinical related data at the point of contact or point of care by specifying the functional requirements needed to support messaging among prescribers, pharmacist and pharmacy providers and other health care entities needing medication-related information.

Unique Ballot ID: EHR_RXPROVFP_R1_I1_2010SEP

Version 2 Messaging

The **Orders and Observations Work Group** announces the formation of a ballot group for the following item:

[Ballot pending Technical Steering Division approval.]

- ***HL7 Version 2 Implementation Guide: Laboratory Test Compendium Framework, Release 1 (1st Informative Ballot)***

This guide provides a process for a laboratory to transmit its directory of service in an electronic mode including updates to those who order laboratory services. Before releasing this document to HL7, the American Clinical Laboratory Association also conducted a 60+ day public comment period on the document and received over a hundred comments from many different organizations in healthcare intended to improve the original work. This implementation guide is based on Chapter 8 of HL7 Version 2.6; however, it has adopted proposals for Version 2.8 to resolve limitations found with v2.6.

Unique Ballot ID: V2_IG_LTCF_R1_I1_2010SEP

Version 3 Messaging

The **Clinical Decision Support Work Group** announces the formation of ballot groups for the following items:

- ***HL7 Version 3 Domain Analysis Model: Clinical Decision Support; Virtual Medical Record, Release 1 (2nd Informative Ballot)***

A Virtual Medical Record (vMR) is a data model for representing clinical information inputs and outputs that can be exchanged between local clinical

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information systems and clinical decision support (CDS) engines such as CDS services. The goal of this project is to create HL7 vMR data models capable of supporting scalable, interoperable CDS. The specification undergoing ballot consists of a technology-neutral Domain Analysis Model (DAM) for the vMR that will serve as the foundation of vMRs for specific implementation technologies. Since the initial May 2010 ballot of this material, the following changes have been made:

- The model has been aligned more closely with the RIM, using the modeling approach used by the US Federal Health Information Model initiative
- Concrete data types have been added

Unique Ballot ID: V3DAM_CDS_VMR_R1_I2_2010SEP

[Ballot pending Technical Steering Division approval.]

- ***HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) – Decision Support Service (DSS) Implementation Guide, Release 1 (1st DSTU Ballot)***

This specification aims to provide guidance regarding the implementation of context-aware knowledge retrieval applications in a Service-Oriented Architecture based on the HL7/OMG Decision Support Services (DSS) Standard. The specification includes:

- Functional requirements for context-aware knowledge retrieval in a SOA;
- Technical specification for the operations and semantic profiles (service payloads) to be supported by Context-aware Knowledge Retrieval DSS implementations.

Since the initial Comment ballot of September 2009, the following changes have been incorporated:

- The knowledge response specification was improved, with significant detail added.
- Examples were added and updated based on changes to the Context-Aware Knowledge Retrieval, Knowledge Request Standard that was balloted in May 2010.
- The specification and examples were updated based on recent updates to the HL7/OMG Decision Support Services specification.

Unique Ballot ID: V3_IG_DSS_KM_INFOBUTTON_R1_D1_2010SEP

The **Clinical Interoperability Council** and **Patient Care Work Groups** announce the formation of a ballot group for the following item:

[Ballot pending Technical Steering Division approval.]

- ***HL7 Version 3 Domain Analysis Model: Emergency Medical Services, Release 2 – US Realm (1st Informative Ballot)***

This document specifies release 2 of a domain analysis model (DAM) for the Emergency Medical Services domain. For the purpose of this project Emergency Medical Services (EMS) are defined as a branch of emergency services dedicated to providing out-of-hospital acute medical care and/or transport to definitive care, to patients with illnesses and injuries which the patient, or the medical practitioner, believes constitutes a medical emergency. The EMS DAM is designed to support the creation of specifications to support the interoperability

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needs of Emergency Medical Services. Since the successful balloting of release 1 of this DAM the following changes have been incorporated:

- Additional descriptions for relationships not described in R1;
- Changes in class relationships to better reflect EMS organization;
- Additional data elements requested by NEMESIS.

Unique Ballot ID: V3_DAM_EMS_R2_I1_2010SEP

The **Health Care Devices** and **Patient Care Work Groups** announce the formation of a ballot group for the following item:

- ***HL7 Version 3 Domain Analysis Model: Detailed Clinical Models for Medical Devices, Release 1 (1st Comment Only Ballot)***

This document describes a Domain Analysis model in UML and the use cases used to derive that model. The model is intended to support the development of device interoperability specifications. The DAM will include packages that will meet the criteria for detailed clinical models in order to support device communication of clinical data in order to improve information capture and to support safety measures. The process is iterative: the initial DAM will contain a limited set of use cases and an information model based on those cases. This iteration will contain three use cases:

- Intubate Patient, Unplanned: In response to a patient's deteriorating condition, a team of clinicians intubates a patient and attaches the patient to a ventilator, confirms that the ventilator is working properly, and confirms that the settings are correct.
- Extubate Patient, Planned: In response to a physician's order, a team of clinicians weans a patient from a ventilator and removes the endotracheal tube. The clinician performs a respiratory assessment on the patient.
- Manage Patient on Ventilator: A clinician assesses a patient on a ventilator and adjusts ventilator and alarm settings as necessary.

Unique Ballot ID: V3DAM_DCM4MEDDEV_R1_O1_2010SEP

The **Patient Care Work Group** announces the formation of a ballot group for the following item:

[Ballot pending Technical Steering Division approval.]

- ***HL7 Version 3 Detailed Clinical Models, Release 1 (1st Informative Ballot)***

Patient Care intends to ballot one or more PDF documents with DCM examples in the upcoming ballot cycle. This will include a subset of two or more from the Top 10: DCM blood pressure, DCM pulse/heart rate, DCM temperature, DCM breathing, DCM length, DCM weight, DCM Braden Scale, DCM Glasgow Coma Scale, DCM Barthel Index, DCM Apgar Score. We hope to get feedback on clinical content, appropriate code binding to vocabularies, and UML representation and table specification for each of the submitted DCM examples. The documents on the PC wiki have been used in the past to develop ideas for constructing DCMs. The format has changed due to further development in HL7 and ISO. The new format will be balloted as PDF for content. Anyone that wishes to review the XMI files as well can ask via the patient care list serve. However, the XMI at this stage is not part of the formal HL7 informative ballot.

Unique Ballot ID: V3_DCMODELS_R1_I1_2010SEP

The **Pharmacy Work Group** announces the formation of ballot groups for the following items:

[Original Consensus Group Ballot; closed to additional enrollment.]

- ***HL7 Version 3 Standard: Pharmacy CMETs, Release 10 (4th Normative Ballot)***

These CMETs provide support for Prescribing, Dispensing and Administration messages, as well as Rx status management, active medications and patient Rx queries. The CMETs being balloted are:

- A_SubstanceAdministrationRequest (COCT_MT350000UV) – An element that encapsulates just the substance administration request portion of a medication order. It can be used in models where the entire order is not needed.
- A_MedicationOrder (COCT_MT360000UV) – A general medication order element that can be used to refer to an entire order. For example usage, it is used in the Medication Dispense model to allow the order to be sent along with the dispense.

Changes since the 3rd Normative ballot in May 2010 include the following:

- Minor updates to material as a result of ballot comments
- Updates to descriptions, based on internal quality review

Unique Ballot ID: V3_RX_CMET_R10_N4_2010SEP

[Original Consensus Group Ballot; closed to additional enrollment.]

- ***HL7 Version 3 Standard: Pharmacy; Common Dispense and Supply Event, Release 1 (2nd Normative Ballot)***

The artifacts in this topic pertain to models and interactions that are common to any type of dispense or supply event. These have been separated from the Medication Dispense and Supply Event topic because they also cover devices and other products. Since the 1st Normative ballot in May 2010, the following changes have been incorporated:

- Minor updates to material as a result of ballot comments
- Updates to descriptions, based on internal quality review

Unique Ballot ID: V3_RX_CDSEVNT_R1_N2_2010SEP

[Original Consensus Group Ballot; closed to additional enrollment.]

- ***HL7 Version 3 Standard: Pharmacy; Common Order, Release 1 (2nd Normative Ballot)***

The artifacts in this topic pertain to interactions that are common to any type pharmacy-related order. These have been separated from the Medication Order topic because they also cover devices and other products that can be ordered from pharmacies. Since the 1st Normative ballot in May 2010, the following changes have been incorporated:

- Minor updates to material as a result of ballot comments
- Updates to descriptions, based on internal quality review

Unique Ballot ID: V3_RX_CMNORDER_R1_N2_2010SEP

[Original Consensus Group Ballot; closed to additional enrollment.]

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- ***HL7 Version 3 Standard: Pharmacy; Medication Dispense and Supply Event, Release 1 (4th Normative Ballot)***

This topic covers the issuing of medication to a patient or representative, as well as bulk supplies of medication. It deals with both community dispensing, as well as dispensing performed by institutional/hospital pharmacies and automated packaging and dispensing systems. Since the 3rd Normative ballot in May 2010, the following changes have been incorporated:

- Minor updates to material as a result of ballot comments
- Updates to descriptions, based on internal quality review

Unique Ballot ID: V3_RX_MDSEVNT_R1_N4_2010SEP

[Ballot and name change pending Technical Steering Division approval.]

[Original Consensus Group Ballot; closed to additional enrollment.]

- ***HL7 Version 3 Standard: Pharmacy; Medication Knowledge-Base Query, Release 1 (4th Normative Ballot)***

This topic, originally titled "HL7 Version 3 Standard: Medication; Drug Knowledge-Base Query, Release 1", has been re-titled as the Medication domain is being merged into the Pharmacy domain. It covers the issuing of queries to medication knowledge-base applications for such information as medication composition, characteristics, and dosage instructions. Since the 3rd Normative ballot in May 2009, the following changes have been incorporated:

- Minor updates to material as a result of ballot comments
- Updates to descriptions based on internal quality review

Unique Ballot ID: V3_ME_DKBQ_R1_N4_2010SEP

[Original Consensus Group Ballot; closed to additional enrollment.]

- ***HL7 Version 3 Standard: Pharmacy; Medication Statement, Release 1 (3rd Normative Ballot)***

This topic deals with the reporting of specific medication administration events and statements about medication use that are not tied to a specific prescription, dispense or administration. The former category is usually relevant in institutional settings, whereas the latter is mostly used to include patient statements in the overall medication profile. Since the 2nd Normative ballot in May 2009, the following changes have been incorporated:

- Minor updates to Medication Statement as a result of ballot comments
- Inclusion of artifacts for Medication Administration event

Unique Ballot ID: V3_RX_MSSEVNT_R1_N3_2010SEP

The **Regulated Clinical Research Information Management Work Group** announces the formation of ballot groups for the following items:

[Ballot pending Technical Steering Division approval.]

- ***HL7 Version 3 Implementation Guide: Drug Stability Reporting (eStability) R2, Release 2 (1st Informative Ballot)***

This implementation guide describes the basic requirements needed for using the Stability standard and the requirements needed for submitting information to the Food and Drug Administration (FDA) using the standard. Release 2 of this implementation guide modifies the initial guide to conform with changes to the message that were included in the subsequently released Normative standard.

Unique Ballot ID: V3_IG_DSRR2_R2_I1_2010SEP

[Ballot pending Technical Steering Division approval.]

- ***HL7 Version 3 Implementation Guide: Regulated Studies; CDISC Content to Message – Study Design, Release 1 (1st Informative Ballot)***

This implementation guide describes how to implement the HL7 Version 3 Standard: Regulated Studies; CDISC Content to Message - Study Design. A New Protocol submission contains information about what will be done, including planned analyses, etc. The study design message transports study summary, trial design, eligibility criteria, and statistical analysis plan.

Unique Ballot ID: V3_IG_CDISC2MSG_SDS_R1_I1_2010SEP

[Ballot pending Technical Steering Division approval.]

- ***HL7 Version 3 Implementation Guide: Regulated Studies; CDISC Content to Message – Study Participation, Release 1 (1st Informative Ballot)***

This is the implementation guide for the HL7 Version 3 Standard: Regulated Studies; CDISC Content to Message - Study Participation. The Study Participation message is intended transmit information about all experimental subjects, investigators, and other relevant entities that are involved in the conduct of an individual clinical study.

Unique Ballot ID: V3_IG_CDISC2MSG_SP_R1_I1_2010SEP

[Ballot pending Technical Steering Division approval.]

- ***HL7 Version 3 Implementation Guide: Structured Product Labeling, Release 5 (1st Informative Ballot)***

SPL Release 5 changes the structure of SPL to leverage the data elements defined in the Common Product Model and reduce the SPL standard to the description of Header and Text information. This implementation guide addresses those changes.

Unique Ballot ID: V3_IG_SPL_R5_I1_2010SEP

Version 3 Specifications, Infrastructure and Foundation

The **Implementable Technology Specification** and **Structured Documents Work Groups** announce the formation of a ballot group for the following item:

- ***HL7 Version 3 Standard: XML Implementation Technology Specification for RIM Serializations, Release 1 (2nd DSTU Ballot)***

This specification describes a RIM-based serialization. The names and types found in the XML instances and the matching schemas are taken directly from the RIM. This RIM serialization is suitable for use wherever RIM-based data is transferred. As a consequence, this serialization may be considered for use wherever the RIM is an appropriate model for expression of the data. All required changes from the prior ballot resolution have been applied.

Unique Ballot ID: V3_XMLITS_RIMSR_R1_D2_2010SEP

The **Infrastructure and Messaging Work Group** announces the formation of a ballot group for the following item:

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- ***HL7 Version 3 Standard: Transmission Infrastructure, Release 2 (2nd DSTU Ballot)***

The Batch Topic is being re-balloted in this release of MCCI with the expectation that the capability of sending batch messages will become normative within Version 3. The RIM has offered support for batches since its inception. The contents of this topic are based on the use of batches in HL7 Version 2. Since the 1st DSTU ballot in May 2010, the following changes have been incorporated:

- Remove the notion of the Message Adapter Batch Acknowledgement which is no longer supported
- Add profile ID to fit the needs of existing implementations
- Implement suggested changes from the prior ballot cycle

Unique Ballot ID: V3_IM_TRANS_R2_D2_2010SEP

The **Modeling and Methodology Work Group** announces the formation of a ballot group for the following item:

- ***HL7 Version 3 Specification: Model Interchange Format (MIF), Release 1 (2nd Informative Ballot)***

HL7 has developed and maintained a set of schemas called the Model Interchange Format (MIF) since 2002. This standard documents the set of schemas that, in turn, defines the syntax for the exchange of HL7 artifacts (static models, services, behavior models, etc.). It is broadly used as a persistence and exchange syntax by HL7 tools. The document includes the requirements for this specification, as adopted by the Tooling Work Group and the Modeling and Methodology Work Group. It is being provided for Informative ballot.

Unique Ballot ID: V3_MIF_R1_I2_2010SEP

The **Modeling and Methodology** and **Infrastructure and Messaging Work Groups** announce the formation of a ballot group for the following item:

[Original Consensus Group Ballot; closed to additional enrollment.]

- ***HL7 Version 3 Standard: Core Principles and Properties of Version 3 Models, Release 1 (4th Normative Ballot)***

HL7 Version 3 Standards are founded on three models - Reference Information Model, Data Types and Vocabulary. The rules for binding these three models together and for using them in the specification of standards and the implementation of these standards need to be balloted and made available as a companion specification in order to facilitate implementation and development of the V3 Standards. Core Principles has been revised and restructured for this ballot to address issues from prior ballots.

Unique Ballot ID: V3_CPPV3MODELS_R1_N4_2010SEP

The **Modeling and Methodology** and **Vocabulary Work Groups** announce the formation of a ballot group for the following item:

[Original Consensus Group Ballot; closed to additional enrollment.]

- ***HL7 Version 3 Standard: Reference Information Model, Release 3 (2nd Normative Ballot)***

This is the first round of Normative balloting for RIM, Release 3. The prior document passed in December 2009. Selected classes and attributes have been added or modified. These are detailed in the preface to the document.

Unique Ballot ID: V3_RIM_R3_N2_2010SEP

The **Services Oriented Architecture** and **Community Based Collaborative Care Work Groups** announce the formation of a ballot group for the following item:

[Ballot pending Technical Steering Division approval.]

- ***HL7 Version 3 Standard: Privacy, Access and Security Services (PASS) – Audit Services, Release 1 (1st DSTU Ballot)***

The proposed specification includes a complete SAIF specification stack (conceptual, platform-independent, and platform-specific)-level analysis for secure audit services in the healthcare environment. Business requirements, information models and functional models are developed to provide the foundation for specific "service aware" implementation technologies. The document uses that foundation to specify a platform-independent model (PIM). The PIM is used as a basis for the creation of an instance of a platform-specific model (PSM), complete with transformation specifications between PIM and PSM.

Unique Ballot ID: V3_PASS_AUDITSERV_R1_D1_2010SEP

Ballot Procedure

General Guidelines

The membership is reminded that ANSI rules dictate that all individuals who were in a normative ballot pool **MUST** be included in the initial ballot pool when the same document goes out for a subsequent normative ballot. Thus, if a document is going out for a 2nd normative ballot, all individuals who were active in the ballot pool (casting either an affirmative, negative or abstain) for the 1st normative ballot are automatically subscribed as members for the subsequent normative ballot.

HL7 will conduct these ballots according to its procedure for electronic balloting. Individuals who sign up for the ballot group will not receive a paper copy of the document or a paper ballot. Instead, they will be notified by e-mail when the ballot package is available. They will download the document from the HL7 web server and will enter their votes and comments using the HL7 Ballot Desktop.

If a member of the ballot group does not have access to the technology being used, or if the person can demonstrate that using the electronic process creates a substantial hardship, he/she may request a paper copy of the ballot package and/or vote using a paper ballot. Because of the extra expense and time delays associated with paper ballots, HL7 does not intend to provide the alternative of using paper to members who have access to the technologies and have no substantial hardship associated with their use.

Voting

HL7 members and others who are materially affected by any of the proposed standards and wish to participate in these ballots must join the respective ballot groups. This can be accomplished by logging on to the Ballot Desktop at the following URL: <http://www.HL7.org/ctl.cfm?action=ballots.home>. Alternately, members can call the HL7 office at (734) 677-7777 and request that the Ballot Group Declaration Form be faxed or mailed to them.

With the exceptions noted above, all voting related activity – joining ballot pools, downloading or reviewing ballot content, uploading comments and voting – is done through the Ballot Desktop. In addition, non-members wishing to take part in this or any HL7 ballot must use the Ballot Desktop to register. Those non-members wishing to use this option are referred to the Paid Participation in HL7 Ballots Instructions posted on the HL7 Ballot Desktop.

All ballot dates are inclusive: votes cannot be cast before the beginning date or after the ending date of a ballot pool. Please note that all times are tracked in the Eastern Time Zone (US). If you have any problems with the ballot desktop, joining, or voting, please contact the HL7 Director of Technical Services at webmaster@HL7.org before the closing of the ballot.

Negative Votes on Normative Ballots: Members are reminded of the following rules from the HL7 GOM regarding the submission of negative votes on normative ballots:

- 14.06.03.01 Submission of Comments – Statements accompanying negative ballots should be submitted as an attachment to the ballot and clearly reference the particular ballot item(s) to which it pertains.
- 14.06.03.02 No Comments or Inappropriate Comments – Negative ballots not accompanied by comments or accompanied by inappropriate comments or comments of no relevance to the ballot proposal shall not be considered. Such ballots will be recorded as a “negative without comment” for the purposes of establishing a quorum and reporting to ANSI. However, these ballots shall not be factored into the numerical requirements for consensus. No effort shall be made to solicit comments from the submitter of a negative without comment.

Important Notes

IMPORTANT NOTE on Balloting Rules: Due to changes in the past several cycles in the HL7 Governance and Operations Manual (GOM), the rules under which balloting takes place have changed slightly. These changes can be summarized as follows:

- The definition for the Consensus Group for Subsequent Normative Ballots of the Same Content (GOM: 14.03.04) has changed. The consensus group for subsequent ballots "shall consist of those individuals, members or nonmembers, who submitted a ballot by the close of the ballot response period; whether affirmative, negative, or abstain." For complete details, please refer to the indicated section.
- As a reminder, the quorum and approval levels stipulated in the GOM will apply to all ballot pools. They are as follows:

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- Informative Ballots – No quorum requirement; 60% affirmative votes for approval.
- DSTU Ballots – No quorum requirement; 60% affirmative votes for approval.
- Normative Ballots – Minimum 10 HL7 members in ballot pool; 60% returning votes for quorum; 75% affirmative votes for approval.
- Comment Only Ballots – No quorum requirement.

Reconciliation Rules: The balloting of all items listed in this announcement is contingent upon completion of the appropriate ballot reconciliation activities as indicated the HL7 GOM sections 13, for Review ballots, and 14, for Normative ballots.

Unique Ballot IDs: Each ballot document has a unique Ballot ID that can be found following its descriptive text. In addition, updated ballot comment spreadsheets will be available on the balloting website at the time the ballots open.

Help

ISSUE – Ballot Pools Not Displayed: If you navigate to the Ballot Desktop and it does not correctly display the ballot pools you have previously signed up for, please click the “May 2010 Ballot Cycle” link in the left-hand navigation pane. This will resolve 90% of users’ issues.

ISSUE – Ballot Pools Not Open for Enrollment: When enrolling in ballot pools, you may notice that some pools are not available for enrollment. This is either because the enrollment period for that ballot has closed, or that ballot is a subsequent normative ballot and is limited to the original consensus group of that ballot.

IMPORTANT: Should you have issues voting, it is important that you contact us before the close of the ballot. Communications received after a ballot has closed cannot be honored.

OTHER ISSUES - Should you have any other issues logging in to the Ballot Desktop, signing up for ballot pools or voting, please contact Don Lloyd (dlloyd@HL7.org), Technical Publications Manager, or Michael Kingery (mkingery@HL7.org), HL7 Webmaster.

Appendix A – Listing of Ballots by Ballot Level for September 2010 Ballot Cycle

Normative Ballots

- ***HL7 Clinical Context Management Specification Version 1.6 (1st Normative Ballot)***
Unique Ballot ID: CCOW_CMS_V16_N1_2010SEP
- ***HL7 Version 3 Standard: Pharmacy CMETs, Release 10 (4th Normative Ballot)***
Unique Ballot ID: V3_RX_CMET_R10_N4_2010SEP
- ***HL7 Version 3 Standard: Pharmacy; Common Dispense and Supply Event, Release 1 (2nd Normative Ballot)***
Unique Ballot ID: V3_RX_CDSEVNT_R1_N2_2010SEP
- ***HL7 Version 3 Standard: Pharmacy; Common Order, Release 1 (2nd Normative Ballot)***
Unique Ballot ID: V3_RX_CMNORDER_R1_N2_2010SEP
- ***HL7 Version 3 Standard: Pharmacy; Medication Dispense and Supply Event, Release 1 (4th Normative Ballot)***
Unique Ballot ID: V3_RX_MDSEVNT_R1_N4_2010SEP
- ***HL7 Version 3 Standard: Pharmacy; Medication Knowledge-Base Query, Release 1 (4th Normative Ballot)***
Unique Ballot ID: V3_ME_DKBQ_R1_N4_2010SEP
- ***HL7 Version 3 Standard: Pharmacy; Medication Statement, Release 1 (3rd Normative Ballot)***
Unique Ballot ID: V3_RX_MSSEVNT_R1_N3_2010SEP
- ***HL7 Version 3 Standard: Core Principles and Properties of Version 3 Models, Release 1 (4th Normative Ballot)***
Unique Ballot ID: V3_CPPV3MODELS_R1_N4_2010SEP
- ***HL7 Version 3 Standard: Reference Information Model, Release 3 (2nd Normative Ballot)***
Unique Ballot ID: V3_RIM_R3_N2_2010SEP

Informative Ballots

- ***HL7 Implementation Guide for CDA Release 2: greenCDA Modules for CCD, Release 1 (1st Informative Ballot)***
Unique Ballot ID: CDAR2_IG_GREENMOD4CCD_R1_I1_2010SEP
- ***HL7 EHR-S Vital Records Functional Profile, Release 1 - US Realm (1st Informative Ballot)***
Unique Ballot ID: EHR_VRFP_R1_I1_2010SEP

ANNOUNCEMENT OF FORMATION OF BALLOT POOLS FOR SEPTEMBER 2010 BALLOT CYCLE

- ***HL7 EHR-System ePrescribing Functional Profile, Release 1 - US Realm (1st Informative Ballot)***
Unique Ballot ID: EHR_ERXFP_R1_I1_2010SEP
- ***HL7 EHR-System Pharmacist/Pharmacy Provider Functional Profile, Release 1 - US Realm (1st Informative Ballot)***
Unique Ballot ID: EHR_RXPROVFP_R1_I1_2010SEP
- ***HL7 Version 2 Implementation Guide: Laboratory Test Compendium Framework, Release 1 (1st Informative Ballot)***
Unique Ballot ID: V2_IG_LTFCF_R1_I1_2010SEP
- ***HL7 Version 3 Domain Analysis Model: Clinical Decision Support; Virtual Medical Record, Release 1 (2nd Informative Ballot)***
Unique Ballot ID: V3DAM_CDS_VMR_R1_I2_2010SEP
- ***HL7 Version 3 Domain Analysis Model: Emergency Medical Services, Release 2 – US Realm (1st Informative Ballot)***
Unique Ballot ID: V3_DAM_EMS_R2_I1_2010SEP
- ***HL7 Version 3 Detailed Clinical Models, Release 1 (1st Informative Ballot)***
Unique Ballot ID: V3_DCMODELS_R1_I1_2010SEP
- ***HL7 Version 3 Implementation Guide: Regulated Studies; CDISC Content to Message – Study Design, Release 1 (1st Informative Ballot)***
Unique Ballot ID: V3_IG_CDISC2MSG_SDS_R1_I1_2010SEP
- ***HL7 Version 3 Implementation Guide: Regulated Studies; CDISC Content to Message – Study Participation, Release 1 (1st Informative Ballot)***
Unique Ballot ID: V3_IG_CDISC2MSG_SP_R1_I1_2010SEP
- ***HL7 Version 3 Implementation Guide: Structured Product Labeling, Release 5 (1st Informative Ballot)***
Unique Ballot ID: V3IG_SPL_R5_I1_2010SEP
- ***HL7 Version 3 Specification: Model Interchange Format (MIF), Release 1 (2nd Informative Ballot)***
Unique Ballot ID: V3_MIF_R1_I2_2010SEP

DSTU Ballots

- ***HL7 Implementation Guide for CDA Release 2: Genetic Testing Reports, Release 1 (1st DSTU Ballot)***
Unique Ballot ID: CDAR2_IG_GENTESTRPT_R1_D1_2010SEP
- ***HL7 Implementation Guide for CDA Release 2 - Level 3: Healthcare Associated Infection Reports, Release 6 - US Realm (1st DSTU Ballot)***
Unique Ballot ID: CDAR2L3_IG_HAIRPT_R6_D1_2010SEP

ANNOUNCEMENT OF FORMATION OF BALLOT POOLS FOR SEPTEMBER 2010 BALLOT CYCLE

- ***HL7 Implementation Guide for CDA Release 2: Progress Note, Release 1 - US Realm (1st DSTU Ballot)***
Unique Ballot ID: CDAR2_IG_PROGNOTE_R1_D1_2010SEP
- ***HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) – Decision Support Service (DSS) Implementation Guide, Release 1 (1st DSTU Ballot)***
Unique Ballot ID: V3_IG_DSS_KM_INFOBUTTON_R1_D1_2010SEP
- ***HL7 Version 3 Standard: XML Implementation Technology Specification for RIM Serializations, Release 1 (2nd DSTU Ballot)***
Unique Ballot ID: V3_XMLITS_RIMSR_R1_D2_2010SEP
- ***HL7 Version 3 Standard: Transmission Infrastructure, Release 2 (2nd DSTU Ballot)***
Unique Ballot ID: V3_IM_TRANS_R2_D2_2010SEP
- ***HL7 Version 3 Standard: Privacy, Access and Security Services (PASS) – Audit Services, Release 1 (1st DSTU Ballot)***
Unique Ballot ID: V3_PASS_AUDITSERV_R1_D1_2010SEP

For Comment Only Ballots

- ***HL7 Version 3 Domain Analysis Model: Detailed Clinical Models for Medical Devices, Release 1 (1st Comment Only Ballot)***
Unique Ballot ID: V3DAM_DCM4MEDDEV_R1_O1_2010SEP