



Health Level Seven International®

3300 Washtenaw Avenue, Suite 227

Ann Arbor, Michigan 48104-4261

Tel: (734) 677-7777

Fax: (734) 677-6622

<http://www.HL7.org>

HL7®
GOVERNANCE and OPERATIONS
MANUAL

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HL7 Governance and Operations Manual

Table of Contents

Introduction.....	9
Notice of Current Edition	9
Additions and/or Revisions Subsequently Adopted	9
01 The Corporation	11
01.01 Primary Office	11
01.01.01 HL7 Headquarters.....	11
01.02 Business Office	11
01.03 Letterhead.....	11
01.04 Media Relations	11
02 Mission and Work Products	11
02.01 Mission Statement	11
02.02 Work Products	12
03 Membership.....	12
03.01 Establishing Membership.....	12
03.02 Membership Declaration.....	12
03.03 Individual Members.....	12
03.04 Organizational Members.....	12
03.04.01 Classes of Organizational Membership	12
03.04.02 Organizational Member's Key Voting Representative	13
03.04.03 Individual Members Associated with an Organizational Member	13
03.05 Student Members	14
03.06 Affiliate Members	14
03.06.01 Affiliate Member's Key Voting Representative.....	14
03.07 Current Membership	14
03.08 Members Emeritus.....	14
03.09 Change of Membership Status due to Change of Employment	14
03.10 Termination of Membership	14
03.10.01 Resignation	14
03.10.02 Failure to Renew	14
03.10.03 Cause	15
03.11 Non-member Rights and Prohibitions.....	15
04 Code of Conduct	15
05 Code of Ethics	16
06 Dues, Fees, and Donations.....	16
06.01 Dues.....	16
06.01.01 Individual	16
06.01.02 Organizational	16
06.01.03 Student	17

HL7 Governance and Operations Manual

Table of Contents

06.02	Fees	17
06.02.01	Hardship Waiver.....	17
06.02.02	Student Waiver.....	17
06.02.03	Professional Courtesy	18
06.02.04	Complimentary and Discounted Working Group Meeting Registration	18
06.03	Donations.....	18
07	Board of Directors	18
07.01	Duties and Powers of the Board of Directors	18
07.01.01	HL7 Liaisons	19
07.02	Limits on Position Representation	19
07.03	Limits to Organizational Representation.....	19
07.04	Director Term of Office	19
07.05	Vacancies	20
07.05.01	Appointment to Fill an Interim HL7 Director Vacancy	20
07.05.02	Appointment to Fill an Affiliate Director Vacancy	20
07.06	Directors Nominated by the Chief Executive Officer	21
07.07	Board of Directors Meetings	21
07.07.01	Observers.....	22
07.07.02	Board Appointed Committee Chairs	22
07.08	Submitting and Resolving Motions via Email.....	22
07.09	Travel for HL7 Board Functions.....	23
07.09.01	Attendance at Working Group Meetings	23
07.09.02	Attendance at the Annual Board Retreat	23
07.10	Committees and Councils.....	23
07.10.01	Advisory Council	23
07.10.02	Finance Committee	24
07.10.03	Governance and Operations Committee	24
07.10.04	International Council	24
07.10.05	Leadership Development and Nomination Committee (LDNC)	25
07.10.06	Policy Advisory Committee	26
07.10.07	Recognition and Awards Committee.....	27
07.11	Officers.....	27
07.11.01	Chair.....	27
07.11.02	Vice Chair.....	28
07.11.03	Secretary	28
07.11.04	Treasurer.....	29
07.12	Officer Vacancies.....	29
07.13	The Executive Committee.....	29
07.13.01	Contract Work Process	29

HL7 Governance and Operations Manual

Table of Contents

08	Governance	30
08.01	Participation in Standards Development and Maintenance.....	30
08.02	Annual Nomination and Election of HL7 Leadership by Administrative Ballot	30
08.02.01	Officers	31
08.02.02	HL7 Directors	32
08.02.03	Affiliate Directors	32
08.02.04	Steering Division Co-chairs.....	32
08.02.05	Technical Steering Committee Affiliate Representative.....	33
08.02.06	International Council Co-chair.....	33
08.02.07	Work Group Co-chairs	33
08.03	Majority Rule	34
08.03.01	Quorum for Bylaws Adoption or Revision	34
08.04	Liability Insurance	34
08.05	Fiscal Policy	34
08.05.01	Expenditure Limits.....	34
08.05.02	Annual Budget.....	34
08.05.03	Investment Strategy	34
08.05.04	Travel for HL7 Related Business	34
08.05.05	Reimbursement of Reasonable Expenses	34
08.06	Conflict of Interest.....	35
08.06.01	Definitions	35
08.06.02	Procedures.....	36
08.06.03	Records of Proceedings.....	36
08.06.04	Compensation Decisions	37
08.06.05	Annual Statements.....	37
08.06.06	Periodic Review	37
08.06.07	Use of Outside Experts	37
08.07	Whistleblower Policy: Reporting Illegalities or Issues of Noncompliance	37
08.07.01	Reporting Encouraged	37
08.07.02	Protection from Retaliation.....	38
08.07.03	Reporting Process.....	38
08.07.04	Investigative Process	38
08.07.05	Resolution Process	38
09	Intellectual Property.....	38
09.01	Copyright.....	39
09.01.01	Copyright Protection.....	39
09.01.02	Commitment.....	39
09.01.03	Previously Copyrighted Material	40
09.01.04	Independently Developed Specifications	40

HL7 Governance and Operations Manual

Table of Contents

09.01.05	Negotiated Use of HL7 Copyrighted Materials	40
09.01.06	Academic Access to HL7 Copyrighted Materials	40
09.01.07	Use of HL7 Copyrighted Materials in Other Educational Scenarios	41
09.01.08	Use of HL7 Copyrighted Materials by Organizational Members	41
09.01.09	HL7 Copyrighted Material Related to Proposed or Final Regulations	41
09.02	Trademarks	41
09.02.01	Registered Trademark	41
09.02.02	Use of HL7 Trademarks	41
09.02.03	Use of Other Trademarks	42
09.03	Patents	42
09.03.01	Commitment	42
09.03.02	Essential Patent Claims	42
09.03.03	Withdrawal and Survival of Commitments for Essential Patent Claims	43
09.03.04	Disclaimer	43
09.04	Material in the Public Domain	43
10	The Technical Steering Committee (TSC)	43
10.01	Chair	44
10.02	Term of Office	44
10.02.01	TSC Chair	44
10.02.02	Elected Members	44
10.02.03	<i>Ad Hoc</i> Members	44
10.03	Removal from Office	44
10.03.01	TSC Chair	44
10.03.02	SD Co-chair	45
10.03.03	Affiliate Representatives	45
10.04	Vacancies	45
10.04.01	TSC Chair	45
10.04.02	SD Co-chair	45
10.04.03	Affiliate Representatives	45
10.05	Meetings	45
10.05.01	Hardship Waiver of Working Group Meeting Fees	46
10.05.02	Observers	46
10.06	Standards Development Framework	46
10.07	Interpretation of Non-normative HL7 Protocol Specifications	46
10.08	Endorsing Tools for Standards Development	46
10.09	The Working Group	46
10.10	US Realm Steering Committee (USR-SC)	46
10.10.01	Purpose	47
10.10.02	Scope	47

HL7 Governance and Operations Manual

Table of Contents

10.10.03	Formal Relationships	47
10.10.04	Composition	47
10.10.05	Term of Membership	47
10.10.06	Inactive Members	48
10.10.07	Reporting.....	48
10.11	HL7 Terminology Authority (HTA)	48
10.11.01	Purpose	48
10.11.02	Scope	48
10.11.03	Participation in the Harmonization Process	48
10.11.04	Composition	49
10.11.05	Criteria for Membership	49
10.11.06	Term of Membership	50
10.11.07	Change of Member's Employment Status	50
10.11.08	Removal and/or Replacement of Member	50
10.11.09	Conduct of Meetings	50
10.12	Architecture Review Board (ARB)	50
10.12.01	Composition	51
10.12.02	Criteria for Membership	51
10.12.03	Term of Membership	52
10.12.04	Change of Member's Employment Status	52
10.12.05	Removal of Member.....	52
10.12.06	Conduct of Meetings	52
10.13	Education Advisory Council (EAC)	52
10.13.01	Structure and Selection.....	52
10.13.02	Meetings.....	53
10.14	Standards Governance Board (SPB)	53
10.15	Product Management Groups.....	53
11	Work Groups	53
11.01	Establishing a Work Group	53
11.01.01	Criteria.....	53
11.01.02	Process	54
11.02	Work Group Change, Merger or Dissolution	54
11.02.01	Changing Name or Mission/Charter.....	54
11.02.02	Changing Assigned Steering Division.....	55
11.02.03	Merger of Two or More Work Groups	55
11.02.04	Dissolution.....	55
11.03	Work Group Co-Chairs	55
11.03.01	Responsibilities	56
11.03.02	Term of Office	56

HL7 Governance and Operations Manual

Table of Contents

11.03.03	Removal from Office	56
11.03.04	Co-chair Vacancy due to Change in Membership Status	57
11.03.05	Voluntary Co-chair Vacancy	57
11.04	Decision-Making Practices	57
11.05	White Papers	57
12	Conferences, Meetings, and Educational Programs.....	58
12.01	Meeting Notice	58
12.02	Meetings in Conjunction with HL7	58
12.03	Special Meetings	58
12.04	Proposals for Consideration of Co-Branded Events.....	59
12.05	Educational Programs	60
12.05.01	Tutorials	60
13	Electronic Ballots	60
13.01	Consideration of Recommended Actions	60
13.02	Naming Convention	61
13.03	Constructing Review Ballot and Protocol Specification Names	61
13.03.01	Organization Identifier	62
13.03.02	Family and Subfamily Name	62
13.03.03	Product Type	62
13.03.04	Product Name	62
13.03.05	Ballot Level.....	62
13.03.06	Examples	62
13.04	Approving Review Ballot and Protocol Specification Names	63
13.04.01	Informative Documents and STU:.....	63
13.04.02	Other Documents	63
13.04.03	Documents in Progress.....	63
14	Review Ballots	63
14.01	Informative Documents	63
14.01.01	Initiation	63
14.01.02	Forming the Consensus Group	63
14.01.03	Ballot Package	64
14.01.04	Handling Comments.....	64
14.01.05	Approval and Publication	65
14.01.06	Withdrawal of an Informative Document	65
14.02	Standards for Trial Use (STU)	65
14.02.01	Initiation	65
14.02.02	Forming the Consensus Group	65
14.02.03	Ballot Package	66
14.02.04	Handling Comments.....	66

HL7 Governance and Operations Manual

Table of Contents

14.02.05	Approval	66
14.02.06	Trial use	66
14.02.07	Results of the Trial Use Period	67
14.02.08	Backwards Compatibility to Base American National Standard	67
14.02.09	Withdrawal of a Standard for Trial Use	68
14.03	Publishing Technical Corrections as Errata.....	68
14.04	Comment-only Ballot	68
14.04.01	Initiation	68
14.04.02	Forming the Consensus Group	68
14.04.03	Ballot Package	68
14.04.04	Results of the Review	68
15	Normative Ballot	69
16	Submission of American National Standards.....	69
17	Maintenance of the Governance and Operations Manual (GOM)	69
17.01	Membership Participation	69
17.02	During the Working Group Meeting	69
17.03	Concurrent Processes Interim to the Working Group Meeting	70
17.03.01	Developing the GOM Revisions	70
17.03.02	Exceptional Revision Requests	70
17.03.03	Developing the Revision List for Next Cycle	70
17.03.04	Executive Committee Action	70
17.04	Effective Date of Revision or Adoption	70
17.05	Periodic Adoption in its Entirety	70

HL7 Governance and Operations Manual

Introduction

The Governance and Operations Manual (GOM) defines standard operating procedures and various policies created to clarify, support, and/or implement the tenets of the Bylaws. The GOM is established to assure the uniformity, equity, quality, efficiency, and compliance of administrative and organizational activities through standard methods and guidelines. GOM maintenance shall be proactive, iterative, and broadly engage the membership as defined in §17.

With the adoption of additions or revisions to the GOM, the HL7 Secretary shall cause them to be added to the manual with annotation in the following table reflecting the date adopted or revised. Additions and revisions shall be announced via the general membership list serve within ten working days of the date on which they were adopted or revised. Periodically the HL7 Secretary, using his or her best judgment, may call for ratification of the GOM in its entirety by the Executive Committee. Upon ratification of the GOM in its entirety it shall be posted to the HL7 web site with a new adoption date and all internal notations of addition or revision removed.

The GOM will be maintained and distributed electronically via the HL7 Web site. A hard copy of the manual is available upon request to those without electronic access. A processing fee, established by the Executive Committee, will be assessed to cover printing, postage, and handling.

Notice of Current Edition

This edition, adopted in its entirety April 20, 2020, is the current edition, which supersedes and rescinds all previous editions of the GOM.

Additions and/or Revisions Subsequently Adopted

The following additions and/or revisions, having been approved by the Executive Committee subsequent to adoption of this edition of the GOM, are included by extension. The correction of a typographical or trivial error will not be recorded as a revision in the following table; although such revisions will appear in the mark-up version for reference. Sections that are renumbered as a result of adding or moving a section or subsection, but are not otherwise revised, are not included in the following table.

Designation	Adopted
04 Code of Conduct [Revised]	05/05/2020
06.01.02.01 Umbrella Organizations [Deleted]	05/05/2020
07.10.02 Finance Committee [Revised]	05/05/2020
07.10.04 International Council [Revised]	05/05/2020
07.11.01.01 Term of Office [Revised]	05/05/2020
07.11.02 Vice Chair [Revised]	05/05/2020
07.11.02.01 Term of Office [Deleted]	05/05/2020
07.11.03 Immediate Past Chair [Deleted with subsequent renumbering]	05/05/2020
07.11.03.01 Term of Office [Deleted]	05/05/2020
08.02 Annual Nomination and Election of HL7 Leadership by Administrative Ballot [Revised]	05/05/2020
08.02.06 International Council Co-chairs [Added with subsequent renumbering]	05/05/2020
09.01.08 Public Access to HL7 Copyrighted Vocabulary Tables [Deleted with subsequent renumbering]	05/05/2020

HL7 Governance and Operations Manual

Table of Contents

Designation	Adopted
10.09 Externally Defined Implementation Guides [Deleted with subsequent renumbering]	05/05/2020
10.14 Standards Governance Board (SGB) [Added]	05/05/2020
10.15 Product Management Groups [Added]	05/05/2020
12 User Groups [Deleted with subsequent renumbering]	05/05/2020
14.01.06 Errata [Deleted with subsequent renumbering]	05/05/2020
14.02.06 Errata [Deleted with subsequent renumbering]	05/05/2020
14.03 Publishing Technical Corrections as Errata [Added with subsequent renumbering]	05/05/2020

HL7 Governance and Operations Manual

01 The Corporation

01.01 Primary Office

As directed by the articles of incorporation and in compliance with the laws of the State of New Jersey, the Corporation shall maintain a primary office in the State of New Jersey. The Corporation may have business offices at such other places as the Board of Directors may, from time to time, designate.

01.01.01 HL7 Headquarters

The organization contracted by the Board pursuant to §07.01 a) to provide technical and administrative services for HL7 shall be designated HL7 Headquarters. It shall be responsible for establishing and maintaining the Business Office and providing such staff and facilities as deemed necessary by the Board to provide such services.

01.02 Business Office

The business office of the Corporation is located at
3300 Washtenaw Avenue, Suite 227
Ann Arbor, Michigan 48104-4261 USA
(734) 677-7777 Fax (734) 677-6622

01.03 Letterhead

The HL7 letterhead, be it memorandum or letter format, shall be used by Officers, other members of the Board, supporting committee or council chairs, and HL7 staff for authorized business and projects exclusively. Officers, other members of the Board and committee or council chairs shall discontinue the use of HL7 letterhead immediately upon completion of their terms or, in the case of HL7 staff or contract employees, upon termination of employment.

01.04 Media Relations

Media relations shall be managed solely by HL7 Headquarters which shall have responsibility for preparation or screening, approval, and distribution of any material intended for release to the media.

Those HL7 members wishing to contribute such material shall provide an electronic copy to the Director of Communications for consideration. Any Work Group co-chair, committee or council chair, or member of the Board of Directors may identify opportunities for press releases that promote HL7 functions, events, operations or Protocol Specifications (§02.02); however, the decision to actually prepare and release such information resides solely with HL7 Headquarters.

02 Mission and Work Products

02.01 Mission Statement

The mission of HL7, as approved by the Board of Directors, is:

To provide standards that empower global health data interoperability.

This effort enables 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 protocol specification – development, adoption, market recognition, utilization and adherence. Shared reference models of the healthcare and technical domains unify the HL7 specifications.

To support this mission, HL7:

- Develops and publishes both ANSI approved normative protocol specifications and various informative documents on a timely basis

HL7 Governance and Operations Manual

- Promotes the use of the protocol specifications and other documentation within the healthcare payer, provider and regulatory community, both nationally and internationally
- Provides education:
 - On understanding the protocol specifications and their common usage
 - On implementation approaches using the protocol specifications
 - On protocol specification compliance and analysis approaches
- Provides conformance certification services
- Provides a methodological framework for creating extensions to the protocol specifications
- Encourages the acceptance and usage of HL7 protocol specifications worldwide through the creation of Affiliate members, and the pursuit of internationalization of the protocol specifications
- Collaborates with other developers of healthcare and information technology standards to leverage our respective skills, knowledge and standards.

02.02 Work Products

Protocol specifications encompass the following work products developed and supported by HL7: all Versions of the HL7 messaging standard; the Clinical Document Architecture (CDA); Arden Syntax; CCOW specifications; Service Oriented Architecture (SOA) standards; any other normative standards subsequently released by HL7; various functional models, implementation guides, Fast Healthcare Interoperability Resources (FHIR®), and Implementation Technology Specifications (ITS); the Reference Information Model (RIM); the Access database; and those informative documents initiated and balloted by the various Work Groups.

03 Membership

03.01 Establishing Membership

Membership shall become effective upon acceptance of a completed application and receipt of designated dues. The Board of Directors shall ensure that no undue financial barriers to HL7 membership exist.

03.02 Membership Declaration

The membership application/renewal form shall include the following declaration as applicable to the membership category: "Application for or renewal of an individual HL7 membership obliges the member to abide by the HL7 Bylaws, Governance and Operations Manual, and Code of Ethics."

Application for or renewal of an organizational HL7 membership obliges the organization and its representatives to abide by the HL7 Bylaws, Governance and Operations Manual, and Code of Ethics."

03.03 Individual Members

Individual membership criteria are defined by HL7 Bylaws §03.03.02

03.04 Organizational Members

03.04.01 Classes of Organizational Membership

Organizational members shall be classified in accordance with their self-characterization selected during the membership application process. HL7 Headquarters holds responsibility for screening membership classifications. If a membership classification is challenged, the HL7 Director of Membership Services shall investigate the classification and determine a resolution. In case of appeal of the decision of the Director of Membership Services, the Executive Committee shall assign the classification. Their decision shall be final.

HL7 Governance and Operations Manual

03.04.01.01 Vendor/Manufacturer

An Organizational Member that produces or sells products or systems that relate to, use, or incorporate HL7 Protocol Specifications (§02.02) shall be classified as a vendor. This classification also accommodates manufacturers (medical devices, etc.).

03.04.01.02 Consultant

An Organizational Member that provides advice, support, and consultative services, but that does not sell products or systems which relate to, use, or incorporate HL7 protocol specifications shall be classified as a consultant.

03.04.01.03 Healthcare Provider/User

An Organizational Member that purchases and implements products, systems, or services which relate to, use, or incorporate HL7 Protocol Specifications shall be classified as a user. The user category may include, but is not limited to, organizational entities such as hospitals, physician practices, physician group practices, and academic faculty practices.

03.04.01.04 Association/Government Agency/University

A special classification created to support organizational membership by professional associations and societies, industry consortia, regulators, government agencies and universities or university-based organizations (other than medical centers which are considered providers) demonstrating an interest in promoting the development, adoption or implementation of HL7 Protocol Specifications (§02.02). Member universities are encouraged to develop HL7-related programs and courses and to engage in informatics standards research.

03.04.01.05 Payer/Third Party Administrator

A special classification created to support organizational membership by health maintenance organizations (HMO), preferred provider organizations (PPO), independent practice affiliations (IPA), utilization review (UR) companies, fiscal intermediaries, third-party administrators (TPA), peer review organizations (PRO), insurers and payers.

03.04.01.06 Pharmaceutical

A special classification created to support organizational membership by pharmaceutical organizations versus a general classification as a manufacturer.

03.04.02 Organizational Member's Key Voting Representative

Each Organizational Member shall identify a Key Voting Representative by name to HL7 Headquarters. The Key Voting Representative shall maintain a current file of signed statements from each of their organization's designated voting representatives naming the Key Voting Representative as proxy in matters pertaining to the reconciliation or recirculation of HL7 Normative Ballots.

It is suggested that the proxy statement take the form of: "Having submitted a HL7 Normative Ballot, should I <name of designated voting representative> be unable to respond, for whatever reason, to the subsequent notice of disposition of negative comments or the recirculation of said Normative Ballot I designate <name of Key Voting Representative> to act as my agent and complete such actions.

03.04.03 Individual Members Associated with an Organizational Member

HL7 places no restrictions on the purchase of individual memberships by its organizational members who wish to extend voting privileges and provide access to the HL7 Protocol Specifications (§02.02) to their sundry divisions. Although categorized as individual members, these individuals typically list the organizational member as their employer; thereby establishing an association. HL7 Headquarters is aware of these relationships and considers those individuals "additional" designated voting representatives of that organizational member. As such these extra-organizational members are extended the same privileges as the designated voting representatives allocated to that organizational member as a benefit of its membership.

HL7 Governance and Operations Manual

03.05 Student Members

A student member [HL7 Bylaws §03.02.01] shall be in a full-time status at an accredited educational institution.

03.06 Affiliate Members

Affiliate Members, as defined in HL7 Bylaws §03.03.04, are established under and governed by the HL7 Affiliate Agreement.

03.06.01 Affiliate Member's Key Voting Representative

Each Affiliate Member shall identify a Key Voting Representative by name to HL7 Headquarters. The Key Voting Representative shall maintain a current file of signed statements from each of the Affiliate's designated voting representatives naming the Key Voting Representative as proxy in matters pertaining to the reconciliation or recirculation of HL7 Normative Ballots.

It is suggested that the proxy statement take the form of: "Having submitted a HL7 Normative Ballot, should I <name of designated voting representative> be unable to respond, for whatever reason, to the subsequent notice of disposition of negative comments or the recirculation of said Normative Ballot I designate <name of Key Voting Representative> to act as my agent and complete such actions.

03.07 Current Membership

All types of members (Student, Individual, Organizational, or Affiliate) shall be deemed current if dues are not in arrears or relinquished due to suspension or expulsion. Those members not deemed current shall not have access to member-only materials and documents.

03.08 Members Emeritus

The Board may, at its discretion, award emeritus status to an HL7 member. Such a designation is intended to allow the organization to prosper from the advice, wisdom, and experience of the individual so recognized. Positions Emeritus shall be held in perpetuity.

Typically, the individual would be identified as [leadership designation] Emeritus; e.g., Chair Emeritus or CTO Emeritus. Such individuals would be encouraged to continue their participation in leadership, albeit as a non-voting member unless specifically designated otherwise, with the proviso that such participation by a non-voting member emeritus shall not count toward quorum.

Internal councils and committees, such as the TSC or International Council, may petition the Board to declare an individual as a member emeritus with a recommendation as to that individual's voting status. Emeritus status shall not be extended to Work Group co-chairs.

03.09 Change of Membership Status due to Change of Employment

Change of membership status due to change of employment shall be declared promptly to the HL7 Director of Membership Services by telephone, facsimile, or e-mail.

03.10 Termination of Membership

03.10.01 Resignation

A membership may be terminated at any time by submitting a letter of resignation to HL7 Headquarters. Dues shall not be refunded upon resignation.

03.10.02 Failure to Renew

Invoices for renewal of membership are sent with sufficient lead time to allow remittance prior to membership year end. The membership of those individuals or organizations who fail to pay their membership renewal fee by the end of the membership year, as indicated on the invoice, shall be terminated.

Termination of membership results in the loss of voting privileges and the individual or organization will no longer receive member benefits, including HL7 mailings, discounts, and access to member-only materials and documents.

HL7 Governance and Operations Manual

Upon receipt of a written request to waive membership termination that, in the opinion of the Executive Director, justifies a delay in dues payment the Executive Director may temporarily waive termination of membership for a period that, in their judgment, is appropriate to the situation. HL7 reserves the right to retain membership information to be used for promotional mailings.

03.10.03 Cause

The Board of Directors may, by a simple majority vote of the Board members present and voting and following a hearing on such allegations, suspend or expel any member for actions which, in the Board's considered opinion, are contrary to the practices and policies of HL7.

Dues shall not be refunded or, if outstanding, collected for the year in which such action occurs.

The Board of Directors may, by a simple majority vote of the Board members present and voting and following a hearing on such action, reinstate any member suspended or expelled. Reinstatement may require the remittance of dues outstanding.

03.11 Non-member Rights and Prohibitions

A nonmember, defined as a person not currently a member of HL7 either individually or as a representative of an organizational or Affiliate member, may purchase protocol specifications from HL7 or may otherwise gain access to protocol specifications through HL7 licensed channels.

Registration and acceptance of HL7's IP Policy for Specified Material is required if said material is to be used other than on a read-only basis for the sole purpose of the personal edification of the nonmember.

Nonmembers are expressly prohibited from reproducing or distributing any HL7 Protocol Specification.

04 Code of Conduct

In the interest of fostering an open and welcoming community, HL7 participants pledge to respect all people who contribute through Work Group participation, change requests, editing the protocol specifications or other documentation, submitting patches or changes, and other activities.

Participants are committed to making HL7 a harassment-free environment for everyone, regardless of level of experience, professional background, gender, gender identity and expression, sexual orientation, disability, personal appearance, body size, race, ethnicity, age, religion, or nationality.

Examples of unacceptable behavior by participants include:

- The use of sexualized language or imagery
- Personal attacks
- Trolling or insulting/derogatory comments
- Public or private harassment
- Publishing other's private information, such as physical or electronic addresses, without explicit permission
- Other conduct deemed unethical or unprofessional

Work Group co-chairs have the right and responsibility to identify comments, commits, code, wiki edits, issues, and other contributions that are not aligned to this Code of Conduct to the Technical Steering Committee (TSC) who may choose to remove, edit, or reject such contributions. Further, the TSC may recommend to the Board of Directors that an HL7 participant be banned temporarily or permanently for other behaviors that they deem inappropriate, threatening, offensive, or harmful. The decision of the Board in such instances shall be final.

HL7 is committed to a [policy of diversity, equity, and inclusion](#) that welcomes all participants and provides them with a pathway to education on and integration into the HL7 community. By adopting this Code of Conduct participants commit themselves to fairly and consistently applying these principles to every aspect of HL7 participation. Participants who do not follow or enforce the Code of Conduct may be permanently banned from HL7 participation.

HL7 Governance and Operations Manual

This Code of Conduct applies both within HL7 meeting and conference spaces and in public spaces when an individual is representing HL7 or the HL7 community.

Instances of harassment, abuse or otherwise unacceptable behavior may be reported by contacting the HL7 Project Manager or any member of the TSC. All complaints will be reviewed and investigated and will result in a response that is deemed necessary and appropriate to the circumstances. The TSC is obligated to maintain confidentiality with regard to the individual reporting such an incident.

05 Code of Ethics

Members of the Board of Directors and employees of HL7 and its management organization shall act to further the best interests of HL7 in their official affairs; they shall be alert regarding relationships with third parties which might affect their independent judgment when acting for or on behalf of HL7, be alert in the conduct of the affairs of HL7 to avoid situations in which they might, directly or indirectly, profit personally, and at all times use their best efforts to enhance the reputation of HL7 for honesty, integrity, candor and lack of bias or discrimination while representing the members and the best interests of HL7.

- They shall avoid situations in which they personally might profit or even give the appearance of profiting from their official HL7 activities.
- They shall not employ the name of HL7 in seeking or accepting payment for professional services. They shall not, directly or indirectly, accept or solicit anything of significant value as a gift, gratuity or favor under circumstances that might affect, or reasonably lead others to believe such action would affect, their impartiality on behalf of HL7. This does not prohibit acceptance of reimbursement for out-of-pocket expenses while acting as an official HL7 spokesperson or of social amenities and token gifts of purely nominal value, consistent with generally accepted business practices and good taste. If there is any doubt as to the relative value of or the propriety of accepting a gift, it may be resolved by either declining to accept the gift or amenity, or obtaining the approval of the Chair or, in the case of employees of HL7 and its management organization, the Executive Director.
- They shall not use the HL7 name or its stationery for other than official HL7 business.
- They shall abide by the rule that HL7 will not endorse any product or service provided by any HL7 member or non-member. Use of the HL7 trademark does not imply endorsement of a specific organization, product or service by HL7.

06 Dues, Fees, and Donations

06.01 Dues

Membership dues, as determined by the HL7 Executive Committee, shall be applicable to the year of membership based on effective date. Membership dues may change from year to year based on the needs of HL7. All dues submitted shall become the property of HL7 and be used to fund operations based on an annual budget and plan approved by the Board of Directors. Organizational members are expected to select an appropriate dues structure related to their current revenues or expenditures at the time of renewal.

06.01.01 Individual

The HL7 Executive Committee may establish different membership dues for individuals residing in North America (Canada, USA, Mexico) versus those residing elsewhere. An individual member wishing to provide additional financial support to HL7 may become an "HL7 Supporter" by doubling their annual dues. Individual member supporters shall receive appropriate recognition for their exceptional financial contribution.

06.01.02 Organizational

Organizational members classified as vendors, consultants, or other suppliers of products and services that incorporate the HL7 Protocol Specifications shall have their dues scaled to a range of annual revenue specific to healthcare systems, services, and/or products.

HL7 Governance and Operations Manual

Organizational members classified as users, primarily health care provider organizations, shall have their dues scaled to a range of annual information technology (IT) expenditures. Other categories, specifically healthcare payer and clearinghouse organizations, shall have their dues scaled to a range of annual gross revenues.

Publicly traded organizations are expected to pay dues and renew membership at the level reflected by such revenues reported in their most recent annual report. Privately held companies are expected to pay dues and renew membership at the level best reflecting their actual revenues of a given type.

Organizations have various levels of membership beyond the basic organizational membership available for an additional fee as defined by the Membership Agreement.

06.01.03 Student

Full-time students shall be offered membership at a rate that does not preclude their participation in HL7.

06.02 Fees

The Executive Committee shall determine the fees to be charged for Working Group Meetings, plenary conferences, educational sessions, publications, and other products and services HL7 may provide.

All fees collected shall become the property of HL7 and be factored into the operational budget.

The Executive Committee shall consider any recommendations to change established fees that arise during the review and approval of the annual budget.

06.02.01 Hardship Waiver

The Executive Director or Associate Executive Director of HL7 may, at their discretion, grant a waiver of fees to any HL7 member in good standing who has attended and paid for at least three of the last four Working Group Meetings and has encountered hardship (e.g., become unemployed) since the last meeting.

06.02.02 Student Waiver

HL7, accepting no responsibility for travel or lodging expenses, will waive registration and tutorial fees at regularly scheduled HL7 Plenary and Working Group Meetings for healthcare informatics students meeting the following criteria:

- Provide proof of current enrollment in an informatics curriculum (medical, nursing, or clinical informatics) at an accredited college or university
- Provide a letter of recommendation from an HL7 member in good standing acknowledging their sponsorship and accepting responsibility for mentoring the student to increase his/her knowledge of the HL7 organization, its procedures and Protocol Specifications (§02.02)
- Demonstrate a commitment to HL7, as evidenced by validated activity report, though active support of a Work Group by taking meeting minutes, helping edit the HL7 Protocol Specifications, authoring or co-authoring white papers, working on the web site, or providing other assistance as requested by Work Group co-chairs, members of the Board of Directors or Executive Committee, or HL7 Headquarters staff.
- Provide assistance with tutorials where such does not conflict with Work Group support activity, by developing and/or editing presentation slides (MS PowerPoint), developing and/or distributing printed support materials, checking attendance, or other assistance as requested by the instructor or HL7 Headquarters staff.

Students seeking a Work Group Meeting fee waiver must submit the proof of enrollment and letter from their sponsor to HL7 Headquarter not later than the close of the normal registration period.

HL7 staff will match students with a Work Group based on the student's interests and the needs expressed by Work Group co-chairs.

HL7 Governance and Operations Manual

06.02.03 Professional Courtesy

HL7 shall extend the member rate for Working Group Meetings, including the discount rate for tutorial sessions, to select representatives of ANSI-accredited SDO and those organizations that have executed an HL7 Statement of Understanding (SOU) or Associate Charter as defined in said SOU or Charter.

It is expected that the courtesy of extending member rates shall be reciprocated by the SDO or organization throughout the term of collaboration. Such courtesies shall be suspended concurrent with the conclusion of the period of collaboration.

06.02.04 Complimentary and Discounted Working Group Meeting Registration

Although still responsible for their personal travel, room and board; HL7 shall extend complimentary Working Group Meeting (WGM) registration to the following individuals:

- Current Board members
- Affiliate Chairs or their designee who shall be a member in good standing of their Affiliate
- Past Board Chairs
- Up to five designated guests of the CEO, approved by the Executive Committee
- Up to five designated guests of the Board Chair, approved by the Board

Tutorial speakers shall receive complimentary or discounted WGM registrations based on their level of engagement. Those speakers presenting three or less quarters (defined as 90 minute sessions, the day being composed of four quarters) shall be allowed to choose either a full one-day complimentary registration for the day tutorials are presented or a 50% discount on registration for the WGM. Those speakers presenting four or more quarters shall receive complimentary WGM registration.

Statements of Understanding (SOU) entered into by HL7 may include provisions for complimentary WGM registration on a reciprocal basis with the approval of the Executive Committee.

06.03 Donations

Any funds or property donated to further the work of HL7 shall become the property of HL7. Every effort shall be made to use donations for the purpose designated by the donor.

Acceptance of donations shall require the approval of the Executive Committee.

Under the provisions of Internal Revenue Code Section 501(c)(6) such donations may not be claimed as tax deductions.

07 Board of Directors

07.01 Duties and Powers of the Board of Directors

The Board of Directors shall:

- Approve the contract for an organization to provide technical and administrative services for HL7 on such terms and conditions as it may deem advisable.
- Approve the employment or contract for such executive staff as the Board may consider necessary to support the activities of HL7, and on such terms and conditions as it may deem advisable.
- Provide for the development and maintenance of an HL7 strategic plan.
- Ratify recommended appointments for the chairmanship of councils and both *ad hoc* and standing committees.
- Review and approve the annual budget.
- Create advisory groups and councils as necessary to fulfill liaison with other organizations; and ratify the recommended appointments for representatives to those organizations.

HL7 Governance and Operations Manual

- Report to the membership annually regarding the goals and objectives of the organization and other such matters as are necessary and advisable.
- Exercise its legal and constituted authority and responsibility in the direction and conduct of the affairs of HL7 in order to promote and attain the objectives of the Organization.
- Engage in such business activities as may be in furtherance of HL7's charitable, scientific, literary and educational purposes including, but not limited to, the pursuit of grants, the purchase and sale of real and personal property, the review of contracts with a value in excess of \$150,000, and the transacting of all other affairs of HL7 not otherwise provided.

07.01.01 HL7 Liaisons

The Chief Executive Officer (CEO), with the approval of the Board, shall appoint representatives to various and appropriate standards development organizations (SDO) and other groups or organizations, as necessary, to represent the interests of HL7.

As a general rule travel and other expenses related to liaison activities will not be reimbursed. Requests for travel and/or other reimbursement related to these liaison activities shall be handled on a case-by-case basis.

Every effort will be made to appoint individuals already associated with and participating in the meetings/activities of the SDO or group in question as the liaison.

Liaisons shall report on their activity in a timely manner to the CEO, who shall advise the HL7 Board of Directors of liaison activity.

Liaisons shall serve concurrent with the term of the agreement or SOU calling for their assignment. In the event of a vacancy the CEO may appoint another liaison to serve for the remainder of the term of the agreement. When a vacancy is filled, the agreement will be amended to reflect the name of the new liaison.

07.02 Limits on Position Representation

No individual shall hold more than one position on the Board of Directors at any given time.

07.03 Limits to Organizational Representation

No organization, in this case the encompassing corporate entity versus a specific HL7 organizational member as defined in Bylaws §03.02.03, shall hold more than one voting position on the Board of Directors.

Should change of employment or corporate acquisition during the term of office of any voting member of the Board result in a violation of this policy, that organization's representative whose term expires first shall not stand for reelection recognizing that the Chair represents a four-year commitment and shall take precedent for retention.

Individuals who, whether through employment, contractual obligation, or other circumstances, represent organizations currently holding a voting position shall not be accepted into nomination unless such nomination (1) represents an incumbent seeking a second term, or (2) is concurrent with the incumbent from said organization completing the allowable number of terms or not seeking reelection.

07.04 Director Term of Office

The term of office for HL7 and Affiliate Directors shall coincide with the Calendar Year.

Directors shall serve two-year overlapping terms, with half the Directors being elected in even-numbered years (term encompassing first the following odd-numbered year, then the subsequent even-numbered year) and half the Directors being elected in odd-numbered years (term encompassing first the following even-numbered year, then the subsequent odd-numbered year).

HL7 and Affiliate Directors are limited to two consecutive terms of office.

HL7 Governance and Operations Manual

07.05 Vacancies

07.05.01 Appointment to Fill an Interim HL7 Director Vacancy

The Chair may choose to appoint an individual to serve out the remaining term of office of the vacant position. Those individuals nominated for HL7 Director during the most recent election, but who were not elected, shall form the primary pool of possible appointees should the Chair choose to pursue an appointment.

The process for selecting an appointee shall be hierarchical and consider the expressed support of the membership for the various candidates. The HL7 Chair, with the assistance of HL7 staff, shall contact the Director nominee receiving the second highest vote tally in the most recent election. Should this individual be unable or choose not to accept the appointment, the candidate with the third highest vote tally shall be contacted. And so on, until a candidate accepts the appointment.

Should no candidate for Director in the most recent election accept the appointment, the Chair may choose to consider those candidates for Officer positions in the most recent election; applying the same process of contacting that candidate with the second highest vote tally, then the third highest vote tally, etc.

As a further contingency, should the slate of candidates for HL7 Director or Officer from the most recent election not produce an appointee; the Chair with the assistance of HL7 staff may consider those nominees from the prior year's election, again prioritizing the order of contact based on most votes received. HL7 Staff shall validate that those nominees approached are current members and still meet the criteria for election. Should this last effort fail to produce an appointee, the HL7 Director position in question shall remain vacant pending the outcome of the next regularly scheduled Board election.

Upon appointment the individual shall be seated to fill the vacancy. If the term of office served in the vacated position is longer than 12 months, it shall be considered a full term for the purposes of eligibility for reelection. The appointee may seek nomination for their position when it becomes open for election unless having completed the term of the vacated position constitutes a second term for the appointee.

07.05.02 Appointment to Fill an Affiliate Director Vacancy

The Chair may choose to appoint an individual to serve out the remaining term of office of the vacated position. Those individuals nominated for Affiliate Director during the most recent election, but who were not elected, shall form the primary pool of possible appointees should the Chair choose to pursue an appointment.

The process for selecting an appointee shall be hierarchical and take into account the expressed support of the Affiliates. The HL7 Chair, with the assistance of HL7 staff, shall contact the Affiliate Director nominee receiving the second highest vote tally in the most recent election. Should this individual be unable or choose not to accept the appointment, the candidate with the third highest vote tally shall be contacted. And so on, until a candidate accepts the appointment.

As a contingency, should the slate of candidates for Affiliate Director from the most recent election not produce an appointee; the Chair with the assistance of HL7 staff may consider those nominees for Affiliate Director from the prior year's election, again prioritizing the order of contact based on most votes received. HL7 Staff shall validate that those nominees approached still meet the criteria for nomination and election. Should this last effort fail to produce an appointee, the Affiliate Director position in question shall remain vacant pending the outcome of the next regularly scheduled Board election.

Upon appointment the individual shall be seated to fill the vacancy. If the term of office served in the vacated position is longer than 12 months, it shall be considered a full term for the purposes of eligibility for reelection. The appointee may seek nomination for their position when it becomes open for election unless having completed the term of the vacated position constitutes a second term for the appointee.

HL7 Governance and Operations Manual

07.06 Directors Nominated by the Chief Executive Officer

The Chief Executive Officer (CEO) shall identify suitable candidates from various sectors of the healthcare community for seats on the Board of Directors. These candidates shall be chosen based on criteria established by the CEO as necessary to meet the objectives set by the Board of Directors.

The Executive Committee shall assist the CEO in assessing and validating candidates and preparing a slate of nominees. The Board of Directors shall ratify individuals from the slate of candidates by two-thirds majority.

These individuals shall serve a two-year term and are limited to two consecutive terms.

Any of these individuals may be dismissed by mutual consent of the HL7 Chair and the CEO, with the concurrence of two-thirds of the Board of Directors.

Should a Director or Officer experience a change of employment or suffer other hardship or circumstance that impacts their ability to fulfill their obligations as members of the Board, the following policies shall apply.

07.07 Board of Directors Meetings

The Board of Directors shall hold at least two meetings per year, one of which shall occur at the time of the Plenary and annual Business Meeting.

Other meetings of the Board of Directors may be held at the call of the Chair, or upon petition by a majority of the voting Members of the Board. Such meetings shall be scheduled at least 24 hours in advance to provide sufficient time for members of the Board to participate.

Any or all members of the Board may participate in a Board meeting or a meeting of a Board committee by means of a conference telephone call or by any means of communication by which all persons participating in the meeting are able to hear one another; such participation shall constitute presence in person at the meeting.

Robert's Rules of Order, current revised edition, shall govern the conduct of the meetings when not inconsistent with this document or any other rules of order the Board of Directors may adopt.

A majority of the voting members of the Board of Directors, including at least the Chair or Vice Chair and one other officer, shall constitute a quorum for conducting official business. Unless otherwise noted, motions shall be resolved by simple majority of quorum.

Motions related to approval of the budget, approval of unbudgeted expenditures requiring Board approval, hiring executive staff, or contractual issues brought before the Board shall be resolved by a majority of all voting members of the Board. Those members of the Board not able to participate in a vote requiring a response from the full Board of Directors shall be contacted by the Secretary asking that they submit their vote in writing, which includes email, to both the Chair and the Secretary for inclusion in the final tally. Votes on such matters shall be recorded by name.

The agenda shall be distributed electronically by close of business of the third working day preceding the scheduled Board Meeting. A packet of supporting documentation, when appropriate, shall accompany the agenda. Items for the consideration of the Board that are not available when the agenda is distributed shall be expeditiously forwarded to Board members as they become available. The Chair shall rule on such matters, but where material is not made available by the day prior to the meeting the appropriate agenda item should be deferred to the next meeting or otherwise disposed.

In the course of a meeting members of the Board shall respect differing opinions recognizing that dissent is healthy and should not be discouraged; however, once the Board has reached a decision all members shall be of one voice supporting the decision of the Board.

Any action required by law to be taken at a meeting of the Board of Directors, or any other action which may be taken at a meeting of the Board of Directors, may be taken without a meeting, if a consent in writing setting forth the action so taken shall be signed by all members of the Board of Directors entitled to vote in respect to the subject matter thereof. Such consent shall have the same force and effect as a unanimous vote and may be stated as such in any document filed with the state of Michigan.

HL7 Governance and Operations Manual

07.07.01 Observers

Board of Directors meetings convened during the Working Group Meetings shall be open to observers unless called into executive session by the Chair. Observers shall be restricted to seating on the periphery as directed by HL7 staff. Observers shall not cause distractions or otherwise interrupt the conduct of the Board Meeting. Observers shall not seek the attention of the Chair and shall not participate in Board deliberations unless specifically requested to comment by a member of the Board.

Current individual members or voting representatives of current organizational or Affiliate members may individually petition to become observers during Board teleconferences. The petition shall specify the teleconference date, the rationale for participating as an observer, and whether the observer expects the Board to take action as a result of such participation. Such petitions shall be granted solely at the discretion of the Chair. Teleconference observers shall clearly announce their presence during the roll call. Teleconference observers shall be held to the same rules of courtesy and participation as defined above for Working Group Meetings.

07.07.02 Board Appointed Committee Chairs

Unless serving on the Board of Directors, an appointed committee chair may attend Board meetings and/or conference calls as an observer with the express purpose of presenting the report of committee activity to the Board. Those appointed committees with co-chairs shall select a single representative to attend and render the report. The representative need not attend the Board meeting or conference call if a member of the Board serving on said committee or designated as the Board liaison is able to present the committee activity report or there is no committee activity to report.

07.08 Submitting and Resolving Motions via Email

Email processing will be used to address Board of Director or Executive Committee motions either of an urgent nature requiring immediate action that cannot be deferred until the next scheduled call/meeting or of a routine, non-controversial nature not requiring extensive debate or deserving of time on the next meeting agenda. Every effort will be made to address each motion as a separate email thread for tracking purposes.

Submissions shall be clearly identified by 'MOTION' in the subject line, e.g.: MOTION <insert text of motion>. The person seconding the motion shall append 'SECOND' to the end of the subject line, e.g.: MOTION <insert text of motion> SECOND. Following submission of the original motion and posting of a second, a two-business day discussion period will take effect preceding a call for vote.

The discussion period shall begin at the start of business, defined as 8:00 a.m. Eastern, of the first business day following the submission of a second. No voting shall occur during the discussion period. Acceptance or non-acceptance of amendments to the original motion made during the discussion period must be acknowledged on the list by the submitter of the original motion and the individual providing a second.

When the discussion period closes, the vote will be initiated by HL7 Headquarters by placing 'VOTE ON' in the subject line preceding the motion; e.g., VOTE ON MOTION <text of motion>. The motion, as amended if appropriate, will be restated at the call for vote. The closing date/time of the vote will be stated in the body of the email. If a vote date limit is not set in the body of the email, the vote period shall default to 5 business days from the initial call for vote. The minimum vote period allowed shall be 2 business days.

Votes may be submitted using "Reply All" to allow the members of the Board of Directors or Executive Committee to monitor progress or sent directly to the Secretary or appropriate staff member. An email vote of "yes" shall be interpreted as an affirmative vote in support of the original, or amended if applicable, motion. In matters of expediency or to achieve a quorum response, members may be contacted by telephone and requested to submit their vote to the list.

HL7 Governance and Operations Manual

A tally of vote status to include the motion, second, and count of those in favor, opposed, or abstaining shall be posted to the list by HL7 Headquarters the day before the close of the voting period using the subject line: TALLY OF MOTION <text of motion>. The number of votes cast, including abstentions shall count toward quorum. Proxy votes are not permitted. As defined in Robert's Rules, the Chair is allowed to vote when his or her vote will materially affect the results of the vote.

07.09 Travel for HL7 Board Functions

07.09.01 Attendance at Working Group Meetings

Board members or their organizations are encouraged and expected to be responsible for those expenses associated with attendance at the Working Group Meetings (WGM) given that the primary purpose for attending the WGM is developing, enhancing, and maintaining HL7 Protocol Specifications [§02.02].

A Board member who, due to hardship, is unable to absorb the expenses associated with attending a WGM shall petition the Executive Committee through the Executive Director for approval of reimbursement of reasonable expenses at least one month prior to the scheduled start of the WGM.

The petition shall include the reason for the request and an estimate of the relief sought by the Board member. The Executive Committee shall seek an expeditious decision on the request via electronic discussion and vote. Approval shall require a two thirds affirmative vote. The Executive Director shall notify the affected Board member of the result of the vote. If the request is approved, the affected Board member shall submit an HL7 Member Travel Expense Report with appropriate receipts to the Executive Director within thirty days of the close of the WGM. These expenses shall be charged to Board travel.

07.09.02 Attendance at the Annual Board Retreat

To establish the strategic direction of HL7 and develop and approve short and long-term objectives; the Board participates in an annual retreat.

HL7 shall provide food and beverage for the annual retreat. Board members shall be responsible for the costs associated with traveling to, accommodations during, and returning from the annual retreat.

A Board member who, due to hardship or circumstance, is unable to absorb all or a portion of these costs may petition the Executive Committee through the Executive Director for approval of reimbursement of all or a portion of reasonable travel expenses at least six weeks prior to the announced start date of the annual retreat.

The petition shall include the reason for the request and an estimate of the relief sought by the Board member. The Executive Committee shall seek an expeditious decision on the request via electronic discussion and vote. Approval shall require a two thirds affirmative vote. The Executive Director shall notify the affected Board member of the result of the vote. If the request is approved, the affected Board member shall submit an HL7 Member Travel Expense Report with appropriate receipts to the Executive Director within thirty days of the close of the annual retreat. These expenses shall be charged to Board travel.

07.10 Committees and Councils

07.10.01 Advisory Council

The Advisory Council shall be comprised of industry, regulatory, and public-sector leaders at the senior executive level selected for their specific expertise to provide the Board of Directors an independent, external perspective on HL7 and its stakeholders.

The Advisory Council shall elect its chair, who shall serve a term not to exceed two years with no more than two consecutive terms, from among its members. The chair shall serve for the remainder of their term on the Advisory Council and may be reelected if reappointed to the council.

The HL7 Chair and the CEO shall confer on identifying and selecting appropriate individuals to participate. Members of the Advisory Council shall serve two-year renewable terms. The Executive Committee shall interact with the Advisory Council.

HL7 Governance and Operations Manual

HL7 shall reimburse the reasonable expenses of those members of the Advisory Council invited and able to attend a one-day retreat with the Executive Committee preceding the Board's annual retreat. The affected members of the Advisory Council shall submit an HL7 Member Travel Expense Report with appropriate receipts to the Executive Director within thirty (30) days of the close of the retreat.

07.10.02 Finance Committee

The Finance Committee shall consist of a chair other than the Treasurer, appointed with the concurrence of the Board; a Director at Large selected by the Board unless the appointed chair is a currently seated Director at Large; a representative appointed by the International Council; and two representatives appointed by the Executive Committee who are current individual member or representatives of current organizational members but not seated members of the Board. The HL7 Vice Chair, Treasurer, Chief Executive Officer (CEO), and Executive Director shall be members *ex officio* with vote. The tenets of **§07.03 Limits to Organizational Representation** shall apply in principle to the membership of the Finance Committee. The presence of the chair and any three voting members shall constitute quorum.

The chair may serve for two years starting on the date of appointment and may be appointed to a second two-year term. It is the prerogative of an incoming HL7 Chair to either allow the incumbent chair to continue his or her term or to appoint another individual to chair this committee. Members shall serve a two-year term beginning with the date of appointment limited to two consecutive terms provided they continue to meet the specified criteria; e.g. a Director at Large or not a seated member of the Board.

The Finance Committee shall review all financial statements and budgets to be presented to the Board of Directors for final action. It shall make recommendations to the Executive Committee regarding the approval of the annual audit of HL7 financial records and tax return. Should the auditor raise concerns in the course of the annual audit regarding HL7 finances or related procedures, the Finance Committee may, with the concurrence of 75% of its members, recommend to the Executive Committee that an additional audit of HL7 finances and procedures is warranted.

The Finance Committee shall recommend to the Executive Committee policies regarding the receipt and expenditure of funds. It shall assist the Treasurer in the preparation of a detailed budget for the coming year to be submitted to the Board of Directors not later than the December board meeting each year. The Finance Committee shall consider and make recommendations to the Executive Committee regarding opportunities to generate additional revenues for HL7.

07.10.03 Governance and Operations Committee

The Secretary, serving as chair, Associate Executive Director, a representative from the TSC, a representative from the International Council, and such other members as the Secretary shall designate shall comprise the Governance and Operations Committee (GOC), which shall be responsible for maintenance of this manual as defined in §17.

07.10.04 International Council

The International Council shall be the collective leadership of the Affiliate members.

The International Council shall coordinate the activities of the Affiliates and advise the Board of Directors on matters of interest to the Affiliates.

The International Council shall approve expenditures of those funds allocated to it in the annual budget with subsequent notification of such expenditures to the Executive Committee.

07.10.04.01 United States Representation

Those members of the Board of Directors who are US citizens or permanent residents living and working in the United States shall select an individual to represent the United States on the International Council. Eligible individuals shall be limited to HL7 members who are US citizens or permanent residents living and working in the US.

HL7 Governance and Operations Manual

07.10.05 Leadership Development and Nomination Committee (LDNC)

Maintaining a strong pool of leadership candidates with the varied skill set needed to govern HL7 is important to the continued success of the organization. The Leadership Development and Nomination Committee (LDNC) is responsible for identifying and preparing such individuals from within and outside the organization to become viable future leaders of HL7 International.

07.10.05.01 Composition and Term

The individual assuming the position of Immediate Past Chair shall be appointed the Chair of the LDNC for a term of two years. The LDNC shall include at least four additional individuals, who shall be current members of HL7 International, nominated by the LDNC chair and approved by the Board. Those individual members shall serve a term of two years with a limit of two consecutive terms. Said individuals shall have:

- 5 or more years of leadership experience in HL7;
- stated and demonstrated an interest in the growth and stability of HL7;
- experience in or collaboration with other SDO, regulatory bodies (national or international), or industry groups.

The LDNC shall select a Vice Chair from among its members to convene the LDNC in the Chair's absence. Should the Chair of the LDNC, for whatever reason, resign said position, the LDNC Vice Chair shall complete the current term as the Chair and the LDNC shall select a new Vice Chair from among its members.

07.10.05.02 Roles and Responsibilities

The LDNC shall be responsible for establishing and maintaining the Leadership Development Program (LDP) to provide the skills and competencies expressed by the Board as necessary for future leaders. The LDNC will identify, interview, and recruit suitable individuals, be they members or non-members, for the LDP with an emphasis on skill sets compatible with those expressed by the Board.

The LDNC shall oversee the mentoring, education, and training of those individuals selected for participant in the LDP with the objective of providing or enhancing the necessary skill sets and competencies.

Mentoring:

- Recruit individuals to mentor members of the LDP
- Match individuals admitted to the LDP with suitable mentors
- Establish goals for and actively track the mentoring relationship

Education:

- Ensure participants in the LDP gain a comprehensive understanding of the HL7 Bylaws, and the Governance and Operations Manual (GOM) with an emphasis on the election process and Board responsibilities.
- Ensure participants in the LDP are aware of the roles and responsibilities of the various internal bodies such as the TSC, International Council, and Advisory Council, for example.
- Ensure participants in the LDP are aware of various ongoing external collaborations with organizations such as ONC, ISO, other Standards Development Organizations (SDO), and those organizations holding Statements of Understanding (SOU) with HL7.
- Ensure participants in the LDP are aware of the relationship with and various services provided by HL7 staff.

Training:

- Enlist third-party experts to create a comprehensive leadership development curriculum.

HL7 Governance and Operations Manual

- Ensure that such training is available and provided to participants in the LDP.
- Notify the membership when such training is being conducted to allow others to attend given the payment of appropriate fees.

The LDNC shall prepare the slate of candidates for election as HL7 Directors or Officers including those members of the LDP who best meet the strategic needs of the organization as expressed by the Board. Any participant considered for a leadership position within HL7 must be a current individual member or designated voting representative of a current organizational member prior to being placed on the ballot. The LDNC shall make every effort to provide at least two candidates for each position on the slate.

The LDNC shall prepare and present progress reports to the Board of Directors as requested, but at least annually.

07.10.05.03 Leadership Development Program (LDP) Participation

Individuals representing a diverse set of skills, interests and demographics either identified by or recommended to the LDNC may, at the discretion of the LDNC chair, be selected for participation in the LDP. Those selected shall have demonstrated an interest and aptitude for leadership; and agree to participate for at least three years including quarterly meetings or conference calls with their assigned mentor.

Those selected for participation in the LDP shall acknowledge that such participation does not guarantee inclusion on any particular slate of candidates for Director or Officer. Those candidates selected for a specific slate would possess the skill set or expertise aligned with those identified by the Board as critical in the upcoming election year.

Further, it is at the participant's discretion as to whether they chose to accept the decision of the LDNC to include them on any given slate of candidates.

07.10.05.04 Leadership Mentors

Those individuals recruited to become mentors to participants in the LDP shall:

- Be active members of HL7 International with five or more years of demonstrated leadership experience either within HL7 (such as past experience on the Board, serving as TSC Chair or Affiliate Chair, etc.) or an equivalent SDO.
- Be well-regarded, ethical, forward thinking/visionaries having demonstrated a commitment to the mission and success of HL7 International.
- Commit to participate in quarterly meetings or conference calls with assigned participants of the LDP for at least a period of three years.
- Maintain records of goals and objectives obtained and report such to the LDNC.

07.10.06 Policy Advisory Committee

The Policy Advisory Committee (PAC) shall consist of a chair appointed by the HL7 Chair with the concurrence of the Board and at least three (3) other members nominated by the appointed chair and approved by the Board. The CEO and HL7 Vice Chair shall be *ex-officio* members with vote.

The chair may serve for two years starting on the date of appointment and may be appointed to a second two-year term. It is the prerogative of an incoming HL7 Chair to either allow the incumbent chair to continue his or her term or to appoint another individual to chair this committee.

The PAC shall undertake policy and regulatory review and analysis within the health information technology (HIT) sector with the objective of identifying emerging issues, trends, and problems related to either policy or standards. Topics in scope include HIT legislation, regulation, contracts and contract negotiations, industry consensus, and international coordination. The PAC shall provide options and recommendations to the Executive Committee (EC) for the resolution of such issues and problems in the form of briefing notes, background documents, discussion papers, and position papers. Any statements for public release developed from such presentations shall be issued by the EC, which may designate an individual to present such statements.

HL7 Governance and Operations Manual

The PAC shall review and comment on any statements, written or oral, espoused as representing an HL7 position [§07.11.01.02] prior to the submission of such statements to the Executive Committee for approval.

07.10.07 Recognition and Awards Committee

The Recognition and Awards Committee (RAC) shall be comprised of a chair, appointed with the concurrence of the Board, the Associate Executive Director (serving as co-chair), and at least three other members, including an Affiliate representative, selected by the appointed chair and ratified by the Board.

The RAC shall be responsible for identifying and recommending to the Board those individuals and organizations deserving of special recognition, honors, or awards. The RAC may, in turn, make recommendations to the Board on establishing appropriate recognition, honors, or awards.

RAC members selected by the chair shall be reviewed by the Board during the January WGM meeting and shall be replaced after having served two consecutive years subject to reappointment following a one-year hiatus. At the discretion of the Associate Executive Director, HL7 staff may be provided for administrative support.

07.11 Officers

07.11.01 Chair

The Chair shall preside at all meetings of the Board of Directors, the Plenary and Business Meetings of the Membership, and with the assistance of the CEO manage liaison or affiliations with other organizations.

The Chair shall report on the activities and state of HL7 at the annual business meeting. In the absence of the Chair the Vice Chair, being the Chair-Elect or the Immediate Past Chair, shall preside.

The Chair shall be a member, *ex officio*, with vote, of all councils and committees including the Technical Steering Committee.

07.11.01.01 Term of Office

Serving as the HL7 Chair entails a four-year commitment; a year as Chair Elect, two years as Chair, and a final year as the Immediate Past Chair.

07.11.01.02 Representing HL7

The Chief Executive Officer (CEO), or alternately the Chair, is charged with representing HL7 to other organizations or entities. This duty may be delegated, with constraints on scope and/or timeframe, to an officer, director, council, committee, or Work Group chair. The designated individual shall prepare and submit timely reports on their activities.

There are numerous situations where a member of HL7, participating in various other initiatives and venues, may wish to represent an HL7 position rather than attributing their statement to themselves or their employer. In general, any written or oral statement represented as an HL7 position must be reviewed within HL7 prior to its release. Such statements shall not appear to favor one vendor, product, or service over another. Nor shall they denigrate any individual or organization. Policies relative to written and oral communications regarding HL7 follow.

Written Communications

This policy primarily addresses position papers, statements of plans and future directions, or philosophy statements. If the communication represents information specific to the status, process, or products of an HL7 Work Group, the document shall be reviewed and endorsed by the Work Group co-chairs and the Policy Advisory Committee [§07.10.06] prior to submission to the EC, which has final approval for release of a document. All such documents released by HL7 shall include a cover letter signed by the CEO and/or Chair. In the event that the EC denies release of a document, for whatever reason, that decision may be appealed to the Board of Directors, whose decision shall be final.

HL7 Governance and Operations Manual

Oral Communications

In the case of oral communications, the speaker should clearly state whom they are representing when making statements regarding HL7. Although anyone is free to represent an individual or employer position at will, when they are speaking on behalf of a Work Group, speakers should only represent positions that have been endorsed by the Work Group and the Policy Advisory Committee and approved by the Executive Committee. If a speaker is unsure of their right to express a given position, they should refrain from responding, but commit to follow up with an answer or direct the question to the appropriate Work Group co-chair or a member of the Executive Committee.

07.11.01.03 Reimbursing Expenses of HL7 Chair and Vice Chair

The organization supporting the individual serving as Chair is encouraged to extend its contribution to HL7 by absorbing the expenses associated with the position. HL7 shall reimburse all reasonable costs accrued by the Chair-elect (seated as the Vice Chair), the Chair, and the Immediate Past Chair (seated as the Vice Chair) associated with the conduct of HL7 business not otherwise absorbed by the individual or the supporting organization. These costs include attendance and participation at Working Group Meetings; participation in Board meetings and retreats; periodic meetings with HL7 staff; and attendance and participation at meetings, conferences, and trade shows as an HL7 representative. Other expenses shall be approved by the Executive Committee and reported to the Board of Directors at its next scheduled meeting.

07.11.02 Vice Chair

The positions of Chair Elect and Immediate Past Chair shall be seated as the Vice Chair of the Board of Directors.

The Chair Elect shall assist the Chair and participate in developing the operating plan for the following year.

The Immediate Past Chair shall assist the incoming Chair, formerly the Chair Elect, and participate in implementation of the jointly developed operating plan.

The Vice Chair shall be a member, *ex officio* without vote, of all councils and committees including the Technical Steering Committee.

07.11.03 Secretary

The Secretary shall provide or oversee the provision of general administrative support for the Board of Directors. In the absence of the Secretary, the presiding officer of the board meeting may appoint an Acting Secretary for the purpose of recording proceedings and motions and tallying votes.

The Secretary, under the direction of the Board of Directors, shall accomplish or cause to be accomplished, the following tasks:

- ensure that minutes of the various Work Groups have been posted to the Web site within two weeks of the close of a Working Group Meeting
- record and publish Board proceedings and motions
- create and distribute Board meeting and Working Group Meeting notices at least 30 days prior to such meetings
- create and distribute voting items and ballots as directed by the Board
- tally votes
- distribute Board agendas
- maintain the roster of Board members
- maintain this Manual and cause updates to be posted to the Web site
- establish and maintain appropriate archives and historical records of all official HL7 business
- maintain any other records required by law

HL7 Governance and Operations Manual

07.11.03.01 Term of Office

The Secretary shall serve for two years being elected in even-numbered years (term encompassing first the following odd-numbered year, then the subsequent even-numbered year).

The Secretary shall serve no more than two consecutive terms.

07.11.04 Treasurer

The Treasurer shall establish orderly mechanisms for the collection of fees, dues, and assessments, and the distribution of monies owed. The Treasurer shall prepare, or cause to be prepared, all financial reports presented to the Board of Directors and to the membership. The Treasurer shall participate in the selection of a certified public accountant to conduct an annual review or audit of the records and financial statements. The selection of an auditor shall be ratified by the Board of Directors.

07.11.04.01 Term of Office

The Treasurer shall serve for two years, being elected in odd-numbered years (term encompassing first the following even-numbered year, then the subsequent odd-numbered year).

The Treasurer shall serve no more than two consecutive terms.

07.12 Officer Vacancies

HL7 Bylaws §06.02 defines the process for filling Officer vacancies.

07.13 The Executive Committee

The HL7 Officers shall be the Chair, the Chair-Elect or Immediate Past Chair acting as the Vice Chair, the Secretary, and Treasurer; who, with the addition of the Chief Executive Officer, Chief Technology Officer, and either the Executive Director or the Associate Executive Director, shall comprise the Executive Committee.

The Executive Committee shall be responsible for operations of the Organization. The Board of Directors may from time to time refer issues to the Executive Committee, whose decision shall be binding.

07.13.01 Contract Work Process

From time to time HL7 may need to engage external contractors to perform specific projects, whether funded by external grants or by HL7 directly. When the need for contract work is identified, the appropriate HL7 Executive Committee (EC) member (typically the Chief Executive Officer (CEO), Chief Technology Officer (CTO), or the Executive Director) shall identify potential contractors and prepare a scope of work and estimate to complete. If the work is covered under an approved budget item or a grant, the contract may be awarded with a second by either the CEO, CTO, or Executive Director and upon notification of the EC of such action. If the work is not covered under an approved budget item or a grant, EC approval is required before an RFP for contract work is issued or a contract is awarded.

In all cases, any member of the EC who is named in the recommendation or is a member of an organization or has a business relationship with an individual or organization named in the recommendation shall not participate in the selection committee; shall recuse themselves from any decision-making discussion regarding the contract; and abstain from voting on the award of the contract.

For contracts exceeding \$10,000, the responsible EC member shall serve as chair of an *ad hoc* selection committee including at least two domain experts and/or appropriate staff to outline the scope of work or service to be contracted; expected qualifications of the contractor or subcontractor; deliverables and work schedule with performance bonus and/or penalties as applicable; and a preliminary budget. The EC shall be informed of the committee members, work description and recommendations before a contract is awarded.

HL7 Governance and Operations Manual

For contracts exceeding \$20,000, the committee shall prepare a formal Request for Proposal (RFP) and the committee chair shall notify the EC of such action. In those cases where the committee chair believes that timeliness, unique expertise or criticality of the project supports direct award of a contract based on the recommendations of the committee, the requirement to issue an RFP may be waived by the EC.

When an RFP is to be issued, the chair of the selection committee shall provide HL7 Headquarters with the contract work announcement template. The contract work announcement shall be posted to the HL7 Contract Work list service, which is open to any individual interested in being apprised of HL7 contract work. In the event of a question or request for clarification additional information regarding the announcement may be disseminated using the Contract Work list service, but the list service shall not be used for interactive discussions among the subscribers.

Individuals interested in the announced contract work shall submit an expression of interest by the date specified via e-mail or to the fax number indicated in the announcement. All expressions of interest shall be forwarded by HL7 Headquarters to the chair of the select committee, who will convene the committee to review and discuss the submissions and develop a recommendation.

Upon completion of their deliberations, the selection committee chair shall present the committee proceedings, including its recommendations, to the EC who shall award the contract.

HL7 Headquarters shall post the notification of award of contract to the Contract Work list service and notify the membership of the award via posting in the next edition of the HL7 Newsletter. The award shall be entered into the HL7 Contract Register and be subject to public inspection. The HL7 Contract Register shall include at least the following elements: contract name, contract description, contract amount, contract period, date contractor selected, contractor name and contact information.

08 Governance

08.01 Participation in Standards Development and Maintenance

All those present in a Work Group shall have the right to participate and cast a vote specific to development and maintenance of the HL7 Protocol Specifications (§02.02), whether in Working Group Meetings, special meetings, teleconferences, or other forums.

08.02 Annual Nomination and Election of HL7 Leadership by Administrative Ballot

Those positions subject to election by the general membership, or some designated portion thereof, shall occur annually by electronic administrative ballot. These include Officers, HL7 Directors, Affiliate Directors, Steering Division Co-chairs, Affiliate representatives to the TSC, International Council Co-chair, and Work Group Co-chairs. Every effort shall be made to present at least two candidates for each position.

Nomination as an Officer, HL7 Director, or Affiliate Director or selection by the Chief Executive Office as a candidate for the Board of Directors carries with it the responsibility to attend Board meetings, both those held in conjunction with the Working Group Meetings (WGM) and those conducted via teleconference. Nominees acknowledge that they have the support of their organizations in seeking a position on the Board and agree that they, either individually or through their organizations, will be responsible for the expenses associated with participation as a Director or Officer.

The call for nominations shall include instructions for acquiring nomination packets. Nomination packets for these positions shall be accepted from May 1 through June 15 of each year. No nominations shall be accepted nor shall any candidates (Officers and HL7 Directors) be solicited by the Leadership Development and Nomination Committee (LDNC) after the close of the nomination period. An individual who is nominated for more than one position must state which position he or she wishes to seek and reject other nominations.

HL7 Governance and Operations Manual

At any point during the nomination period for Officers and HL7 Directors should the LDNC note a lack of nominees for any given position the following may occur:

- The Committee may recruit nominees for said position(s). Those nominees, if any, recruited by the Committee shall meet the criteria stipulated in the two paragraphs above specific to being considered “in nomination” and submission of packets.
- A member of the Committee, should they be qualified and wish to run, may resign from the Committee prior to seeking nomination. Said individual shall meet the criteria specific to being considered “in nomination” and submission of petitions.
- Committee members may sign nomination packets for any eligible candidate.
- If there is an excess of nominees for one position, the Committee may suggest to all of the nominees for that position that they consider running for a position lacking sufficient nominees. Under these circumstances, a nominee may, upon notification to HL7 Headquarters, switch the position for which they are running without submitting a new packet.

There shall be no campaigning conducted using any HL7 managed electronic communications (e.g., list servers, chat forums, wiki pages, etc.). Any such activity shall be cause for disqualification.

Elections shall occur from July 1 through July 31 of each year. The ballot shall support write-in votes where appropriate. Write-in candidates shall be subject to validation against the specified criteria of the position being sought. A single post to an appropriate list server indicating an individual's intent to run as a write-in candidate with accompanying position statement shall not be construed as campaigning.

At the conclusion of the election period the chair of the LDNC shall review the tally of the returned ballots with the HL7 Executive Director or Associate Executive Director. Although there may be multiple nominees representing or related to a single organization, under the tenets of §06.01.01 should more than one representative of or individual related to a given organization be elected only one may be seated. In such a case, the individual who received the most votes (reflecting the decision of the voters) from among those related to a given organization shall serve. In the case of HL7 Directors, those individuals eliminated due to limits on organizational representation shall be replaced by those other candidates who received the most votes.

In the event of there being three or more candidates contending for an Office, the winner shall be deemed to be the candidate collecting the largest vote total, a plurality. In the event of a tie there shall be a runoff election.

Run-off elections, if necessary, shall occur from August 7 through August 21 of each year. In lieu of run-off elections, candidates involved in a tie vote may opt to resolve the issue by drawing lots or one candidate may choose to defer to the other.

The results of the elections shall remain on file for one year and shall be produced upon submission of a written request for results identifying a specific election by a current individual member or a voting representative of a current organizational or Affiliate member. In addition, those candidates involved in an election, who may not be individual members or designated voting representatives of an organizational or Affiliate member, may submit a written request for the results of the specific election in which they were a candidate.

08.02.01 Officers

In order to be considered “in nomination” the candidate must be named as a nominee by at least ten individuals who are either current individual members or voting representatives of current organizational members of HL7 International. To ensure that no single organizational member exerts undue influence in the nomination process only the first two voting representatives of any given organizational member shall be counted as supporting the nomination of any given candidate.

HL7 Governance and Operations Manual

Nominees for an Officer position (Chair-elect, Secretary, or Treasurer) must have been a current individual member or designated voting representative of a current Organizational member of HL7 International for at least the last two years and shall have prior leadership experience in HL7 such as committee or council chair, Work Group co-chair, TSC member, or member of the Board of Directors.

HL7 Headquarters shall provide the official Officer ballot to current individual members and designated voting representatives of current organizational and Affiliate members reflecting those individuals nominated by their peers, themselves, or the Leadership Development and Nomination Committee (LDNC). The winners of the election shall be announced at the annual Plenary meeting.

Newly elected Officers shall be seated January 1 of the following year.

08.02.02 HL7 Directors

In order to be considered “in nomination” the candidate must be named as a nominee by the Leadership Development and Nomination Committee or at least ten individuals who are either current individual members or voting representatives of current organizational members of HL7 International. To ensure that no single organizational member exerts undue influence in the nomination process only the first two voting representatives of any given organizational member shall be counted as supporting the nomination of any given candidate.

Nominees for HL7 Director must be current individual members or designated voting representatives of current Organizational members and should have held leadership positions at the Work Group, council, and/or committee level.

HL7 Headquarters shall provide the official HL7 Director ballot to current individual members and the designated voting representatives of current organizational members reflecting those individuals nominated by their peers, themselves, or the Leadership Development and Nomination Committee (LDNC). The winners of the election shall be announced at the annual Plenary meeting.

Newly elected HL7 Directors shall be seated January 1 of the following year.

08.02.03 Affiliate Directors

Using their designated processes, the Affiliate chairpersons shall identify candidates for Affiliate Director. All nominations shall be submitted to HL7 Headquarters by the close of the nomination period.

Nominees for Affiliate Director must be designated voting representatives of a current Affiliate member and should have held leadership positions at the Work Group, council, and/or committee level.

HL7 Headquarters shall provide the official Affiliate Director ballot to the chairpersons of the various Affiliate members reflecting those individuals nominated by the Affiliate chairpersons. Each Affiliate shall have a single vote. The winner of the election shall be announced at the annual Plenary meeting.

The newly elected Affiliate Director shall be seated January 1 of the following year.

08.02.04 Steering Division Co-chairs

One of each of the Steering Division (SD) co-chairs shall be elected each year. During the second WGM each year those SD co-chairs not up for reelection that year shall form an *ad hoc* TSC nomination committee with the objective of ensuring at least two candidates for each available position. The committee shall elect its own chair with the concurrence of the TSC. Should the Work Groups fail to nominate sufficient candidates, the *ad hoc* committee shall reach out to viable candidates for inclusion on the ballot. The TSC nomination committee shall disband at the close of the nomination period.

Nominees for Steering Division Co-chair must be current individual members or representatives of current Organizational or Affiliate members and, although not required, should be either current or past co-chairs of one of the WG comprising the Steering Division.

HL7 Governance and Operations Manual

HL7 Headquarters shall provide the official Steering Division Co-chair ballot to the various Work Groups comprising each Steering Division reflecting those individuals nominated by those Work Groups or the TSC *ad hoc* nomination committee. Each Work Group shall have a single vote. The winner of the elections shall be announced during the annual Plenary meeting.

The newly elected Steering Division Co-chairs shall take office January 1 of the following year.

08.02.05 Technical Steering Committee Affiliate Representative

An Affiliate representative shall be elected each year to serve a two-year term. Nominations for Affiliate representative shall be accepted from the Affiliate chairs. Individuals who are nominated for more than one position (Affiliate representative and SD co-chair) will be asked to choose which nomination they wish to accept, thereby rejecting the other(s).

Nominees for TSC Affiliate Representative must be representatives of current Affiliate members and, although not required, should be either current or past WG co-chairs.

HL7 Headquarters shall provide the official TSC Affiliate Representative ballot to the designated voting representatives of the various Affiliate members reflecting those individuals nominated by the Affiliate chairpersons. Each Affiliate chairperson, having assessed the votes of their designated voting representatives, shall cast a single vote for their desired candidate. The winner of the election shall be announced during the annual Plenary meeting.

The newly elected TSC Affiliate Representative shall take office January 1 of the following year.

08.02.06 International Council Co-chair

Nominations for International Council Co-chair shall be accepted from Affiliate member designated voting representatives. Nominees for International Council Co-chair must be a current member of an HL7 International Affiliate.

HL7 Headquarters shall provide the official International Council Co-chair ballot to current Affiliate chairpersons. Each Affiliate chairperson shall cast a single vote for their desired candidate. The winner of the election shall be announced during the annual Plenary meeting.

The newly elected International Council Co-chair shall take office January 1 of the following year.

08.02.07 Work Group Co-chairs

Nominations for Work Group co-chair shall be open to HL7 members. Self-nominations shall be accepted.

Nominees for Work Group co-chair must be current individual members; individuals who represent a current Organizational member although not necessarily as a designated voting representative; or individuals who represent a current Affiliate member although not necessarily as a designated voting representative. Nominees should have demonstrated an interest in the subject matter by being subscribed to the Work Group's primary list server; attending meetings; and participating in teleconferences of the Work Group.

HL7 Headquarters shall provide an official Work Group co-chair ballot to those eligible members of each Work Group holding co-chair elections reflecting those individuals nominated by their peers or themselves.

Eligible voters shall be those members subscribed to the WG's primary list server 5 working days prior to the start of the election period who:

- are current individual members, or
- have a domain name reflecting the name of a current Organizational member, or
- have been validated by a current Affiliate member.

A list of those elected to co-chair Work Groups shall be provided to the Work Groups and posted during the annual Plenary meeting with newly elected WG co-chairs assuming their duties January 1 of the following year.

HL7 Governance and Operations Manual

08.03 Majority Rule

All formal motions made within HL7 Work Groups shall be decided by simple majority of the quorum of that Work Group, unless otherwise specified in documented Work Group decision-making practices. Work Groups may, at their discretion, adopt practices requiring thresholds higher than simple majority as long as those practices are documented and adopted by two thirds vote of the members of the Work Group present and voting at the time.

08.03.01 Quorum for Bylaws Adoption or Revision

Only current individual members and the designated voting representatives of current Affiliate and organizational members may participate in and cast a vote on administrative ballots for the adoption or revision of Bylaws. Some combination of at least 100 current individual members and designated voting representatives of current Affiliate and organizational members must cast a vote for revision or adoption of the Bylaws to constitute quorum.

08.04 Liability Insurance

The Executive Director on behalf of the Board of Directors shall contract for an appropriate form of Directors and Officers liability insurance to fund the contingent liability attendant to the referenced indemnification, to the greatest extent possible at reasonable expense.

08.05 Fiscal Policy

08.05.01 Expenditure Limits

The Executive Committee shall recommend categorical expenditure limits escalating through the staff, the Executive Director, the CTO, and the CEO, which shall be presented in a matrix document for approval by the Board. Expenditure limits shall be subject to periodic review.

Expenditures exceeding the established limits shall be approved by the Board.

08.05.02 Annual Budget

The Treasurer and Executive Director shall have the primary responsibility for preparing the proposed annual budget. They shall prepare a detailed, annotated budget, with guidance from the Executive Committee. It shall be the goal of the Treasurer to present the subsequent year's preliminary budget to the Board of Directors prior to the annual business meeting. The final budget for the next year, endorsed by the Finance Committee and the Executive Committee, shall be presented to the Board of Directors no later than the December board meeting each year.

08.05.03 Investment Strategy

The Executive Committee, with the advice of the Finance Committee, shall define and periodically review the HL7 Investment Strategy. The Investment Strategy shall be ratified by the Board of Directors and filed with the Executive Director who is responsible for its execution.

Any current individual member or voting representative of a current organizational or Affiliate member may request a copy of the Investment Strategy from the Executive Director.

08.05.04 Travel for HL7 Related Business

If the Chair or the CEO requests a Board member or chair of a Work Group, council or committee to represent HL7 at a conference, seminar, or other venue that he or she was not already planning to attend and the individual is unable to further support HL7 by absorbing the expense of attending, HL7 shall reimburse reasonable expenses associated with the individual's attendance. The individual shall submit an HL7 Member Travel Expense Report with appropriate receipts to the Associate Executive Director within thirty days of the close of the event. These expenses shall be charged to Board travel.

08.05.05 Reimbursement of Reasonable Expenses

HL7 shall reimburse the necessary and reasonable expenses incurred by individuals conducting authorized HL7-related travel. Requests for reimbursement must be submitted on the HL7 Travel Expense Report available on the web site. The expense report must include receipts for:

HL7 Governance and Operations Manual

- Coach class airfare
- Lodging
- Meals exceeding \$25
- Transportation
- Parking
- Telephone or communications charges, including Internet access
- Any other authorized expenditures

HL7 shall NOT reimburse:

- The cost of or fees associated with an upgrade to Business or First-Class airfare
- Dry cleaning, laundry, or valet expenses
- Entertainment expenses or meals for others unless pre-authorized by the Executive Director
- Rental car expenses unless pre-authorized by the Executive Director

HL7 expects that taxis and shuttle services will be the normal mode of transportation as they are much less expensive than rental vehicles when gas and parking are factored into the expense. Should a traveler seek reimbursement for rental expenses that were not pre-authorized, HL7 reserves the right to reimburse an amount considered by HL7 to be the equivalent of comparable taxi service.

If travel by personal vehicle in lieu of air travel is deemed appropriate and approved by the Executive Director, reimbursement for such travel, at the current IRS Mileage Rate for actual miles traveled, shall be limited to the equivalent of coach-class airfare as determined by HL7.

Should the traveler select accommodations at other than the approved facility, assuming a facility has been specified, or occupies an upgraded room; HL7 reserves the right to reimburse an amount equivalent to the single occupancy rate quoted by the approved facility.

Every effort should be made to submit expense reports, with appropriate receipts, within 30 days of completion of the authorized travel. Under no circumstances will HL7 process expense reports received 90 or more days after completion of approved travel. The Executive Director is responsible for enforcing this policy. Exceptions to this policy require the approval of the Executive Committee.

08.06 Conflict of Interest

The purpose of the conflict of interest policy is to protect the interest of HL7 when it is contemplating entering into a transaction or arrangement that might benefit the private interest of an Officer or director of HL7 or might result in a possible excess benefit transaction. This policy is intended to supplement but not replace any applicable state and federal laws governing conflict of interest applicable to nonprofit organizations.

08.06.01 Definitions

Interested Person: any director, Officer, or member of the Executive Committee, who has a direct or indirect financial interest, as defined below, is an interested person.

Financial Interest: a person has a financial interest if the person has, directly or indirectly, through business, investment, or family:

- An ownership or investment interest in any entity with which HL7 has a transaction or arrangement
- A compensation arrangement with HL7 or with any entity or individual with which HL7 has a transaction or arrangement, or
- A potential ownership or investment interest in, or compensation arrangement with, any entity or individual with which HL7 is negotiating a transaction or arrangement.

HL7 Governance and Operations Manual

A financial interest is not necessarily a conflict of interest. Under §08.06.02.02 a person who has a financial interest may have conflict of interest only if the Board, which considers transactions or arrangements with a value exceeding \$150,000 or the Executive Committee, which considers transactions or arrangements with a value up to \$150,000, decides that a conflict of interest exists.

Compensation: direct and indirect remuneration including gifts or favors that exceed Internal Revenue Service guidelines.

08.06.02 Procedures

08.06.02.01 Duty to Disclose

In connection with any actual or possible conflict of interest, an interested person must disclose the existence of the financial interest and be given the opportunity to disclose all material facts to the members of the Board or Executive Committee, whichever is considering the proposed transaction or arrangement.

08.06.02.02 Determining Whether a Conflict of Interest Exists

After disclosure of the financial interest and all material facts, and after any discussion with the interested person, he or she shall leave the meeting while the determination of a conflict of interest is discussed and voted upon. The remaining Board or Executive Committee members shall decide if a conflict of interest exists.

08.06.02.03 Addressing the Conflict of Interest

An interested person may make a presentation at the meeting, but after the presentation, he or she shall leave the meeting during the discussion of, and the vote on, the transaction or arrangement involving the possible conflict of interest.

The chairperson of the Board or Executive Committee, whichever is considering the transaction or arrangement, shall, if appropriate, appoint a disinterested person or *ad hoc* committee to investigate alternatives to the proposed transaction or arrangement.

The Board or Executive Committee, exercising due diligence, shall determine whether a more advantageous transaction or arrangement with a person or entity that would not give rise to a conflict of interest can be obtained with reasonable effort.

If a more advantageous transaction or arrangement is not reasonably possible under circumstances not producing a conflict of interest, the Board or Executive Committee, whichever is considering the transaction or arrangement, shall determine by a majority vote of the disinterested members whether the transaction or arrangement is in the best interest of HL7, for its own benefit, and whether it is fair and reasonable. In conformity with the above determination it shall make its decision as to whether to enter into the transaction or arrangement.

08.06.02.04 Violations of the Conflict of Interest Policy

If the Board or Executive Committee, whichever is considering the transaction or arrangement, has reasonable cause to believe a member has failed to disclose actual or possible conflicts of interest, it shall inform the member of the basis for such belief and afford the member an opportunity to explain the alleged failure to disclose.

If, after hearing the member's response and after making further investigation as warranted by the circumstances, the Board or Executive Committee determines the member has failed to disclose an actual or possible conflict of interest, it shall take appropriate disciplinary and corrective action.

08.06.03 Records of Proceedings

The minutes of the Board and Executive Committee shall contain:

- The names of the persons who disclosed or otherwise were found to have a financial interest in connection with an actual or possible conflict of interest, the nature of the financial interest, any action taken to determine whether a conflict of interest was present, and the decision as to whether a conflict of interest in fact existed.

HL7 Governance and Operations Manual

- The names of the persons who were present for discussions and votes relating to the transaction or arrangement, the content of the discussion, including any alternatives to the proposed transaction or arrangement, and a record of any votes taken in connection with the proceedings.

08.06.04 Compensation Decisions

A voting member of the Board or Executive Committee who receives compensation, directly or indirectly, from HL7 for services is precluded from voting on matters pertaining to that member's compensation.

A voting member of any committee whose jurisdiction includes compensation matters and who receives compensation, directly or indirectly, from HL7 for services is precluded from voting on matters pertaining to that member's compensation.

Any voting member of the Board, the Executive Committee, or any committee whose jurisdiction includes compensation matters and who receives compensation, directly or indirectly, from HL7, either individually or collectively, is prohibited from providing information to any committee regarding compensation.

08.06.05 Annual Statements

Each director, Officer and member of the Executive Committee shall annually sign a statement which affirms such person:

- Has received a copy of the conflict of interest policy including current Internal Revenue Service guidelines on the value of acceptable gifts or favors,
- Has read and understands the policy
- Has agreed to comply with the policy, and
- Understands that to maintain its federal tax exemption HL7 must engage primarily in activities which accomplish one or more of its tax-exempt purposes.

08.06.06 Periodic Review

To ensure HL7 operates in a manner consistent with its purposes and does not engage in activities that could jeopardize its tax-exempt status, periodic reviews shall be conducted. The periodic reviews shall, at a minimum, include the following subjects:

- Whether compensation arrangements and benefits are reasonable, based on competent survey information and the result of arm's length bargaining.
- Whether partnerships, joint ventures, and arrangements with management organizations conform to written policies, are properly recorded, reflect reasonable investment or payments for goods and services, further the purposes of HL7 and do not result in inurement, impermissible private benefit or in an excess benefit transaction.

08.06.07 Use of Outside Experts

When conducting the periodic reviews as provided for in §08.06.06, HL7 may, but need not, use outside advisors. If outside experts are used, their use shall not relieve the Board of its responsibility for ensuring periodic reviews are conducted.

08.07 Whistleblower Policy: Reporting Illegalities or Issues of Noncompliance

08.07.01 Reporting Encouraged

HL7 encourages members, whether volunteers or employees, to bring forward complaints, reports or inquiries about presumed illegal practices or serious violations of HL7 policy, including questionable conduct by HL7 itself, by its leadership, volunteers, employees, or by others on its behalf. Appropriate subjects to be raised under this policy would include financial improprieties, accounting or audit matters, ethics violations, or other similar illegal or improper practices or policies which may not be compliant with state or federal law.

Operational processes with existing complaint mechanisms defined should be addressed using those mechanisms, such as matters related to the reconciliation of negative ballots, election processes, or

HL7 Governance and Operations Manual

issues related to the maintenance of the Governance and Operations Manual (GOM) or HL7 Essential Requirements (ER). This policy is not intended to provide a means of appeal from outcomes in such other matters.

08.07.02 Protection from Retaliation

Retaliation by or on behalf of HL7 against employees or volunteers for making good faith complaints, reports or inquiries under this policy or for participating in a review or investigation under this policy is strictly prohibited. This protection extends to those whose allegations are made in good faith but prove to be mistaken. However, HL7 reserves the right to discipline persons who make bad faith, knowingly false, or vexatious complaints, reports or inquiries or who otherwise abuse this policy. Such disciplinary action may include loss of employment and expulsion from the organization.

08.07.03 Reporting Process

Complaints, reports or inquiries under this policy may be made anonymously. All such complaints, reports or inquiries shall be treated confidentially. Each shall describe in detail, to the extent known to the submitter, the facts demonstrating the basis for the complaint, report or inquiry. Complaints, reports or inquiries submitted under this policy may, at the discretion of the submitter, be directed to the Executive Director or Chairperson of the Board of Directors; if both of those persons are implicated in the complaint, report or inquiry, it should be directed to the Vice-chair of the Board. The recipient of such a complaint, report or inquiry submitted under this policy shall be designated the Lead Investigator and may seek additional assistance as needed.

It must be recognized that HL7 may be unable to fully evaluate a vague or ambiguous complaint, report or inquiry, especially if made anonymously. In which case said complaint, report or inquiry may not be instantiated. Reports or complaints for which no reasonable method exists to investigate, instantiate or to be further collaborated shall be dismissed out of hand.

08.07.04 Investigative Process

Upon receipt of a complaint, report or inquiry under this policy the Lead Investigator shall jointly inform HL7 Headquarters and the Executive Committee of such receipt; outlining the issue raised unless doing so would compromise the investigation. The Lead Investigator shall begin an investigation of the alleged misconduct. The Lead Investigator may, at their discretion, ask HL7 Headquarters to distribute, via appropriate list servers, a message calling for any individual with knowledge of the issue to come forward offering an anonymous channel to do so.

Should the nature of the complaint be related to a violation of state or federal law, the Lead Investigator shall engage the Executive Director or Associate Executive Director or Chief Executive Officer (CEO) to address the need for legal counsel and/or outside investigative services. Such investigations, whether internal or external, shall be conducted in a fair, impartial, thorough, and thoughtful manner.

08.07.05 Resolution Process

Upon completion of the investigative process, whether internal or external, the Lead Investigator shall prepare a report of the outcome of the investigation and resolution of the issue with a recommendation as to final distribution; said report to be delivered to the Board of Directors. The Lead Investigator shall confer with those involved in the investigation to determine if any related documentation shall be sealed to protect confidentiality.

All documentation related to the investigation and resolution of those substantiated complaints, reports or inquiries submitted under this policy shall be maintained by HL7 Headquarters for a period of seven years.

09 Intellectual Property

Intellectual property rights shall be extended to any HL7 material (Informative, STU, or Normative) that has passed ballot. Beginning with the approval of balloted material and continuing for a period of 90-days from the date of publication access to said ballot material shall, with the exception of that material subject to prior agreement or named in proposed or final rules (§09.01.10), be restricted to HL7 International and Affiliate members.

HL7 Governance and Operations Manual

This provision shall include those drafts of such material representing the Work Group's effort to prepare the material for final review and subsequent request for publication. The responsible Work Group shall ensure that such materials are stored in a manner as to only be accessible to the membership, as defined in the Co-chair Handbook, until such restrictions are lifted by Headquarters.

Intellectual property issues are often expressed in legal terms that may require interpretation. The reader is encouraged to seek legal counsel for interpretation of the contents of this section and their relevance to you or your organization. HL7 acknowledges that a participant's knowledge of intellectual property and possible infringement is limited to his or her own personal knowledge and does not include knowledge or constructive knowledge of any other member or non-member.

09.01 Copyright

All HL7 Protocol Specifications (§02.02) are protected under the provisions of US and International copyright law. Rights are granted based on type of HL7 membership. Those HL7 Protocol Specifications identified by the Executive Committee as publicly available for distribution may be distributed, in whole or in part, by current HL7 members without concern for violation of the prohibitions expressed in the **Bylaws** under **§02.03.02 Individual Membership** or **§02.03.03 Organizational Membership**.

09.01.01 Copyright Protection

The HL7 Protocol Specifications (§02.02) are an evolving and expanding body of work prepared by the members of HL7. They are protected as works of copyrightable authorship under applicable US and international copyright principles. Consistent with these principles, HL7 asserts and holds domestic and international copyrights to the HL7 Protocol Specifications. Recognizing that the HL7 Protocol Specifications are the work product of the membership of HL7, and that HL7 is the collective representative of all of the member's interests, these copyrights are asserted and held by Health Level Seven International in its capacity as the representative of its total membership. All members of HL7 have and will continue to possess the usage rights to the HL7 Protocol Specifications as authorized by the HL7 member agreements and International Affiliate agreements.

To achieve the twin objectives of

- assuring the integrity of the HL7 Protocol Specifications, and
- guaranteeing that users may secure from a reliable source a verified version of a particular HL7 Protocol Specification,

HL7 has and will continue to enforce the copyrights it holds in the HL7 Protocol Specifications. As dissemination and implementation of the HL7 Protocol Specifications continues, it is imperative that HL7 have a method to assert and enforce its role to maintain the official editions of the HL7 Protocol Specifications. Copyright provides this enforcement and protection mechanism.

09.01.02 Commitment

All those contributing to the HL7 Protocol Specifications (§02.02), be they members or non-members, grant a free, irrevocable license to HL7 to:

- incorporate any contributions regardless of media or form, and any subsequent modifications thereof, in the creation or maintenance of HL7 Protocol Specifications;
- copyright in HL7's name any Protocol Specification even though it may include portions of said contributions; and
- permit others, at HL7's sole discretion, to reproduce in whole or in part the resulting Protocol Specifications.

All contributors further acknowledge that, to the best of their personal knowledge, all contributions are free of encumbrance as it relates to the intellectual property rights of others.

HL7 Governance and Operations Manual

09.01.03 Previously Copyrighted Material

The use of previously copyrighted material in HL7 Protocol Specifications (§02.02) is discouraged; rather the material should be referenced by name and source including any known licensing requirements. However, if such material is deemed sufficiently important to merit insertion the appropriate Work Group chair shall petition HL7 Headquarters to seek formal authorization for its use, both in the HL7 Protocol Specifications and by the membership. A note citing the copyright and authorization for use shall be included in the HL7 Protocol Specifications; without such authorization the material may not be inserted in the HL7 Protocol Specifications.

09.01.04 Independently Developed Specifications

The submission of independently developed specifications for consideration as a potential HL7 Protocol Specification (§02.01) or to serve as the basis for HL7 Protocol Specification development is encouraged. In order to ensure unencumbered development a written release of unrestricted world rights to use a specification as the basis for development of an HL7 Protocol Specification and for all future revisions and editions of that HL7 Protocol Specification is required.

The copyright to the original text and its future development outside of HL7 is not forfeit as a result of giving permission to use the specification as the basis for an HL7 Protocol Specification; however, the results of such development outside of HL7 shall not be referred to as an HL7 Protocol Specification. The original copyright of the base specification will be cited in the front matter of the approved HL7 Protocol Specification.

Unless available through other licensing mechanisms such as Creative Commons and like collaborative agreements; HL7 Headquarters shall consider and enter into negotiations with any organization wishing to reproduce, embed and/or distribute HL7 copyrighted materials within their proprietary documentation (hardcopy and online) and within their applications. The CTO shall be responsible for ensuring due diligence in the negotiations for the release and use of HL7 intellectual property.

In all cases, such use shall require a contract that shall include, among other items, the following imperatives: (a) HL7 shall be clearly identified as publisher of the Protocol Specifications and holder of the copyright, and (b) any additions, omissions, or other modifications to the HL7 Protocol Specifications shall be clearly identified to end-users. The CEO shall be the signatory for HL7 on any and all such contracts.

The proposed contract resulting from the aforementioned negotiations shall be reviewed and approved by the Executive Committee prior to execution.

09.01.05 Negotiated Use of HL7 Copyrighted Materials

Unless available through other licensing mechanisms such as Creative Commons and like collaborative agreements; HL7 Headquarters shall consider and enter into negotiations with any organization wishing to reproduce, embed and/or distribute HL7 copyrighted materials within their proprietary documentation (hardcopy and online) and within their applications. The CTO shall be responsible for ensuring due diligence in the negotiations for the release and use of HL7 intellectual property.

In all cases, such use shall require a contract that shall include, among other items, the following imperatives: (a) HL7 shall be clearly identified as publisher of the Protocol Specifications and holder of the copyright, and (b) any additions, omissions, or other modifications to the HL7 Protocol Specifications shall be clearly identified to end-users. The CEO shall be the signatory for HL7 on any and all such contracts.

The proposed contract resulting from the aforementioned negotiations shall be reviewed and approved by the Executive Committee prior to execution.

09.01.06 Academic Access to HL7 Copyrighted Materials

Unless available through other licensing mechanisms such as Creative Commons and like collaborative agreements; HL7 copyrighted materials shall be made available on a by-request basis to faculty of accredited educational institutions that are members of HL7 for the purpose of teaching for-credit courses in healthcare informatics or related subjects.

HL7 Governance and Operations Manual

Non-member faculty making such requests will be advised of the benefits of membership and encouraged to join HL7. If the faculty member declines membership, limited access to only those materials appropriate to the course in question will be granted for a period not to exceed the duration of such course in the approved curriculum.

In all cases faculty will attribute such material to HL7 and notify students that reproduction of HL7 material or the use of HL7 material in any sense beyond the stated curriculum is expressly prohibited.

09.01.07 Use of HL7 Copyrighted Materials in Other Educational Scenarios

Unless available through other licensing mechanisms such as Creative Commons and like collaborative agreements; a member desiring to include and/or distribute HL7 copyrighted materials in non-academic educational scenarios shall submit a request to the HL7 Associate Executive Director for the consideration of the Executive Committee. The request shall include a description of the educational event; the specific HL7 copyrighted materials involved; and the method by which access to such materials will be restricted to designated attendees.

All such material shall be attributed to HL7 and attendees shall be notified that reproduction of HL7 material or the use of HL7 material in any sense beyond the educational event is expressly prohibited. Within two weeks of the approved use or distribution of such materials, the member shall submit a list of those individuals given access to or provided a copy of the materials.

09.01.08 Use of HL7 Copyrighted Materials by Organizational Members

Organizational members are granted use of HL7 protocol specifications in the development of software applications and messaging systems for direct use or distribution without additional licensing fees.

09.01.09 HL7 Copyrighted Material Related to Proposed or Final Regulations

Upon notification of the publication of proposed or final regulations of any national jurisdiction including by reference any HL7 protocol specification Headquarters shall make the cited HL7 protocol specification readily available to the general public through the HL7 web site.

09.02 Trademarks

09.02.01 Registered Trademark

Use of any HL7 registered trademark, whether printed or electronic, to endorse, promote, foster, or criticize any commercial product, vendor, or service, or to express personal views about legislative or regulatory issues is prohibited. Use of the HL7 trademark by HL7 members does not imply endorsement of any given organization, product, or service by HL7.

09.02.02 Use of HL7 Trademarks

Use of Health Level Seven International trademarks in URL domains or to brand a specific product or service without the express written consent of Health Level Seven International is strictly prohibited.

HL7 has worked for years to build a strong organization that is known worldwide for quality and integrity. The trademarks owned by HL7 are an important part of maintaining that strength and reputation. The following are guidelines regarding the use of Health Level Seven-owned trademarks.

HL7®, HEALTH LEVEL SEVEN®, CARE CONNECTED BY HL7®, CCD®, CDA®, FHIR®, the FHIR logo® [FLAME DESIGN] and GREENCDA™ are trademarks owned by HL7 International. All of the above, with the exception of GREENCDA™, are registered with the United States Patent and Trademark Office.

All non-trademark uses of the foregoing marks should include the ® or ™ symbol as appropriate and indicate in text that: "<insert artifact name(s)> is the registered trademark of Health Level Seven International. For example: "HL7, CDA, FHIR and the FHIR logo [FLAME DESIGN] are the registered trademarks of Health Level Seven International." For GREENCDA™ you should omit the word "registered".

HL7 Governance and Operations Manual

Please refer to Fast Healthcare Interoperability Resources as the "HL7® FHIR® standard". When referencing the FHIR® standard in a web site, document, presentation, or otherwise refer to it as the "HL7® FHIR® standard" in a place of prominence. In subsequent uses, please refer to it as the "FHIR® standard" or "FHIR®", using the ® symbol as often as is practical, at least once on each page of printed matter, usually in connection with the first or dominant usage. The FHIR [Flame Design] logo should always include the ® symbol.

The HL7 web site provides an [FAQ](#) to help you better understand fair use of the Health Level Seven-owned trademarks.

09.02.03 Use of Other Trademarks

The use of trademarks or service marks, other than those registered by HL7, in HL7 Protocol Specifications (§02.02) is discouraged; however, when used the first occurrence of the mark will be indicated by the appropriate symbol and the name of the trademark owner will be annotated in the front matter of the HL7 Protocol Specification.

09.03 Patents

Participant's knowledge of any essential patent claims or outstanding patent applications that may be applicable to the HL7 Protocol Specifications (§02.02) is not contingent on having conducted a patent search nor is a patent search a requirement for contributions by the participant.

09.03.01 Commitment

All participants shall identify to HL7 Headquarters, through the issuance of a letter of assurance, any patents or patent applications felt to be applicable to the HL7 Protocol Specifications (§02.02). This assurance shall be provided without coercion and shall take the form of either:

- A general disclaimer to the effect that the patent holder will not enforce any of its present or future patent(s) that would be required to implement the proposed HL7 Protocol Specifications relevant to any person or entity using the patent(s) to comply with the HL7 Protocol Specifications, or
- A statement that a license will be made available without compensation or under reasonable rates, with reasonable terms and conditions that are demonstrably free of any unfair discrimination. This assurance shall apply, at a minimum, from the date of the HL7 Protocol Specification's approval to the date of the HL7 Protocol Specification's withdrawal, being irrevocable during that period.

09.03.02 Essential Patent Claims

"Essential Patent Claims" means claims of a patent or patent application (if issued) that would necessarily be infringed upon by implementation of the HL7 Protocol Specification (§02.01). A claim is necessarily infringed hereunder only when it is not possible to avoid infringement because there is no commercially plausible non-infringing alternative for implementing the HL7 Protocol Specification, including the protocols, application program interfaces, and/or data structures disclosed with particularity in the HL7 Protocol Specification in order to enable products to interoperate, interconnect or communicate as defined within the HL7 Protocol Specification.

Notwithstanding the foregoing, Essential Patent Claims shall not include any claims other than as set forth above even if contained in the same patent as essential claims; or that, if licensed, would require a payment of royalties by the licensor to unaffiliated third parties. Moreover, essential patent claims shall not include:

- any enabling technologies that may be necessary to make or use any product or portion thereof that complies with the HL7 Protocol Specification but are not themselves expressly set forth in the HL7 Protocol Specification (e.g., compiler technology, existing high-level application programs, basic operating system technology, and the like); or
- the implementation of other published standards developed elsewhere and merely referred to in the body of the HL7 Protocol Specification, or

HL7 Governance and Operations Manual

- any portions of any product and any combinations thereof the purpose or function of which is not required for compliance with the HL7 Protocol Specification or that read solely on any implementations of any portion of the HL7 Protocol Specification that are not required by the HL7 Protocol Specification.

09.03.03 Withdrawal and Survival of Commitments for Essential Patent Claims

Upon a member's notice of withdrawal from membership or termination of membership for any reason pursuant to §03.10, the commitments of the withdrawing or terminating member stipulated under §09.03.01 shall survive, but only with respect to

- any HL7 Protocol Specification (§02.02) adopted by normative ballot within 60 days after notice of withdrawal or effective date of termination, and
- any contribution of that member that has been, or that later is, incorporated in any HL7 Protocol Specification by normative ballot.

09.03.04 Disclaimer

HL7 is not responsible for either identifying patents for which a license may be required to implement an HL7 Protocol Specification (§02.02) or for conducting inquiries into the legal validity or scope of those patents that are brought to its attention. HL7 Headquarters shall notify the membership via email of any patent claims leveled against the HL7 Protocol Specifications.

09.04 Material in the Public Domain

The public domain is that body of knowledge and innovation to which no person or other legal entity can establish or maintain proprietary interests. Material from the public domain included in the HL7 Protocol Specification (§02.02) shall, whenever possible, include annotation citing source as evidence of its status.

10 The Technical Steering Committee (TSC)

A Technical Steering Committee (TSC) shall be established to facilitate the coordination and activities of the Working Group. It shall be comprised of the co-chairs from each of the four Steering Divisions (SD), two Affiliate representatives, and appropriate HL7 staff. No individual shall hold more than one voting position on the TSC. The SD co-chairs shall share a single vote at the TSC for the purposes of formal motions; but otherwise both will be fully participating members of the TSC. Each of the Affiliate representatives shall cast an individual vote on formal motions. The Chief Technology Officer (CTO) as well as the Co-chairs of the Architecture Review Board (ARB) shall be *ex officio* members with vote. The ARB Co-chairs shall share a single vote on formal motions. The TSC shall elect its own Chair.

Should the TSC identify an imbalance or the need for specific expertise, they may vote to include *ad hoc* members with vote to correct the situation. Should an *ad hoc* member be elected to or otherwise attain a voting position on the TSC they shall be seated in said position and shall not retain *ad hoc* status.

Additional information on TSC organization and function, including decision making practices (DMP), can be found on the [TSC Wiki](#).

The TSC shall be responsible for product project approval and management oversight including:

- Establishing and maintaining an HL7 Architecture, development methodologies, and work processes to be used by The Working Group in developing HL7 Protocol Specifications
- Ensuring that the efforts of The Working Group to produce protocol specifications proceeds at a reasonable pace
- Ensuring that The Working Group collaborates smoothly and covers the scope of work in a consistent manner.
- Managing the ballot and distribution process for those HL7 Protocol Specifications identified by the Executive Committee as intended to be freely available to the public.

HL7 Governance and Operations Manual

10.01 Chair

The TSC shall select its chair at a regularly scheduled meeting during the last Working Group Meeting of the year in odd numbered years. Candidates must be regular members currently seated or recently elected, including *ad-hoc* members but excluding *ex officio* members or from among qualified former TSC members. The individual selected as TSC Chair must be a current member of HL7.

All current TSC members with vote shall cast an individual vote for TSC Chair via an electronic ballot provided by HQ.

The selected individual shall take office in January of the following even numbered year.

10.02 Term of Office

Ex officio members of the TSC are not subject to a term of office beyond that prescribed by their respective offices.

10.02.01 TSC Chair

The TSC Chair shall serve a term of two years without term limits.

Should the individual selected to serve as TSC Chair not be a current member of the TSC they shall serve their term as an *ad hoc* member of the TSC.

Should the individual selected to serve as the TSC Chair be a current member having only a year remaining of their term as an SD or Affiliate representative and is not subsequently elected to another term as a representative, the second year of their term as TSC Chair shall be served as an *ad hoc* member of the TSC.

10.02.02 Elected Members

SD co-chairs and Affiliate representatives shall serve a term of two years without term limits.

10.02.03 Ad Hoc Members

An *ad hoc* member serves at the pleasure of the TSC Chair; but in no instance should their term exceed two-years subject to reappointment.

10.03 Removal from Office

Criteria for removal shall include:

- mismanagement or obfuscation of TSC projects or processes
- failure to attend two consecutive Work Group Meetings without notice or the subsequent presentation of mitigating circumstances; or
- failure to participate in at least 60% of the TSC teleconferences held in the preceding calendar year;
- failure to meet the commitment of at least two hours per week to the TSC.
- undesirable or disruptive behavior that deviates from the Code of Conduct (§04)

10.03.01 TSC Chair

Should the Executive Committee (EC) be advised or determine, at any time, the performance of the TSC Chair to be egregious or detrimental to committee process, they may:

- defer the issue; choosing to counsel and observe the TSC Chair's ongoing performance, or
- make a motion to the Board for the removal of the TSC Chair.

Having deferred the issue and noting no significant improvement within 90 days, the EC shall make a motion to the Board for the removal of the TSC Chair.

Upon receipt of a motion for removal of the TSC Chair the Board shall, following sufficient debate to ensure due process, vote on the motion.

HL7 Governance and Operations Manual

A decision to remove the TSC Chair shall result in 1) that individual immediately stepping down from the position of TSC Chair; 2) removal of that individual from the TSC web page and TSC Member list; and 3) initiation of a process pursuant to § 10.01.04.01 to identify a replacement TSC Chair.

10.03.02 SD Co-chair

Should the performance of a Steering Division (SD) co-chair at any time be judged egregious or detrimental to good practice by the SD they may, using their decision-making practices, make a motion to the TSC for removal of said SD co-chair.

Upon receipt of a motion for removal of a SD co-chair the TSC shall take appropriate action which may range from counseling to removal of non-participating or non-performing co-chairs following sufficient fact gathering to ensure due process.

A decision to remove an SD co-chair shall result in 1) that individual immediately stepping down from the position of SD co-chair; 2) removal of that individual from the list of SD co-chairs on the Steering Division's web page and TSC Member list; and 3) initiation of a process pursuant to § 10.01.04.02 to identify a replacement SD co-chair.

10.03.03 Affiliate Representatives

Should the performance of an Affiliate representative at any time be judged egregious or detrimental to good practice by members of the International Council they may, using their decision-making practices, make a motion to the TSC for removal of said Affiliate representative.

Upon receipt of a motion for removal of an Affiliate representative the TSC shall take appropriate action which may range from counseling to removal of the non-participating or non-performing representative following sufficient fact gathering to ensure due process.

A decision to remove an Affiliate representative shall result in 1) that individual immediately stepping down from the position of TSC representative; 2) removal of that individual from the TSC Member list; and 3) initiation of a process pursuant to § 10.04.03 to identify a replacement Affiliate representative.

10.04 Vacancies

Members no longer able to fulfill their responsibilities shall resign from the TSC.

10.04.01 TSC Chair

Upon the resignation or removal of the chair, the TSC shall select another individual, be they a current or former member, to complete the remaining term of office.

10.04.02 SD Co-chair

Upon the resignation or removal of an SD co-chair, the SD, following its decision-making practices, shall appoint an interim co-chair.

10.04.03 Affiliate Representatives

Upon the resignation or removal of an Affiliate representative, the International Council shall designate an individual to complete the remaining term of office.

10.05 Meetings

The TSC Chair shall convene the TSC at least once during each Working Group Meeting (WGM). Interim to the WGM, the TSC shall convene via teleconference on a schedule established by the TSC Chair.

Election to the TSC, either as a Steering Division co-chair or Affiliate representative, carries with it the responsibility to attend TSC meetings, whether held in conjunction with the WGM or conducted via teleconference. TSC nominees and members acknowledge that they have the support of their organizations in seeking a position on the TSC and agree that they, either individually or through their organizations, will be responsible for the expenses associated with participation as a TSC member.

HL7 Governance and Operations Manual

10.05.01 Hardship Waiver of Working Group Meeting Fees

The HL7 Executive Director or Associate Executive Director may, at their discretion, grant a waiver of fees to any current TSC member who has paid attendance for at least three of the last four Working Group Meetings and has encountered hardship (e.g., become unemployed) since the last meeting. This waiver is limited to once per TSC term.

10.05.02 Observers

TSC meetings held during a Working Group Meeting shall be open to observers unless called into executive session by the TSC Chair. Observers shall be restricted to seating on the periphery as directed by HL7 staff. Observers shall not cause distractions or otherwise interrupt the conduct of the TSC meeting. Observers wishing to contribute to the meeting shall seek the attention of the TSC Chair and wait to be recognized.

10.06 Standards Development Framework

The Technical Steering Committee (TSC) shall be responsible for the development and maintenance of a standards development framework to define, clarify, and delineate the processes employed by HL7. The following, at minimum, shall be addressed: overall governance of the framework, common processes, specific processes that may be applicable to individual product lines or product families, support processes, and performance checkpoints. These elements should be described in sufficient detail to act as a guide to both experienced standard developers as well as those new to the HL7 process. Certain artifacts which articulate this framework may be balloted in order to formalize and promote the good practices inherent in the HL7 process. Beyond the overall framework, product families may, with the approval of the TSC, adopt specific supporting methodologies.

10.07 Interpretation of Non-normative HL7 Protocol Specifications

The Chief Technology Officer (CTO) or, in his or her absence, the TSC Chair shall be responsible for official interpretation of all non-normative HL7 Protocol Specifications (§02.02).

Requests for interpretation of an HL7 Protocol Specification shall be submitted by letter to HL7 Headquarters. In addition to the specific query, the request shall include the submitter's name, affiliation, address, telephone, and email address. Such submissions shall be routed to the CTO and TSC who may refer the request to the appropriate Work Group for consideration.

The CTO or TSC Chair, in collaboration with the TSC, shall respond in kind to written requests for interpretation. These written interpretations shall be retained on file and made available electronically. When determined by the CTO or TSC Chair to be of value to the membership, reference to a current interpretation may be included in the TSC Update section of the next HL7 eNews.

10.08 Endorsing Tools for Standards Development

The TSC shall be responsible for ensuring that any tools created or promoted for the development of HL7 Protocol Specifications (§02.02) are thoroughly tested and documented, and that such tools have established maintenance and support mechanisms. Upon such assurance, the TSC may endorse those tools for use by the membership. The decision of the TSC shall be final.

10.09 The Working Group

Collectively the various Work Groups established by the Technical Steering Committee to focus on particular aspects of the HL7 protocol specifications shall be known as The Working Group.

10.10 US Realm Steering Committee (USR-SC)

The Board of Directors, supporting the vision of providing the best and most widely implemented international healthcare standards while still accommodating the specific requirements of the US Realm (USR), has created the US Realm Steering Committee (USR-SC). The USR-SC shall collaborate with the Technical Steering Committee (TSC) to oversee and coordinate the technical efforts of the Working Group to ensure focus on the overall HL7 International mission while still addressing US Realm requirements. The USR-SC maintains a [web page](#) with cross reference to the US Realm Task Force (USR-TF).

HL7 Governance and Operations Manual

10.10.01 Purpose

The USR-SC shall review and provide oversight to USR projects during the approval process; allowing the USR-SC to identify gaps and/or overlaps with other Working Group projects and USR requirements. The USR-SC shall be responsible for establishing appropriate governance, management and methodologies for USR standards development based on existing best practices of the TSC.

10.10.02 Scope

The USR-SC shall be responsible for overseeing the execution of USR standards development within HL7 International while assuring that such efforts are aligned with the overall product and services strategy set forth by the Board of Directors. The USR-SC shall restrict its activities to oversight of USR projects brought forward for development by the various Work Groups (WG); relying on the TSC to ensure that the various WG collaborate in an efficient and consistent manner to meet HL7 International objectives. Should the USR-SC see a need for more direct interaction with the various WG, it shall work through the TSC to achieve such oversight. In all cases, the USR-SC shall coordinate its communications through the TSC, the primary source for status and guidelines regarding HL7 standards and standards development.

10.10.03 Formal Relationships

The USR-SC may recommend representation on other HL7 committees, such as the International Council, but such recommendations are subject to review and approval of the Board of Directors. Members of the USR-SC may also act as liaisons to Board-appointed committees at the discretion of the Board of Directors.

Formal relationships between the USR-SC and any organizations outside of HL7 International shall be governed by Statements of Understanding (SOU) or other agreements between HL7 International and such organizations as established by the Executive Committee.

10.10.04 Composition

The USR-SC shall be composed of the following voting members:

- A Chair appointed by the Board of Directors
- A Vice Chair selected by the Chair and approved by the Executive Committee
- The TSC Chair
- The Chief Technical Officer (CTO)
- Four individuals, each representing one of the four TSC Steering Divisions
- One individual, typically one of the co-chairs, representing the Architecture Review Board (ARB)
- Three at large members, at least one of whom shall represent the Affiliates
- Up to four *ad-hoc* members representing external stakeholder organizations

The TSC Steering Division representatives shall be selected by the USR-SC Chair from a list of recommended candidates submitted by their respective Steering Divisions and approved by the TSC.

The at large members may self-nominate, be nominated by a current HL7 member, or solicited by the USR-SC Chair, Vice Chair or CTO. The USR-SC Chair shall select members from among the list of nominees for approval by the TSC.

Ad-hoc members shall be chosen by the USR-SC Chair and approved by the TSC.

10.10.05 Term of Membership

Other than the USR-SC Chair and Vice Chair, members of the USR-SC shall serve a two-year term from their date of appointment, with initial terms staggered such that approximately half of member terms expire in any given year.

HL7 Governance and Operations Manual

Other than the USC –SC Chair and Vice Chair, members shall be eligible for reappointment at the discretion of the TSC.

The USC-SC Chair may be reappointed at the discretion of the Board of Directors. The USR-SC Vice Chair may be replaced or reappointed by the Chair with the approval of the EC.

10.10.06 Inactive Members

Any USR-SC member who is declared inactive by the USR-SC Chair may be removed from the USR-SC by vote of the Executive Committee, whose decision shall be final.

10.10.07 Reporting

While functioning as a component of the TSC, the USR-SC is a duly constituted Board of Directors committee. As such, the USR-SC shall submit reports to the Board quarterly or as otherwise requested by the Board.

10.11 HL7 Terminology Authority (HTA)

The HTA is responsible for the creation, implementation, and management of HL7 processes involving external terminology management. These processes shall be influenced by input from the Vocabulary Work Group and existing HL7 terminology practices. The [activities of the HTA](#) are intended to complement maintenance of terminology that is used by HL7 Protocol Specifications. The HTA shall work through the Technical Steering Committee (TSC) to implement any processes or policies that impact the Working Group.

10.11.01 Purpose

The HTA, as a representative body of HL7 International, shall ensure that HL7 provides timely and high-quality terminology products and services needed for standards development. The HTA shall serve as the single point of contact for any external terminology with which HL7 has established, or in the future shall establish, formal relationships. The HTA works with both the Vocabulary Work Group, responsible for technical terminology structures in HL7 Protocol Specifications, and HL7 Unified Terminology Governance, responsible for improving the development and use of HL7-authored terminology.

10.11.02 Scope

The HTA is exclusively focused on terminology used in HL7 Protocol Specifications that is derived from or associated with external terminology systems. Responsibilities include:

- Develop and maintain quality processes and measures related to HL7 terminology derived from external terminology
- Provide advice, where needed, on the acceptability of external vocabulary proposed for inclusion in HL7 terminology
- Maintain relationships with external terminology authorities to ensure legal use of their products.

10.11.03 Participation in the Harmonization Process

The HTA shall:

- Be a steward representative to the Harmonization Process
- Review vocabulary content from external terminologies and indicate if this content does/does not meet the requirements of contractual and MOU agreements with external terminology providers, including technical review of the proposals
- Consider proposals submitted by vocabulary facilitators. in response to requests for new coded content, as to whether content coverage requested is provided by an external terminology. If deemed appropriate for derivation from or addition to an external terminology, the HTA shall recommend that the proposal be revised to reflect the use of the appropriate external terminology. Should the recommendation be accepted, the HTA shall manage any content change submissions to the involved external terminology authority.

HL7 Governance and Operations Manual

- Review, upon request and ideally well before harmonization, proposals for and development of external terminology content prior to harmonization submission providing assistance and feedback on the external content
- Ensure an HTA representative participates in Harmonization calls
- Provide a representative for the Facilitators Round Table on Thursday evening during the WGM
- Review the posted harmonization minutes for any assigned action items; any resulting new content; or any assigned identifiers being returned for harmonization

10.11.04 Composition

The HTA shall be composed of a minimum of six current members of HL7 appointed by the Board of Directors including one Vocabulary WG co-chair plus at least two members representing International Affiliates. The HL7 Chief Technology Officer (CTO) shall issue a call for nominations to the HTA prior to the HL7 Plenary and present a slate of recommended candidates to the Board based on these nominations and other considerations. The Board shall ensure that such appointments are consistent with goals and objectives of the HTA and best serve the interests and responsibilities of HL7 International.

Following the HL7 Plenary in odd-numbered years and the seating of any new appointees, the HTA shall select a chair from among its members who shall assume his or her duties the following January.

Following the HL7 Plenary in even-numbered years and the seating of any new appointees, the HTA shall select a vice chair from among its members, who shall assume his or her duties, primarily the conduct of business in the Chair's absence, the following January.

10.11.05 Criteria for Membership

10.11.05.01 Qualifications

Candidates for membership in the HTA must recognize the importance of, and have a commitment to, the development and use of appropriate terminology as a critical success factor for HL7. They must be current members of HL7 or an HL7 Affiliate with strong written and verbal communication skills and expertise in at least one, but preferably all, of the following areas as assessed by the CTO:

- Large scale or enterprise-level development or management of terminologies with a focus on achieving working/semantic interoperability between data exchange stakeholders in both intra- and inter-enterprise contexts.
- Good terminology practices as defined by the Cimino desiderata coupled with in depth knowledge of the HL7 core principles for terminology
- Knowledge of the design and use of one or more of the large-scale reference terminologies commonly used in the healthcare domain; such as SNOMED CT, LOINC, ICD-10, etc.
- Realizing the implications of developing and managing an extension to one or more of the large-scale reference terminologies cited

10.11.05.02 Commitment

Candidates shall provide documentation of support for their participation on the HTA from their employers or a like statement of their personal commitment if individual members of HL7. Members of the HTA are expected to:

- Participate in 75% of scheduled conference calls
- Dedicate up to 2 hours each week around the time of the harmonization meetings, in addition to conference calls, to HTA deliverables
- Attend at least two of the three Working Group Meetings each year in person

HL7 Governance and Operations Manual

10.11.05.03 Trial Participation

Candidates wishing to be considered for appointment to the HTA may be expected or invited to participate in HTA discussions as non-voting individuals prior to becoming a candidate to ensure their ability to meet the expected commitments and demonstrate the appropriate qualifications. This will allow 'new' HL7 members to fully participate in the HTA and contribute to the work even if they are not yet personally known by the CTO, HTA Chair or Vice Chair.

10.11.06 Term of Membership

Members of the HTA shall serve a two-year term from their date of appointment, with three members being appointed in odd-numbered years and three members being appointed in even-numbered years. Members shall be eligible for reappointment for two additional terms.

Prior members may be appointed following a one term hiatus. The two-year hiatus may be overruled by the CTO or by the Board upon a motion from the majority of HTA members. Members may resign with notice or be replaced upon request.

10.11.06.01 Notification of Renewal

The Board shall provide two months' notice to the HL7 membership and HL7 Affiliates when HTA members are subject to reappointment or new appointments to the HTA are being considered. Comments relevant to such appointments may be submitted during this period for consideration by the Board prior to making their appointments to the HTA.

10.11.07 Change of Member's Employment Status

Should a member of the HTA experience a change in employment status, the Board reserves the right to seek the member's resignation from the HTA based on real or perceived "preponderance of influence" or any other concerns as expressed by the other members of the HTA or the Board; e.g. change of the HTA member's focus or priorities with respect to HL7 as expressed or demonstrated by the member's new employer or contract holder.

10.11.08 Removal and/or Replacement of Member

Any HTA member who, in the opinion of the HTA Chair or Vice Chair, is unable to satisfy the expected commitment based on both meeting attendance records and general effectiveness of participation may, with approval by the Board, be removed from the HTA at any point during their term.

Should an HTA member resign or be removed, the CTO shall make a recommendation to the Board for a replacement appointee who, with the Board's approval, shall serve the remainder of said individual's term.

10.11.09 Conduct of Meetings

HTA decision-making practices (DMP), as documented, shall be followed.

All HTA meetings shall be open to any interested party. Minutes shall be taken at all meetings and posted on the HTA wiki. HL7 and the SDO community in general are free to comment, criticize, or raise additional issues.

Each member is obligated to fully and fairly disclose to the Chair any real or potential conflict of interest the member has or may have with respect to any matter or item being considered, discussed or addressed by the HTA. In the case of such a conflict, the member must recuse themselves from both the discussion and subsequent vote on the item.

10.12 Architecture Review Board (ARB)

The Architecture Review Board (ARB) shall be responsible to the TSC for the development and maintenance of a coherent standards architecture which defines the relationship among the HL7 Protocol Specifications (§02.02) as well as the relationship of the HL7 Protocol Specifications to other standards and components of local implementations.

HL7 Governance and Operations Manual

This architecture shall also address the business components of the production and management of the HL7 Protocol Specifications; governance related to the HL7 Protocol Specifications; and the scope of the HL7 standardization effort. The specific contributions and scope of the ARB, as defined by the TSC, are available online at the [ARB overview page](#)

10.12.01 Composition

The ARB shall have two Co-chairs appointed by the Chief Technology Officer (CTO) with the approval of the TSC. The ARB shall have such additional members as deemed appropriate by the CTO and ARB Co-chairs to support productivity and task load based on the availability of willing candidates with appropriate skill sets subject to TSC approval.

There shall be no formal constraints or requirements for representation of any Work Group, Steering Division, or Organizational or Affiliate member. ARB candidates shall be chosen by the CTO and ARB Co-chairs. The TSC shall ensure that appointments to the ARB are consistent with the goals and objectives currently defined for the ARB and best serve the interests and responsibilities of HL7. While it is desirable that the ARB be representative of all the various communities involved in HL7, the CTO and TSC formally acknowledge that the primary criteria for ARB membership are qualifications and commitment of time and effort.

The ARB may, at its discretion, solicit the contribution of specific expertise in support of its activities by inviting select individuals to participate as *ad hoc* members with vote for the term of the specific activity or project.

10.12.02 Criteria for Membership

10.12.02.01 Qualifications

Candidates for membership in the ARB must recognize the importance of, and have a commitment to, enterprise architecture as a critical success factor for HL7. They must be current members of HL7 or an HL7 Affiliate with strong written and verbal communication skills and expertise in at least one, but preferably both, of the following areas as assessed by the CTO:

- Large scale enterprise-level architecture contexts with a focus on achieving working interoperability between software components/interfaces in both intra- and inter-enterprise contexts. Interoperability contexts include both traditional “messaging” exchanges of static semantics as well as more complex, multi-component scenarios involving both static semantics and dynamic behavioral interactions.
- HL7 “core infrastructure” components including complex data types, vocabulary binding, structured documents, methodology and modeling, infrastructure and messaging, implementation and conformance, etc.

10.12.02.02 Commitment

Candidates shall provide documentation of support for their participation on the ARB from their employers or a like statement of their personal commitment if individual members of HL7. Members of the ARB are expected to:

- Participate in 75% of weekly conference calls
- Dedicate 6 - 10 hours each week, in addition to conference calls, to ARB deliverables
- Attend at least two of the three Working Group Meetings each year

Given that an ARB member has met the criteria established in a. and b. above, the CTO may, at his or her discretion, grant a waiver of the Work Group Meeting attendance requirement (c. above) given suitable documentation of hardship; e.g., lack of funding.

HL7 Governance and Operations Manual

10.12.02.03 Trial Participation

Candidates wishing to be considered for full membership in the ARB may be expected or invited to participate in ARB discussions as *ad hoc* individuals prior to becoming a full member to ensure their ability to meet the expected commitments and demonstrate the appropriate qualifications. This will allow 'new' HL7 members to fully participate in the ARB and contribute to the work even if they are not yet personally known by the CTO or either ARB Co-chair.

10.12.03 Term of Membership

The CTO and ARB Co-chairs shall consider staggering appointments to the ARB to ensure continuity of knowledge of recent history and ongoing goals and objectives of the ARB.

10.12.03.01 ARB Co-chairs

There shall be no limit on the duration of service of the ARB Co-chairs subject to the approval of the TSC.

10.12.03.02 Other Members

All members of the ARB shall serve a two-year term from date of appointment, without term limits, subject to renewal at the discretion of the CTO and ARB Co-chairs with the approval of the TSC.

10.12.03.03 Notification of Renewal

The CTO shall provide two months' notice to the HL7 membership and HL7 Affiliates when certain ARB appointments are subject to renewal. Comments relevant to the renewal action may be submitted during this period for consideration by the CTO and ARB Co-chairs prior to making their recommendations on renewal to the TSC.

10.12.04 Change of Member's Employment Status

Should a member of the ARB experience a change in employment status, the TSC reserves the right to seek the member's resignation from the ARB based on real or perceived "preponderance of influence" or any other concerns as expressed by the TSC; e.g. change of the ARB member's focus or priorities with respect to HL7 as expressed or demonstrated by the member's new employer or contract holder.

10.12.05 Removal of Member

Any ARB member who – in the opinion of the CTO or either ARB Co-chair -- is unable to satisfy the expected commitment based on both meeting attendance records and general effectiveness of participation may, with approval by the TSC, be removed from the ARB at any point during their term.

10.12.06 Conduct of Meetings

All ARB meetings shall be open to any interested party. Minutes shall be taken at all meetings and posted on the ARB wiki. HL7 and the SDO community in general are free to comment, criticize, or raise additional issues.

10.13 Education Advisory Council (EAC)

The Education Advisory Council (EAC) shall provide subject matter expertise to the HL7 Director of Education (DOE) facilitating decisions related to the HL7 educational program.

10.13.01 Structure and Selection

The EAC shall have a minimum of six members, who shall be current HL7 members or representatives of a current Affiliate with relevant experience and expertise. EAC appointments shall be for two years subject to renewal without limits. Approximately half of the members shall be selected each year to ensure staggered terms for continuity. The EAC shall select a chair from among its members at a regularly scheduled meeting during the last WGM of the year in odd-numbered years. The chair shall serve for two years with a limit of two consecutive terms.

HL7 Governance and Operations Manual

June of each year, the DOE shall announce to HL7 and Affiliate membership the areas for which training will be developed for the next two years. Those members interested in serving on the EAC shall submit a letter of interest to the DOE on/before June 30th demonstrating subject matter expertise in the area(s) for which training is to be developed. The DOE, in conjunction with the EAC, shall review the letters of interest and recommend at least three individuals thought to best meet the stated criteria for appointment to the EAC. The DOE shall present those names to the Executive Committee for approval on/before July 31st. The decision shall be finalized in August and announced electronically prior to the annual plenary meeting.

Should the EAC note a lack of specific expertise or should its membership fall below six individuals for whatever reason, the DOE, in conjunction with the Executive Committee, may invite HL7 members or Affiliate representatives with relevant expertise to serve on the EAC.

10.13.02 Meetings

The EAC shall meet during each WGM and via teleconference bi-weekly. The EAC shall provide a representative to the education facilitators luncheon during the WGM. The luncheon and EAC meeting during the WGM shall be open to all interested parties. Teleconference participation is open to those individuals registered on the EAC list server.

Meetings and teleconferences shall be announced through the EAC list server, web page and wiki page. Meeting agendas shall be determined by the DOE in consultation with the EAC chair. The EAC list server shall be used for discussion and notification. Documents shall be available on the EAC wiki and web page.

10.14 Standards Governance Board (SPB)

The Standards Governance Board (SGB) establishes the precepts (rules) that management and methodology groups apply as operational instructions across domains within the scope of the Technical Steering Committee (TSC). These precepts provide the basis for consistency across product families and product lines when used to define the creation, maintenance and balloting of standards products, while supporting organizational strategic goals and vision.

SGB members are appointed by and report to the TSC.

10.15 Product Management Groups

Product Management Groups (CDA-MG, FHIR-MG, Version 2-MG) provide day-to-day oversight of the processes related to their respective products throughout their lifecycle. This includes ensuring product quality, monitoring scope and consistency with Standards Governance Board (SGB) precepts and aiding in the resolution of product related intra- and inter-work group issues.

Members of the various Product Management Groups are appointed by the Technical Steering Committee (TSC) from candidates recommended by the SGB. Product Management Groups report to the TSC.

11 Work Groups

11.01 Establishing a Work Group

11.01.01 Criteria

Individuals interested in establishing a new Work Group shall schedule time with the TSC Chair and the CTO to establish their conformance to the following criteria:

- There is a demonstrated need for the creation of a Work Group such as a government mandate, the results of “gap” analysis, or a stakeholder imperative and such need is of a scope that precludes it being addressed as a project by an existing Work Group.
- The expressed need is within the scope of HL7 and creation of the proposed Work Group shall facilitate HL7 accomplishing its mission and objectives.
- There is a minimum of five HL7 members who have agreed to active participation in the proposed Work Group and they possess the necessary expertise and commitment to accomplish its goals.

HL7 Governance and Operations Manual

Should the TSC Chair and CTO concur on the creation of a new Work Group they shall advise on appropriate collaboration with existing Work Groups and designate the SD to which the proposed Work Group shall be assigned. As a pre-cursor to Work Group formation, the interested individuals may request that the TSC provide a wiki page (wiki.hl7.org) and list serve for support during the formation period; said wiki page and list serve to be deactivated should the new Work Group not be subsequently approved by the TSC.

Otherwise, the TSC Chair and CTO shall recommend the appropriate Work Group for the interested individuals to approach with a project proposal.

11.01.02 Process

With the concurrence of the TSC Chair and the CTO, the individuals proposing a new Work Group shall complete and submit a [Work Group Proposal Template](#) to the designated SD co-chairs who shall distribute it to the co-chairs of all existing Work Groups across the various SD. Within 30 days of receipt of the template the designated SD co-chairs shall convene a conference of the co-chairs of all assigned Work Groups for the purpose of accepting or rejecting the proposal. Concurrent with the conference to consider the proposal the co-chairs of other SD Work Groups shall report any instances of overlap with the focus or intent of the proposed Work Group to the designated SD co-chairs.

The proposal shall be moved to the TSC for consideration upon a two-thirds affirmative vote by those Work Group co-chairs placing a vote with at least sixty percent of the Work Groups within the SD returning a vote. Failure to achieve quorum (60%) shall result in the proposal and record of votes cast moving forward to the TSC for consideration. Given quorum, failure to receive a two-thirds affirmative vote shall cause the proposal to be rejected. A rejected proposal may be appealed to the TSC up to thirty days from the date of rejection. The TSC shall resolve an appeal within thirty days of submission.

Upon approval by the designated SD, the SD co-chairs shall immediately submit a request for review of the proposal to the TSC Chair who shall advise the TSC members of the intent to review the proposal within thirty days. The TSC shall address the Work Group proposal under the tenets of its documented decision-making practices. If approved, the TSC Chair shall inform the Board of the creation of a new Work Group and the HL7 staff representative shall notify Headquarters to initiate all necessary infrastructure activity appropriate to the creation of a new Work Group. The HL7 Director of Communications shall coordinate with the Director of Marketing to determine whether the formation of this Work Group is deserving of a press release.

A TSC decision to reject the proposal may be appealed to the HL7 Executive Committee within thirty days of the TSC decision. The Executive Committee shall set a date to resolve the appeal and notify the appellant. The decision of the Executive Committee shall be final.

11.02 Work Group Change, Merger or Dissolution

11.02.01 Changing Name or Mission/Charter

Given approval under the Work Group's documented decision making practices, the co-chairs shall complete and submit a [Work Group Change Request](#) to change the name of the Work Group or revise its mission and charter. The request shall be presented to the parent Steering Division of the Work Group to include a draft Work Group charter citing the proposed name and including any proposed revisions. Upon approval by the parent Steering Division, using its documented decision-making practices, the revised Work Group charter shall be distributed to the co-chairs of all Work Groups and the Affiliate chairs. Further, the HL7 staff representative shall notify Headquarters to initiate all necessary changes to the infrastructure to reflect the Work Group's new name, mission, and charter.

An SD decision to deny or approve the proposal may be appealed to the TSC within thirty days of the SD decision. The TSC shall set a date to resolve the appeal and notify the appellant. Should the appellant be a member of the TSC, they shall recuse themselves from resolution of the appeal. The decision of the TSC shall be final. Should the approval of the Work Group's new name, mission or charter be overturned on appeal, the HL7 staff representative shall notify Headquarters to initiate all necessary changes to the infrastructure to reinstate the Work Group's previous name, mission and charter.

HL7 Governance and Operations Manual

11.02.02 Changing Assigned Steering Division

A Work Group wishing to change its assigned TSC Steering Division shall complete and submit a [Work Group Change Request](#) to both its currently assigned Steering Division co-chairs and the co-chairs of the Steering Division it proposes joining. For the change to become effective both the source and target Steering Divisions must approve the request using their published decision-making practices. The Work Group may appeal the Steering Divisions' decisions to the TSC whose decision shall be final. Consideration on size and group composition shall be left to both the source and target Steering Divisions.

11.02.03 Merger of Two or More Work Groups

Two or more Work Groups (WG) may, for whatever reason and following their documented decision-making practices, decide to consolidate their membership and work items. Upon such a decision, the members of the WGs involved shall designate one of the WGs as the surviving WG. Subsequently, the co-chairs of the dissolving WG(s) shall complete and submit a [Work Group Change Request](#) for dissolution [§11.02.04] citing the proposed merger. Concurrently, the co-chairs of the surviving WG shall complete and submit a [Work Group Change Request](#) to change the name of the WG and its mission and charter [§11.02.01] citing the proposed merger. Upon approval of the request to dissolve and request for name/mission and charter change, the consolidated WG shall undertake a reconciliation of their former respective DMP with the objective of establishing a comprehensive DMP for the consolidated WG.

11.02.04 Dissolution

Given approval under the Work Group's documented decision making practices, the co-chairs shall complete and submit a [Work Group Change Request](#) to the TSC Chair and CTO for dissolution of the Work Group. Reasons for considering dissolution include lack of interest or expertise as evidenced by participation consistently falling below five members or achievement of the objectives of the Work Group. The request should seek to identify those Work Groups that might assume the work of the dissolving Work Group. The TSC Chair and CTO may propose and seek alternatives to dissolution.

With the concurrence of the TSC Chair and CTO, the dissolving Work Group co-chairs shall seek the approval of the appropriate Work Group(s) to assume responsibility for their work products. The Work Group(s) shall confirm consent by a two-thirds affirmative vote of their members casting a vote. The dissolving Work Group co-chairs shall complete and submit the Work Group Change Request to the parent SD co-chairs. The results of the attempt to achieve consent for the assumption of work products shall be reported on the request.

The parent SD co-chairs shall distribute the request to all other Work Group co-chairs and schedule a vote of the parent SD Work Group co-chairs to consider the request for dissolution within 30 days of submission. If appropriate, all Work Group co-chairs shall petition their Work Group members for candidates to join the affected Work Group in an effort to forestall its dissolution. Should sufficient members come forward, the request to dissolve the Work Group is moot.

Upon an affirmative vote by two-thirds of the parent SD Work Group co-chairs casting votes with at least 60% of the Work Groups returning a vote, the parent SD co-chairs shall submit the request to the TSC Chair who shall advise the TSC members of the intent to review the request for dissolution within thirty days. The TSC shall address the request to dissolve under the tenets of its documented decision-making practices. Upon approval, the TSC Chair shall notify the Board of the dissolution of a Work Group and the disposition of that Work Group's work products; the HL7 staff representative shall request that Headquarters take the appropriate actions to effectively remove the Work Group from the organization

11.03 Work Group Co-Chairs

Each Work Group shall have a minimum of two co-chairs to ensure leadership in the event that one or the other is unable to attend a Working Group Meeting with the actual number of co-chairs determined by the Work Group using their decision-making practices.

HL7 Governance and Operations Manual

[HQ shall be informed](#) upon a decision by a Work Group to increase the number of co-chairs which shall result in the subsequent call for nominations and annual election for such additional positions. The Work Group may, using their decision-making practices, designate an individual to fill the additional position interim to the seating of a duly elected co-chair or for such period as stipulated by vote of the Work Group. The designated interim co-chair shall be [identified to HQ](#) and may be nominated for election.

Likewise, [HQ shall be informed](#) upon a decision by a Work Group to decrease the number of active co-chairs. Those individuals in positions being eliminated shall serve the remainder of their term, if possible. The newly authorized number of active co-chairs shall constitute the basis for eligible positions during subsequent elections.

11.03.01 Responsibilities

The co-chairs are responsible for the conduct of the Work Group in the development of the HL7 protocol specifications in the designated domain; for collecting and publishing the minutes of all Work Group meetings during and interim to the Working Group Meetings including teleconferences; for encouraging the submission of minutes or notes from all meetings of any sub-groups, task forces, or project teams related to the Work Group; for ensuring that the portion of the protocol specifications for which they are responsible is properly balloted; for resolving negative normative ballot comments appropriately; and for reporting compliance with established procedures to the TSC. Guidance on co-chair responsibilities can be found in the [Co-chair's Handbook](#).

11.03.02 Term of Office

Co-chairs shall serve two-year terms without term limits. Terms shall be staggered to ensure continuity of leadership, with half the co-chairs of a Work Group being elected in even numbered years and half elected in odd numbered years. Upon establishment of a new Work Group, an appropriate number of co-chairs shall be elected to an initial one-year term to establish staggered terms.

11.03.03 Removal from Office

At any time, a Work Group that judges the performance of a co-chair egregious may, using their decision-making practices, make a motion to the TSC for removal of that co-chair.

Criteria for removal shall include:

- failure to attend two consecutive Work Group Meetings without notice or the subsequent presentation of mitigating circumstances; or
- failure to participate in at least 60% of the Work Group teleconferences held in the preceding calendar year;
- undesirable or disruptive behavior that deviates from the Code of Conduct (§04); or
- failure to fulfill the responsibilities set forth in §11.03.01

Upon receipt of a motion for removal of a co-chair the TSC shall take appropriate action which may range from counseling to removal of non-participating or non-performing co-chairs following sufficient fact gathering to ensure due process.

The decision to remove a co-chair shall result in that individual immediately stepping down from the position of co-chair and [notification to HQ](#) for the removal of that individual from the list of co-chairs on the Work Group's web page. The Work Group may, using their decision-making practices, designate an individual to serve as co-chair interim to the seating of a duly elected co-chair or for such period as stipulated by vote of the Work Group. The designated interim co-chair shall be [identified to HQ](#) and may be nominated for election.

Alternately the Work Group, using their decision-making practices, may decide to eliminate rather than fill the vacated position. [HL7 Headquarters shall be informed](#) of said decision resulting in a reduction of the number of active co-chairs for that Work Group.

HL7 Governance and Operations Manual

11.03.04 Co-chair Vacancy due to Change in Membership Status

Should a seated co-chair be notified of a change in membership status due to either the loss of individual membership or loss of membership by their organization or Affiliate, that individual shall have 30 days from the date of notification to reinstate membership by submitting or having their organization or Affiliate submit payment in full. Requests to extend the 30 day period shall be considered on a case-by-case basis. If unresolved by the end of that period, that individual shall immediately step down from the position of co-chair.

The Work Group shall [notify HL7 Headquarters](#) of the loss of a co-chair and request a subsequent election. Resolution of the individual's membership status subsequent to stepping down would allow them to seek nomination for election as a co-chair. The Work Group may, using their decision-making practices, designate an individual other than the individual who stepped down to serve as a co-chair interim to the seating of a duly elected co-chair or for such period as stipulated by vote of the Work Group. The designated interim co-chair shall be [identified to HQ](#) and may be nominated for election.

11.03.05 Voluntary Co-chair Vacancy

Should a seated co-chair voluntarily vacate their position, for whatever reason, the Work Group shall [notify HL7 Headquarters](#) of the loss of a co-chair and request a subsequent election. The Work Group may, using their decision-making practices, designate an individual to serve as a co-chair interim to the seating of a duly elected co-chair or for such period as stipulated by vote of the Work Group. The designated interim co-chair shall be identified to HQ and may be nominated for election.

Should the Work Group, using their decision-making practices, decide to eliminate rather than fill the vacant position, they shall [inform HL7 Headquarters](#) of said decision resulting in a reduction of the number of active co-chairs for that Work Group.

11.04 Decision-Making Practices

All HL7 Work Groups shall follow a documented set of decision-making practices (DMP). The DMP is written from the point of view of a group with open membership. Most sections apply to all groups and committees and are not modifiable. Sections that may be modified via the [DMP Modification Template](#) include §5.1 Quorum Definition; §7 Electronic Voting; and §8 Proxy Participation (for closed committees). Proposed modifications shall be made via the [DMP Modification Template](#) and submitted to the parent Steering Division (SD). Upon approval by the SD, the Template shall be submitted to the Technical Steering Committee for final approval.

The practices in effect in each Work Group shall be adopted by majority vote of that Work Group and shall not conflict with the HL7 Bylaws, HL7 Governance and Operations Manual, HL7 Essential Requirements, or the current edition of ANSI Essential Requirements. Working sessions of each Work Group shall be governed by the rules set forth in the DMP. Meetings hosted jointly shall follow the DMP of the host Work Group.

There is no requirement for Work Group proceedings to be overly formal; although situations may arise that require such formality. In the event that a situation occurs that mandates the use of formal procedures or for situations not otherwise addressed in the DMP, Robert's Rules of Order shall govern. As situations demand, a Work Group may force the institution of this formality through a majority vote of the Work Group.

11.05 White Papers

A WG may, on occasion, decide to prepare and publish a white paper; i.e. an authoritative report or guideline informing readers in a concise manner about a complex issue and presenting the issuing body's philosophy on the matter. A white paper is meant to help readers understand an issue, solve a problem, or reach a decision.

A white paper shall be initiated by a Project Scope Statement (PSS) and follow the prescribed approval process. The document may take the form of a **Work Group White Paper** (WGWP), reflecting the WG's position on a given issue and intended for a specific interest group, or an **HL7 White Paper**, purporting to represent the HL7 position on an issue, decision, or resolution and intended for the broader standards community.

HL7 Governance and Operations Manual

The WGWP shall use the [WGWP Template](#) and be approved via WG peer review; while the HL7 White Paper shall be processed and balloted as an Informative document. For specific guidance see the Co-chair Handbook.

All white papers shall be subject to review within five years of publication and subsequently updated, reaffirmed, or withdrawn following the same process as current balloted HL7 artifacts.

12 Conferences, Meetings, and Educational Programs

12.01 Meeting Notice

Members shall be notified of all meetings and valid assemblies a minimum of 30 days prior to the scheduled date by postings to the HL7 list server and via the HL7 Web site.

12.02 Meetings in Conjunction with HL7

Any organization wishing to convene a meeting in conjunction with an HL7 Working Group Meeting may do so given the following conditions.

- The HL7 Executive Committee approves the request.
- The purpose of the proposed meeting is one of the following:
 - To jointly develop standards
 - To coordinate with HL7
 - To share in educational opportunities
- The members of the organization pay HL7 registration fees and register as Working Group Meeting attendees.

The HL7 member discount on registration fees will be extended to all members of the organization meeting jointly. These individuals shall receive all goods and services (e.g., lunches, breaks, handout materials, etc.) typically provided to Working Group Meeting attendees.

HL7 will be responsible for providing meeting space and reasonable audiovisual equipment for joint sessions during the Working Group Meeting.

Priority in scheduling will shall be given to:

- Member organizations of the Joint Initiative for SDO Global Health Informatics Standardization for work on JIC projects
- Associate Charter organizations or those organizations holding an HL7 SOU
- Other ANSI accredited standards developing organizations
- Professional societies and organizations
- Consortia and user group organizations

12.03 Special Meetings

Any Work Group or other duly recognized body of HL7 may propose to the Technical Steering Committee (TSC) convening a special meeting; e.g., an out-of-cycle meeting occurring interim to the regularly scheduled Working Group Meetings. The purpose of such special meetings may be educational or promotional, to permit extended work on issues to be returned to the larger group for action, to develop a course of action to be presented to the larger group, or to take advantage of circumstances to promote interest in and work on material for HL7.

Proposals shall be submitted to HL7 Headquarters using the [Out-of-cycle Meeting Request](#) sufficiently in advance to allow for a decision by the TSC and still accommodate the required thirty days prior notice. Proposals will include:

- The purpose of the meeting

HL7 Governance and Operations Manual

- Expenses to be borne by HL7, if any
- The name of the individual(s) in charge of the meeting
- The meeting location, date and time or frequency if the requested meeting is recurring

With the exception of special meetings proposed in lieu of regular Working Group Meeting sessions, which must be approved by the Executive Committee, the TSC shall take action to approve or disapprove the special meeting proposal at its next meeting or conference call whichever comes first. If the special meeting is approved and HL7 funding has been requested, the Executive Committee shall stipulate the amount of funding to be provided. No special meeting shall represent itself as an official HL7 meeting without the express written approval of HL7.

Approved special meetings must be generally announced to the membership, via list server and/or other means, at least thirty days prior to the meeting. Special meetings being held in conjunction with meetings of another organization may publish the meeting notice as part of the other organization's program announcement. A co-chair of the group or their duly appointed representative must attend any special meeting. A recording secretary shall be appointed for the meeting and minutes returned to HL7 Headquarters and distributed to the membership of the broader group no later than thirty days following the special meeting.

Approval for recurring special meetings shall be in effect:

- Until the series is completed, or
- Until the receipt by HL7 Headquarters of a statement that such special meetings are no longer necessary, or
- Until the sponsoring group is disbanded, or
- Until the sponsoring group fails to hold two consecutive special meetings according to its schedule.

Any deviations from the original request shall require a separate approval from the TSC. The requesting group shall supply an agenda, meeting dates, times and locations for all such regularly-scheduled special meetings to HL7 Headquarters at least thirty days in advance of the meeting for posting on the HL7 website and via HL7 list servers. Groups should attempt to schedule special meetings more than ninety days in advance to facilitate member planning.

12.04 Proposals for Consideration of Co-Branded Events

Individuals or groups seeking approval for a meeting or event (e.g., Connectathon) that will be branded as an HL7 event but co-hosted or co-located with another group(s), shall submit a proposal to HL7 HQ at least 4 months in advance of the proposed event. The purpose of such special meetings may be educational or promotional. The proposal shall include:

- A completed HL7 Tactical Marketing Plan form
- A budget, including any funds request of the co-sponsoring organizations, suggested registration fees and sponsorship levels, details about how shortfalls shall be handled as well as how net surplus will be handled.
- A work plan detailing what is expected of/contributed by each organization (e.g., sponsorship solicitation, handling registration, meeting space, AV, F&B, signage, etc.)

The completed proposal/budget shall be submitted to the Executive Committee for review at its next meeting, but not more than 10 days following receipt of the request. The Executive Committee shall review the proposal and decide as to the merit of the request based on several details such as:

- The proposed meeting dates do not conflict with other events on the HL7 calendar
- HL7 staff have sufficient time/resources to undertake the work plan for the event
- There is sufficient ROI for staff resources and/or any funding that is requested

HL7 Governance and Operations Manual

- Budget is cost neutral or positive

Following approval by the Executive Committee, events that require approval from another body within HL7 shall be forwarded to the secondary body for approval. The secondary body shall decide within 10 days following receipt of the request.

Should approval be granted:

- HL7 staff will notify the requester
- HL7 staff will work with organizers to arrange registration, AV and other required details.
- Within 15 days following the event, the requestor shall deliver to HL7 staff a report of the event, including accomplishments/next steps, the total number of registrants, and the final budget.

12.05 Educational Programs

The HL7 Director of Education has responsibility and accountability for all HL7 educational programs; including development and implementation of an education strategic plan, financial impact analysis for each project, and any other deliverables needed to meet the objectives established by the Board. The Director of Education shall call upon the subject matter expertise of the Education Advisory Council and others, as necessary, to build and maintain a successful education program for HL7 International.

12.05.01 Tutorials

Tutorials to be presented at Working Group Meetings (WGM) and/or Education Summits shall be scheduled sufficiently in advance to allow for review and discussion by the Education Advisory Council during the WGM that precedes their proposed occurrence.

Proposed tutorials should meet the following criteria:

- The topic should be of broad interest to the Working Group or to one of its Work Groups
- The topic should be of interest to all classes and types of HL7 members
- The format should be limited to a single meeting space and normal A/V support

Special requests must be presented as a formal proposal to the Education Advisory Council for recommendation. The Education Advisory Council will promptly review and make a recommendation on the proposal, presenting it to the Director of Education for final endorsement. Special requests include tutorials that use paid trainers, a broader meeting room format, outside sponsorship, etc. Considerations for special requests will include: the importance to advancing the broad goals of HL7; conflicts with the regular meetings of the Working Group; cost; benefits to HL7 such as increasing attendance; and financial risk.

13 Electronic Ballots

All HL7 ballots, be they administrative, review, or normative, shall be conducted electronically. Electronic ballots shall provide, as appropriate:

- The means to form a consensus group and provide necessary notifications.
- The means to capture the vote and associated comments.
- A method for resolving negative comments and reconciling the normative ballot.

13.01 Consideration of Recommended Actions

Prompt consideration shall be given to proposals made for developing new or revising existing HL7 Protocol Specifications. The TSC shall approve recommendations for all actions pertaining to approval or adoption of HL7 Protocol Specifications, or any portion thereof, prior to submission for ballot.

HL7 Governance and Operations Manual

13.02 Naming Convention

A naming convention has several basic objectives:

- Help potential readers determine whether a document is an ANSI-approved standard or other document type
- Help potential readers locate a document in a hierarchy of documents
- Help potential readers determine the purpose of a document
- Help potential readers determine the relevance of a document to their need

To meet these objectives, a well-constructed document name should include:

- The organization(s) releasing the document
- The family of standards relevant to the document
- The document type designation
- A descriptive title
- The document release identifier

13.03 Constructing Review Ballot and Protocol Specification Names

The full document name shall begin with an organizational identifier followed by family name, product type and release number with a subfamily name, product type and release number, if applicable, then the product name and release number followed by the realm designation, if applicable, and the ballot type and number. In the case of a reaffirmation ballot the term “Reaffirmation of” shall precede the organization identifier.

The naming construct is described below using a notation of {required} or [optional] with literals expressed in ***bold italics***.

STRUCTURE	Comments
[Reaffirmation of]	
{Organization Identifier}	
{	One or more of the following 3 line items required
[Family Name] [Product Type] [<i>Release</i> [Release Number]] :	
[Sub-family Name] [Product Type] [<i>Release</i> [Release Number]] :	
[Product Name] [<i>Release</i> [Release Number]]	
}	
[Realm Designation]	See HL7 Version 3 Standard > Vocabulary > HL7 Value Sets > HL7 Realm
The following elements are specific to ballot names and shall not appear in final document names.	
[Designation] [Ballot Type] <i>Ballot</i>	Designation shall be 1st, 2nd, etc.
<i>PI ID</i> {Project Insight ID number}	Ballot metadata; ID number shall have hyperlink to Project Insight

HL7 Governance and Operations Manual

13.03.01 Organization Identifier

The Organization Identifier shall be:

- a) HL7 indicating a Health Level Seven International document
- b) HL7/Other [such as NCPDP] indicating an HL7 document published in conjunction with another organization

13.03.02 Family and Subfamily Name

The standard family names are Version 2.x (V2.x); Version 3 (V3) [note: V3 itself does not have a release number, although each of its products typically will]; Clinical Document Architecture® (CDA®) [note: CDA shall be further designated as R1 or R2]; Electronic Health Records System-Functional Model (EHRS-FM); Fast Healthcare Interoperability Resource (FHIR®); where a document includes reference to two or more family names it may be identified as a Cross Paradigm Specification.

In the case of a Standard or Standard for Trial Use (STU) the full family name shall be used; e.g., Fast Healthcare Interoperability Resource or Clinical Document Architecture®. In lieu of the full family name the appropriate acronym may be used for Implementation Guides, Profiles, and other documentation.

Subfamily names are specific to a given family and are not further defined in this document.

13.03.03 Product Type

Product types are defined as Specification or Standard; Domain Analysis Model (DAM); Service Functional Model (SFM); Functional Model (FM); Functional Profile (FP); Implementation Guide (IG); Logical Model [note: a Logical Model is not a Cross Paradigm Specification]; Profile, White Paper, and Guidance [for documents such as a Cookbook or Companion Guide]. The TSC may, at their discretion, declare additional product types.

13.03.04 Product Name

The Product Name is specified by the Work Group when they initiate a PSS to create a new or update an existing Protocol Specification; however, the Product Name may be revised upon submission of the Notice of Intent to Ballot ([NIB](#)).

13.03.05 Ballot Level

The Ballot Level defines the type of Review Ballot being undertaken: Informative; STU [note: STU numbering is independent of the normative release level the product may ultimately be assigned]; or Comment-only [note: a Comment-only ballot is not typically numbered given that it is issued for a specific reason, such as reaffirmation, or as a precursor to an Informative or STU ballot].

The TSC has issued specific guidance as to sub-numbering the release number for a STU update. Please refer to [TSC Policy and Guidance to Work Groups on STU Updates vs. STU Ballots](#).

13.03.06 Examples

[NOTE: hyperlinks illustrated but not included]

HL7 CDA® R2 Implementation Guide: Patient-friendly language for Consent Directives, Release 1 (1st Informative Ballot) PI ID [1130](#)

HL7 EHR-System Usability Conformance Criteria, Release 1 (Comment-only Ballot) PI ID [995](#)

HL7 FHIR® Profile: Data Access Framework (DAF), Release 1 (1st STU Ballot) PI ID [1143](#)

HL7 Business Architecture Model (BAM), Release 1 (1st Informative Ballot) PI ID [915](#)

HL7 Service Functional Model: Care Coordination Service (CCS), Release 1 (1st STU Ballot) PI ID [924](#)

HL7 Version 3 Standard: Biomedical Research Integrated Domain, Release 2 (1st STU Ballot) PI ID [1120](#)

HL7 Governance and Operations Manual

HL7 Version 2.7.1 Implementation Guide: Message Transformations with OASIS Tracking of Emergency Patients (TEP), Release 1 (2nd Informative Ballot) PI ID [970](#)

Reaffirmation of HL7 Version 3 Standard: Pharmacovigilance - Individual Case Safety Report, Part 1: The Framework for Adverse Event Reporting, R2 (1st Normative Ballot) PI ID [1258](#)

All examples shown above reflect ballot names; the ballot designation and Project Insight ID shall not appear in the document name used for publication.

13.04 Approving Review Ballot and Protocol Specification Names

13.04.01 Informative Documents and STU:

Ballot and protocol specification names shall be approved by the TSC. In the case of ballots during the Notice of Intent to Ballot ([NIB](#)) process. In the case of protocol specifications during the review and approval process of the [Publication Request Template](#).

13.04.02 Other Documents

The Work Group proposing a new document title or a change to an existing document title, for other documents published as official HL7 documents (carrying an HL7 copyright and logo) shall obtain approval from the TSC as early as possible; preferably before the document is circulated widely for review, but certainly prior to publication.

13.04.03 Documents in Progress

The TSC may require a change to the title of documents already in progress, in ballot, or in technical editing after ballot for conformance with an established convention.

14 Review Ballots

A review ballot shall be used to review and validate the content of informative documents, the subject matter of proposed standards for trial use (STU), and other items that, after due consideration of the TSC, are not yet deemed appropriate for a normative ballot. All review ballot types (Informative, STU, and Comment-only) require a project scope statement ([PSS](#)) and must comply with the HL7 [project approval process](#).

14.01 Informative Documents

An Informative Document is the product of a Work Group that is not currently deemed normative, but nonetheless is intended for general publication. It explains or supports the structure of the HL7 Protocol Specifications (§02.02) or provides detailed information regarding the interpretation or implementation of an HL7 Protocol Specification. The TSC holds the authority to approve the issuance of an informative document ballot.

Following approval of the informative document the submitting Work Group may, with the concurrence of the TSC, submit the document to a normative ballot for subsequent consideration as an American National Standard.

14.01.01 Initiation

The TSC, in compliance with its defined processes, may initiate the ballot of an informative document. Once initiated, the ballot shall remain active until such time as the subject matter of the ballot has been approved or withdrawn from consideration.

14.01.02 Forming the Consensus Group

All current members shall be notified of the intent to form a consensus group and ballot an informative document. at least thirty (30) days prior to the start of the ballot period. This notification shall occur via the various HL7 newsletters and member list servers and shall include the dates of enrollment in the consensus group. Members shall indicate their interest by enrolling in the appropriate consensus group via the HL7 Ballot Desktop during the enrollment period which shall end with the opening of the ballot period.

HL7 Governance and Operations Manual

Nonmembers who wish to participate in an Informative Document consensus group must register their intent with HL7 Headquarters during the stated enrollment period by completing the Non-Member Enrollment process through the HL7 Ballot Desktop. Nonmembers shall be assessed a fee established by HL7 Headquarters for such participation.

14.01.02.01 US Realm-specific Consensus Group

A Work Group may declare an informative document as US Realm-specific in that its function is to constrain an HL7 Protocol Specification (§02.02) for implementation in the United States of America (USA). The Work Group may request that the consensus group be restricted to those applicable to US Realm-specific documents; i.e. current individual members or representatives of current organizational members whose primary address or place of business is in the USA. The consensus group for US Realm-specific documents shall be managed by HL7 staff via the Ballot Desktop prior to release of the ballot material.

A materially affected party who does not meet the criteria for participation in a US Realm-specific ballot may petition the TSC to join the consensus group. The request to participate in a US Realm-specific consensus group shall be sent to the Associate Executive Director and shall include the rationale justifying participation. The TSC decision on such requests shall be final.

14.01.03 Ballot Package

The ballot package shall be available to all members of the consensus group for thirty days following the opening of the ballot period. Participants are encouraged to provide constructive comments for improving the content or language of the subject matter under review.

14.01.04 Handling Comments

At the close of the ballot the responsible Work Group (WG) shall capture all comments using the HL7 Ballot Reconciliation Report unless the WG has petitioned for and been granted a waiver of such use by the Technical Steering Committee (TSC). The responsible WG shall consider all comments with the intent of improving the quality and clarity of the informative document. While not on a par with a normative reconciliation package, the results of the Work Group's consideration of the comments submitted as recorded on the Ballot Reconciliation Report shall be posted to the Ballot Desktop.

A negative without comment shall be considered as "no response" and shall not be factored into the numerical requirements for approval. No effort shall be made to solicit comments from the submitter of a negative without comment.

The process of consideration of the comments is not synonymous with nor shall it assume the rigor of normative reconciliation. There is no requirement to resolve negative comments and seek withdrawal of the negative. Nevertheless, the responsible Work Group is encouraged to annotate each negative comment on the reconciliation report with a disposition of "Persuasive", "Not Persuasive", "Considered for Future Use", or "Not Related" with a recorded vote and an explanation for the Work Group's decision in accordance with the Work Group's Decision-Making Practices (DMP) to maintain transparency on decisions made. A negative ballot withdrawn at the request of the submitter shall be recorded as an affirmative.

The issue of substantive change shall not be applicable to an informative document. In the instance of an approved informative document with substantive change resulting from review, it is left to the discretion of the responsible Work Group to either submit to another ballot or move forward with the revised informative document.

If the informative document fails to be approved, it again falls to the discretion of the responsible Work Group, after appropriate revision if necessary, to either submit to another review ballot, withdraw the document from consideration, or repackage the content and submit it to the TSC for consideration of submission to a normative ballot.

HL7 Governance and Operations Manual

14.01.05 Approval and Publication

There is no quorum required for an informative document. The informative document shall be considered approved if, following ballot review, sixty percent (60%) of the combined affirmative and negative votes cast are affirmative.

Upon approval and posting of the ballot reconciliation report the responsible Work Group shall vote to submit a [Publication Request Template](#) to the TSC Project Manager, who shall include an item on the agenda of the next TSC meeting for the consideration of affirmation of release for publication. The Work Group vote shall be recorded in the minutes and reported on the Publication Request Template <HL7 Work Group making this request and date/URL of approval minutes>.

14.01.06 Withdrawal of an Informative Document

A Work Group that, through its decision-making practices, identifies an Informative Document to be withdrawn shall submit a [Notice of Withdrawal of a Protocol Specification](#) form to the Technical Steering Committee. This form will identify the subject protocol specification and provides the process to request input, review and approval of the request to withdraw the document from various HL7 entities.

14.02 Standards for Trial Use (STU)

HL7 no longer produces “Draft” Standards; they are now designated as Standards for Trial Use (STU). Therefore, the term “Draft Standard for Trial Use (DSTU)” has been discontinued.

The Project Life Cycle for Product Development (PLCPD), defined in the HL7 Development Framework (HDF), establishes the implementation by at least two parties in a test scenario to prove interoperability as a required standards project deliverable unless waived by the TSC. This involves the development of a trial standard and its release for use to establish interoperability.

While there is no ANSI requirement for due process regards a trial standard, given that the ultimate objective is the creation of a normative standard it is appropriate to validate the content of the trial standard by subjecting it to review prior to its release for use.

Should the content of the proposed standard not be approved, for whatever reason, it may simply be withdrawn from consideration. Following a successful review, the trial standard, in the appropriate form, may be presented to the TSC for release as a Standard for Trial Use (STU).

14.02.01 Initiation

The TSC, in compliance with its defined processes, may initiate the review of the subject matter of the proposed STU. Once initiated, the review ballot shall remain active until such time as the subject matter of the proposed STU has been approved or withdrawn from consideration.

14.02.02 Forming the Consensus Group

All current members shall be notified of the intent to form a consensus group and ballot the content of a proposed standard for trial use at least thirty (30) days prior to the start of the ballot period. This notification shall occur via the various HL7 newsletters and member list servers and shall include the dates of enrollment in the consensus group. Members shall indicate their interest by enrolling in the appropriate consensus group via the HL7 Ballot Desktop during the enrollment period which shall end with the opening of the ballot period.

The minimum consensus group shall be ten current individual members or individuals representing at least three current organizational members. The ballot shall not commence if the minimum consensus group requirement is not met.

Nonmembers who wish to participate in a STU consensus group must register their intent with HL7 Headquarters during the stated enrollment period by completing the Non-Member Enrollment process through the HL7 Ballot Desktop. Nonmembers shall be assessed a fee established by HL7 Headquarters for such participation.

HL7 Governance and Operations Manual

14.02.03 Ballot Package

The ballot package shall be available to all members of the consensus group for thirty days following the opening of the ballot period. Reviewers are encouraged to provide constructive comments for improving the content or language of the subject matter under review.

14.02.04 Handling Comments

At the close of the review ballot the responsible Work Group (WG) shall capture all comments using the HL7 Ballot Reconciliation Report unless the WG has petitioned for and been granted a waiver of such use by the Technical Steering Committee (TSC). The responsible WG shall consider all comments with the intent of improving the quality and clarity of the proposed standard. While not on a par with a normative reconciliation package, the results of the Work Group's consideration of the comments submitted as recorded on the Ballot Reconciliation Report shall be posted to the Ballot Desktop.

A negative without comment shall be considered as "no response" and shall not be factored into the numerical requirements for approval. No effort shall be made to solicit comments from the submitter of a negative without comment.

The process of consideration of the comments is not as complete or rigorous as normative reconciliation. There is no requirement to resolve negative comments and seek withdrawal of the negative. Nevertheless, the responsible Work Group is expected to annotate each negative comment on the reconciliation report with a disposition of "Persuasive", "Not Persuasive", "Considered for Future Use", or "Not Related" with a recorded vote and an explanation for the Work Group's decision in accordance with the Work Group's Decision-making Practices (DMP) to maintain transparency on decisions made. A negative ballot withdrawn at the request of the submitter shall be recorded as an affirmative.

The issue of substantive change shall not be applicable to a STU. In the instance of an approved STU with substantive change resulting from review, it is left to the discretion of the responsible Work Group to either submit to another review ballot or move forward with a request to the TSC to release the revised content as a standard for trial use.

14.02.05 Approval

The proposed STU shall be considered approved if sixty percent (60%) of the combined affirmative and negative votes cast by the review group are affirmative. Upon approval and posting of the ballot reconciliation report the responsible Work Group shall vote to submit a [Publication Request Template](#) to the TSC Project Manager, who shall include an item on the agenda of the next scheduled TSC meeting for the consideration of affirmation of release for publication. The Work Group vote shall be recorded in the minutes and reported on the Publication Request Template <HL7 Work Group making this request and date/URL of approval minutes>.

If the proposed STU fails to be approved, it again falls to the discretion of the responsible Work Group, after appropriate revision if necessary, to either submit to another review ballot, withdraw the document from consideration, or repackage the content and submit it to the TSC for consideration as a normative ballot.

14.02.06 Trial use

Once approved a STU shall be released for use to refine and enhance its content through demonstrations of interoperability. Due consideration should be given to the need for timeliness in moving the STU into the normative process. Therefore, the trial use period should be of sufficient duration to provide for viable proof of concept yet not so long as to unnecessarily delay the initiation of the normative ballot process.

A guideline for the trial use period is from one to two years for trial use and comment which should be followed by one year or less for completion of the normative ballot period. The STU shall be viable for the specified trial use period, the subsequent normative ballot process, and up to six months following publication of the normative HL7 Protocol Specification. The Executive Committee (EC) may, at its discretion, extend the viability of a STU for up to five years beyond the close of the trial use period.

HL7 Governance and Operations Manual

14.02.06.01 Standard for Trial Use Front Matter

The front cover of a STU shall include the following statement.

“Publication of this standard for trial use (STU) has been approved by Health Level Seven International (HL7). This STU is not an accredited American National Standard. The comment period for use of this STU shall end *[indicate the number of months allocated for evaluation and review]* months from the date of publication. Suggestions for revision should be submitted at <http://www.hl7.org/stucomments/index.cfm> .

Following this *[the number of months shown above]* month evaluation period, this STU, revised as necessary, will be submitted to a normative ballot in preparation for approval by ANSI as an American National Standard. Implementations of this STU shall be viable throughout the normative ballot process and for up to six months after publication of the relevant normative standard.”

The use of the ANSI logo or trademark on a STU is strictly prohibited and at no time shall the STU be referred to as an American National Standard for Trial Use.

14.02.06.02 Extending the Trial Use Period or Reopening a STU for Trial Use

A Work Group may petition the TSC to extend the trial use period of a STU typically for up to one year from the end of the existing period. Longer duration or subsequent extensions may be granted by the TSC, but at no point shall a STU be extended beyond 5 years from its original release for comment date without the express approval of the Executive Committee. The request for extension shall stipulate the reason an extension is needed; the proposed length of the extension; what actions the Work Group will take to facilitate a normative ballot of the proposed standard following the trial use period; and whether the request for extension is supported by the current and any additional organizations committed to implementation. The decision of the TSC or, in the case cited above, the EC regards the approval and length of an extension is final.

A Work Group may petition the TSC to reopen the trial use period for an expired STU. The request to reopen the trial use period shall stipulate the reason for reopening the trial use period; the proposed length of the new trial use period; what actions the Work Group will take to facilitate a normative ballot of the proposed standard following the trial use period; and whether the request to reopen the trial use period is supported by the current and any additional organizations committed to implementation. The decision of the TSC regards the approval and length of the new trial use period is final.

14.02.06.03 Extended Trial Use Period Related to a Regulatory Issue

A STU that has been extended in response to a regulatory issue shall only be available for comment if it is the current version of the STU. Participants may submit comments for consideration for a next release, be it another STU or a Normative version. Such comments shall only be submitted for the most current published version of the STU in question.

14.02.07 Results of the Trial Use Period

Where the evaluation and comment period results in a need for substantive changes to the STU, the resulting content for normative ballot may embody such changes or a revised STU may be released for further evaluation without recourse to a review ballot. In either case, should there be a need for substantive changes, the normative ballot content or the subsequent revised STU is not bound to maintain compatibility with the initial STU. Under such circumstances, given that the intent of an STU is to improve the viability of the subsequent normative HL7 Protocol Specification (§02.02), it is the obligation of the responsible Work Group to select enhancement over compatibility with the initial STU.

14.02.08 Backwards Compatibility to Base American National Standard

Typically, a STU is used to prototype a new artifact and would therefore not be a candidate for backwards compatibility. However, should a Work Group use a STU to validate maintenance to an existing American National Standard (ANS), it shall comply with any rules for backwards compatibility specific to the ANS being updated.

HL7 Governance and Operations Manual

Within the context of the STU itself, there is no requirement that the final specification brought to normative ballot be backwards compatible to the initial release of the STU. This does not excuse any requirement for the final content submitted to normative ballot to be backwards compatible to the ANS it is updating, if such is a requirement of that specific HL7 Protocol Specification (§02.02).

14.02.09 Withdrawal of a Standard for Trial Use

A Work Group that, through its decision-making practices, identifies a Standard for Trial Use to be withdrawn shall submit a [Notice of Withdrawal of a Protocol Specification](#) form to the Technical Steering Committee. This form will identify the subject protocol specification and provides the process to request input, review and approval of the request to withdraw the document from various HL7 entities.

14.03 Publishing Technical Corrections as Errata

A [publication request](#) for errata addressing either an informative document or a Standard for Trial Use (STU) shall comply with [TSC guidance on technical corrections](#) and be accompanied by a cover letter drafted by the responsible Work Group. The cover letter shall cite the rationale supporting such a request and be submitted for the approval of the Chief Technology Officer (CTO). Refer to the [CTO errata cover letter template](#) for guidance.

14.04 Comment-only Ballot

A Work Group, with the concurrence of the TSC, may submit proposed content or requirements documents, such as a Domain Analysis Model (DAM), to comment-only review. The intent is to gather input from members outside of the Work Group on the viability and clarity of the proposed content or requirements document. The review of proposed content or requirements documents does not seek a vote, per se, but will capture all comments.

A comment-only ballot shall be used for the reaffirmation of an HL7 American National Standard (ER §03.04.01). The ballot shall record the position [yes or no] of the membership and any materially affected and interested party as to whether the cited HL7 American National Standard should be reaffirmed.

14.04.01 Initiation

The TSC, in compliance with its defined processes, may initiate a comment-only review of proposed content and requirements documents. At its discretion, the TSC may allow a Work Group to conduct multiple comment-only review cycles.

14.04.02 Forming the Consensus Group

All current members shall be notified of the intent to form a consensus group for comment-only review at least thirty (30) days prior to the opening of the review period. This notification shall occur via the various HL7 newsletters and member list servers and shall include the dates of enrollment in the consensus group. Members shall indicate their interest by enrolling in the appropriate consensus group via the HL7 Ballot Desktop during the enrollment period which shall end with the opening of the review period.

Nonmembers who wish to be part of the comment-only consensus group may do so at no cost but must register their intent with HL7 Headquarters during the stated enrollment period by completing the Non-Member Enrollment process through the HL7 Ballot Desktop.

14.04.03 Ballot Package

The ballot material shall be available for thirty days following the opening of the comment-only review period. Participants are encouraged to provide constructive comments for improving the content or clarity of the ballot material.

14.04.04 Results of the Review

At the close of the comment-only review period the responsible Work Group (WG) shall capture all comments using the HL7 Ballot Reconciliation Report unless the WG has petitioned for and been granted a waiver of such use by the Technical Steering Committee (TSC). The responsible WG shall consider all comments received during the review period with the intent of improving the quality and clarity of the submitted content before seeking the approval of the TSC for submission to a subsequent ballot.

HL7 Governance and Operations Manual

The Work Group shall post the results of their consideration of the comments submitted as recorded on the Ballot Reconciliation Report to the HL7 Ballot Desktop. There is no requirement to respond to any comment or advise any submitter of the disposition of their comments. Given that this is a comment-only review; the issue of substantive change is moot.

15 Normative Ballot

A normative ballot is undertaken with the approval of the TSC. It is intended to process and validate those protocol specifications intended for submission to ANSI for consideration as American National Standards. The normative ballot process, designed to adhere to the tenets of *ANSI Essential Requirements: Due process requirements for American National Standards*, is fully defined in §02 of *HL7 Essential Requirements: Due process for HL7 American National Standards*.

16 Submission of American National Standards

Having previously reported project initiation and upon approval by normative ballot, the TSC shall cause the subject protocol specifications to be submitted to ANSI as a candidate for acceptance and acknowledgment as an American National Standard in compliance with then applicable ANSI requirements. This process is fully documented in §03 of *HL7 Essential Requirements: Due process for HL7 American National Standards*.

17 Maintenance of the Governance and Operations Manual (GOM)

The Governance and Operations Manual (GOM) shall be a dynamic document with proactive, iterative, and participatory maintenance designed to keep the manual current with HL7 operational requirements.

Those entities tasked with implementation of HL7 process and procedure may, in the course of normal operations, identify a need to deviate from those processes and procedures documented in the GOM. In such circumstances, the responsible entity is not constrained from addressing the request for deviation directly rather than deferring until a suitable revision can be submitted to the Governance and Operations Committee (GOC) for processing. Instead the responsible entity, using their respective processes, should take appropriate action to address the request for deviation. Subsequently, should the action taken rise to the level of an organizational change rather than a one-off deviation, the responsible entity shall then submit a request for revision of the GOM to the GOC for appropriate action.

17.01 Membership Participation

The membership shall be an active participant in maintenance of the GOM. They will be engaged through

- an open forum at each WGM to collect comments and recommendations for maintenance of the GOM,
- the ability to [submit comments and recommendations](#) for maintenance of the GOM interim to the WGM, and

17.02 During the Working Group Meeting

To ensure that all members are aware of current GOM revisions, an extract of the table of “Additions and/or Revisions Subsequently Adopted” reflecting the results of the most recent revision cycle shall be sent to all subscribers of the HL7 list server before or during each Working Group Meeting (WGM). A revision cycle (RC) shall commence concurrent with each WGM. A RC shall be designated by the two-digit calendar year and the typical months WGM occur; i.e. YY01, YY05, YY09.

The Governance and Operations Committee (GOC) shall conduct an Open Forum during each WGM. The scheduled time of the GOC open forum shall be made available to the membership at each morning's general session prior to the open forum. GOC members will be available during the open forum to:

- Answer any questions related to those revisions to the GOM announced at that WGM
- Capture issues for proposed revisions to be considered by the Executive Committee

HL7 Governance and Operations Manual

In addition, the scheduled time shall also be announced during the WG Co-chair's Dinner held at each WGM.

17.03 Concurrent Processes Interim to the Working Group Meeting

17.03.01 Developing the GOM Revisions

The GOC shall prepare documentation with markup reflecting the revision proposals adopted by the EC. This documentation shall be submitted to a peer review process. While a particular revision may dictate additional peer review resources, generally peer review will engage the following HL7 member lists: Board of Directors, Affiliate Chairs, Technical Steering Committee (TSC), Work Group co-chairs, and Process Improvement Work Group.

The peer review period shall be scheduled for thirty days with a closing date preferably at least thirty days prior to the opening date of the next WGM. The GOC and Process Improvement Work Group shall jointly resolve the comments as received such that the GOC can finalize the revisions for consideration and adoption by the Executive Committee prior to the opening of the WGM.

17.03.02 Exceptional Revision Requests

Exceptional revision requests may result from ongoing process review or the comments received during the peer review of revision proposals for the current revision cycle. The GOC shall assess the criticality of the exceptional revision request. If deemed necessary and given sufficient time to conduct a focused peer review of at least two weeks duration, the GOC may seek the approval of the Executive Committee to include the work item in the current revision cycle. Otherwise, the request shall become a candidate for the next revision cycle.

17.03.03 Developing the Revision List for Next Cycle

Following any given WGM, the GOC shall consolidate all comments and recommendations collected during that WGM or captured since the last revision cycle into a proposed revisions list for consideration for adoption by the Executive Committee (EC). Any proposed revision not adopted by the EC shall be deferred for consideration in the next revision cycle or, if so directed, removed from further consideration.

Correction of any typographical or other trivial errors; any items addressing ANSI audit report results; and any items resulting from changes to *ANSI Essential Requirements* shall be considered as adopted proposed revisions and processed accordingly.

17.03.04 Executive Committee Action

Following any given WGM, the GOC shall prepare a motion for the Executive Committee to consider those issues captured by the GOC in the current revision cycle for adoption as proposed revisions.

Upon completion of peer review, preferably at least two weeks prior to any given WGM, the GOC shall prepare a motion for the Executive Committee to consider adoption of the proposed revisions resulting from the current revision cycle. The Executive Committee proceedings shall include notice of those revisions subsequently adopted. Those revisions not adopted may, at the discretion of the EC, be returned to the GOC for additional work during the next revision cycle or declared of no further concern.

17.04 Effective Date of Revision or Adoption

Revisions or additions to the GOM shall be effective on the date stipulated upon adoption by the Executive Committee. An updated GOM shall be posted to the HL7 Web site within ten working days of the closing date of each WGM.

17.05 Periodic Adoption in its Entirety

The Secretary, with the concurrence of the Governance and Operations Committee (GOC), may periodically call for the Executive Committee (EC) to ratify the GOM in its entirety. Upon approval of the Secretary's motion to adopt the GOM in its entirety:

- The GOM shall, within ten working days, be posted to the HL7 web site with an adoption date reflecting the decision of the EC and with all notation of addition or revision removed

HL7 Governance and Operations Manual

- The Secretary shall institute a call for review of all current organizational documentation to ensure compliance with the procedures defined in and the terminology used by the current GOM as adopted by the EC.