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HL7®

GOVERNANCE and OPERATIONS

MANUAL

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HL7 Governance and Operations Manual

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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 add them to the manual with annotation in the following table reflecting the date adopted or revised. Additions and revisions will be posted within ten working days of the date on which they were adopted. 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 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 of the Governance and Operations Manual, adopted in its entirety February 27, 2012, 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 under standing work item 001 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.

<u>Designation</u>	<u>Adopted</u>
03.07 Nonmember Rights and Prohibitions [Revised]	08/26/2014
04.01.03 Organizational [Revised]	01/02/2014
04.01.03.01 Supporter [Deleted]	01/02/2014
04.01.03.02 Benefactor [Deleted]	01/02/2014
06.01.02.03 HL7 Director Nomination Criteria and Voting Pool [Revised]	08/26/2014
06.01.02.04 Nomination and Election Process [Revised]	01/02/2014
06.01.02.04 Nomination and Election Process [Revised]	08/26/2014
06.01.02.04 Nomination and Election Process [Revised]	12/12/2014
06.01.02.05 Appointment of an Interim HL7 Director to Fill a Vacancy [Revised]	01/02/2014
06.01.03 Nomination and Election of Affiliate Directors [Revised]	01/02/2014
06.01.03 Nomination and Election of Affiliate Directors [Revised]	12/12/2014
06.01.03.01 Appointment of an Interim Affiliate Director to Fill a Vacancy [Revised]	01/02/2014
06.02 Duties and Powers of the Board of Directors [Revised]	05/04/2015
06.02.01 Managing the HL7 Roadmap <i>et al</i> [Deleted]	05/04/2015
06.02.01.01 Strategic Initiatives [Revised]	01/02/2014
06.02.01.02 Roadmap Tasks [Revised]	01/02/2014
06.02.01.03 Impact on Annual Budget [Revised]	01/02/2014
06.09 Whistleblower Policy: Reporting Illegalities or Issues of Noncompliance <i>et al</i> [Revised]	05/04/2015
07.05 Secretary [Revised]	04/29/2014
09.01 The Technical Steering Committee (TSC) [Revised]	01/02/2014
09.01.01.01 TSC Chair [Revised]	01/02/2014
09.01.01.02 Steering Division Co-chairs [Revised]	01/02/2014
09.01.01.03 Affiliate Representatives [Revised]	01/02/2014
09.02.04.06 Technical and Support Services Steering Division (T3SD) WG Co-chairs [Revised]	01/02/2014

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09.03 Architecture Review Board (ARB) <i>et al.</i> [Revised]	04/29/2014
10.05 Marketing Council [Deleted with subsequent renumbering]	08/26/2014
10.05 Membership and Strategic Resources Committee [Revised]	05/04/2015
10.06 Nomination Committee <i>et al.</i> [Revised]	08/26/2014
10.10 Process Improvement Committee (PIC) [Deleted]	04/29/2014
10.10 Strategic Initiatives Committee <i>et al.</i> [Deleted]	05/04/2015
13.01.02 Forming the Consensus Group (Revised)	12/12/2014
13.01.02.01 US Realm-specific Consensus Group (Revised)	12/12/2014
13.01.04 Handling Comments [Revised]	05/04/2015
13.01.06 Errata (Added with subsequent renumbering)	12/12/2014
13.02.02 Forming the Consensus Group (Revised)	12/12/2014
13.02.04 Handling Comments [Revised]	05/04/2015
13.02.06 Errata (Added with subsequent renumbering)	12/12/2014
13.03.02 Forming the Consensus Group (Revised)	12/12/2014
13.03.04 Results of the Review [Revised]	05/04/2015
17.02 During the Working Group Meeting [Revised]	01/02/2014
17.03.01 Developing the GOM Revisions [Revised]	01/02/2014
19 User Groups <i>et al.</i> [Added]	05/04/2015

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 §06.02 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 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.

01.04 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.

01.05 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 Purpose, Objectives, and Approach

02.01 Comprehensive Framework

The Modeling and Methodology Work Group shall undertake the development and maintenance of a comprehensive standards development framework to define, clarify, and delineate the processes employed by HL7. The framework shall address at least common processes, standards specific processes, and support and governance processes in sufficient detail to act as a guide to those new to the HL7 process and provide checkpoints to those involved in the process. The comprehensive framework may be promulgated as a standard in order to promote the good practices inherent in the HL7 process.

02.02 Protocol Specifications

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, 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.

02.03 Mission Statement

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

To provide standards for interoperability that improve care delivery, optimize workflow, reduce ambiguity and enhance knowledge transfer among all of our stakeholders, including healthcare providers, government agencies, the vendor community, fellow SDOs and patients. In all of our processes we exhibit timeliness, scientific rigor and technical expertise without compromising transparency, accountability, practicality, or our willingness to put the needs of our stakeholders first.

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

The mission of HL7 encompasses the complete 'life cycle' of a 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:

- a) Develops and publishes both ANSI approved normative protocol specifications and various informative documents on a timely basis
- b) Promotes the use of the protocol specifications and other documentation within the healthcare payer, provider and regulatory community, both nationally and internationally
- c) Provides education:
 - i. On understanding the protocol specifications and their common usage
 - ii. On implementation approaches using the protocol specifications
 - iii. On protocol specification compliance and analysis approaches
- d) Provides conformance certification services
- e) Provides a methodological framework for creating extensions to the protocol specifications
- f) 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
- g) Collaborates with other developers of healthcare and information technology standards to leverage our respective skills, knowledge and standards.

02.04 Contract Work Process

Upon notification of the availability of a contract, either external or internal, the HL7 Executive Committee shall designate a select committee of domain experts and appropriate staff to outline the work or service to be contracted including scope of work; expected qualifications of the contractor or subcontractor; deliverables and work schedule with performance bonus and/or penalties as applicable; and a preliminary budget. The select committee shall only prepare a formal Request for Proposal (RFP) for those contracts valued at more than \$20,000.

Unless the HL7 Executive Committee determines that timeliness or criticality of the project support direct award of the contract based on the recommendation of the select committee, the chair of the select committee shall provide HL7 Headquarters with the contract work announcement template. The contract work announcement shall be posted to the HL7 ContractWork 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 ContractWork list service, but the list service shall not be used for interactive discussions among the subscribers.

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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.

The select committee shall present their proceedings, including recommendations, to the HL7 Executive Committee who shall award the contract. Any member of the Executive Committee who is named in the recommendation or is a member of an organization or has a business relationship with an individual named in the recommendation shall be absent from any decision-making discussion and vote on the award of the contract.

HL7 Headquarters shall post the notification of award of contract to the ContractWork list service and notify the membership of the award via posting in the next edition of the HL7 eNewsletter. 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.

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.

03.01.01 Current Member

All types of members (Student, Health Professional, 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.

03.01.02 Student Member

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

03.01.03 Health Professionals

This membership category is open to physicians, nurses, pharmacists and the many other licensed individuals who are working for healthcare provider organizations and are **directly engaged in providing care to patients OR have 10 years of patient care experience and are currently working for a healthcare organization in an administrative role**. Health Professionals joining HL7 under this limited program should be interested in actively sharing clinical requirements for standards needed to support an increasingly patient-centric healthcare system, and in having access to information and trends currently affecting both the industry and Health Professional practices. Health Professionals who wish to participate in ballots, use the HL7 standards, and participate in governance elections may do so by selecting an appropriate full membership category.

03.02 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; thus 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.

03.03 Classification of Organizational Members

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. This characterization shall be for the purpose of assessing balance in the consensus group relating to normative issues.

03.03.01 Classes of Organizational Membership

03.03.01.01 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.).

03.03.01.02 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.

03.03.01.03 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.

03.03.01.04 Associations/Government Agencies/Universities

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..

03.03.01.05 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.

03.03.01.06 Pharmaceutical

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

03.04 Termination of Membership

03.04.01 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.

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03.04.02 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. 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.

03.04.03 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.

03.05 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.

03.06 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." or "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."

03.07 Nonmember 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 Dues, Fees, and Donations

04.01 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.

04.01.01 Student

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

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04.01.02 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.

04.01.03 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.

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. 04.01.03.01 Umbrella Organization

04.01.03.01 Umbrella Organization

Any organizational member wishing to enroll other organizations as HL7 members must apply for and receive recognition as a Benefactor at the highest level. As appropriate recognition of their exceptional financial contribution, HL7 shall confer on such Benefactors the additional benefit (not currently available to other organizational members) of the ability to enroll one or more other organizations (which may or may not be Subsidiaries, Affiliates, Divisions, or Operating Companies of the Benefactor) as organizational members under the rubric “Umbrella Organization”. Such additional enrollment shall be accomplished under a contract developed by HL7 Headquarters and reviewed and approved by the Executive Committee.

The contract shall include payment of the membership dues of all additional organizational members by the Umbrella Organization (Benefactor). Administrative procedures may be developed to allow the additional organizational members to be identified independent of the Umbrella Organization should this prove more efficient. The contract may allow for quantity discounts on the current dues rate of such additional organizational members. All such additional organizational members shall be granted full rights and responsibilities relevant to the category in which they are enrolled regardless of the dues rate established by the contract.

04.02 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.

04.02.01 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.

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04.02.02 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:

- a) Provide proof of current enrollment in an informatics curriculum (medical, nursing, or clinical informatics) at an accredited college or university
- b) 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)
- c) 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.
- d) 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.

04.02.03 Professional Courtesy

HL7 shall extend the member rate for Working Group Meeting, including the discount rate for tutorial sessions, to ANSI-accredited SDO and other organizations that have executed an HL7 Statement of Understanding (SOU) or Associate 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.

04.02.04 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:

- a. Current Board members
- b. Affiliate Chairs or their designee who shall be a member in good standing of their Affiliate
- c. Past Board Chairs
- d. Up to five designated guests of the CEO, approved by the Executive Committee
- e. 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 at the recommendation of the Organizational Relations Committee (ORC) with the approval of the Executive Committee.

04.03 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.

05 Participation

05.01 HL7 Protocol Specification 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.

05.02 Work Group Co-chair Nomination and Election

05.02.01 Co-chair Nomination

Headquarters shall notify the membership of a 30-day period for nomination of co-chairs at least 60 days prior to each Working Group Meeting (WGM) when an election is to be held. Self-nominations shall be accepted. 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.

Nominees shall be either a current individual member or representative of a current organizational or Affiliate member. The organizational or Affiliate member Key Representative shall confirm the status of those nominees not already designated as voting representatives of the organizational or Affiliate member. All nominees shall be contacted by Headquarters to validate their status as a candidate. Any candidate may decline nomination without question. The same criteria shall apply to write-in candidates.

05.02.02 Co-chair Ballots

At the close of the nomination period a ballot shall be prepared for each Work Group holding co-chair elections. It shall include all validated candidates for co-chair, allow for write-ins equivalent to the number of co-chairs being elected, and instruct the voter to select and/or write-in the appropriate number of names.

05.02.03 Absentee Voting

Current individual members and the designated voting representatives of current organizational or Affiliate members who are subscribers of a Work Group's primary list server but who are not able to attend the WGM may submit an electronic or written absentee ballot to HL7 for the co-chair of that Work Group so long as it is received on or before the Wednesday preceding the scheduled WGM. Absentee ballots shall remain sealed and under the control of the Associate Executive Director pending the tally of the ballots. Absentee ballots shall be validated against the list server subscription lists and the WGM attendees list before being added to the tally.

05.02.04 Voting at the Working Group Meeting

Work Group co-chair elections shall be announced at each general session and shall open on Monday of the Working Group Meeting and continue through the following Wednesday. Work Group co-chairs are encouraged to also announce the co-chair election in their opening comments. The polls shall open with the general session and close at 5:00 PM Monday through Wednesday.

Anyone in attendance at the WGM whose badge holder, issued at registration, identifies them as a Member and who are subscribers of the Work Group's primary list server as of the Wednesday preceding the WGM may pick up and complete that Work Group's co-chair ballot at the HL7 registration desk any time during the polling hours Monday through Wednesday.

The ballots shall be controlled by reference to a list of subscriber email addresses to the Work Group's primary list server. A polling site shall be established in proximity to the HL7 registration desk to allow voters to expeditiously complete the ballot and return it to the ballot box on the registration desk.

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05.02.04.01 Variance to Voting Process

The Associate Executive Director or a staff member specifically designated by the Executive Director is empowered to resolve any variance to the stated process for electing co-chairs at the Working Group Meeting (WGM). The actions available include, but are not limited to: accepting the results of the election even though in variance to process; declaring those elected as acting co-chairs pending an official election at the next WGM; deferring the election either at the request of the Work Group or due to the Work Group not meeting during a given WGM, in which case the terms of the affected co-chairs would be extended until the election is held; or declaring the results of an election null and void with an official election to be held at the next scheduled WGM, in which case the terms of the affected co-chairs would be extended until the election is held. A Work Group may seek the opinion of the Executive Director should they disagree with the decision of the Associate Executive Director or designated staff.

05.02.05 Tally and Announcement

The ballot box shall be secured by HL7 staff when the polls close each day. The Associate Executive Director shall oversee the tally, including absentee ballots. If this tally results in a tie, the decision will be made by drawing lots, unless one of the candidates involved wishes to defer to the other. The results of co-chair elections shall be announced during the Thursday general session, posted on the announcement board near the registration desk, and provided to the Work Groups. All ballot materials shall be retained for one month from the close of the WGM in case of a call for recount.

05.03 Administrative Ballots

Only current individual members and the designated voting representatives of current organizational members may participate in and cast a vote on administrative ballots such as the election of officers and Board members and the adoption or revision of Bylaws. Administrative ballots are not subject to reconciliation or appeal.

05.03.01 Quorum for Bylaws Adoption or Revision

Some combination of at least 100 current individual members and designated voting representatives of current organizational members must cast a vote for revision or adoption of the Bylaws to constitute quorum.

05.04 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.

06 Governance

06.01 Board of Directors

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

06.01.01 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.

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06.01.02 Nomination and Election of Officers and HL7 Directors

06.01.02.01 Nomination and Election Schedule

Nominations shall be accepted from May 1 through June 15 of each year.

Elections shall occur from July 1 through July 30 of each year.

Runoff elections, if necessary, shall occur from August 7 through August 21 of each year.

06.01.02.02 Officer Nomination Criteria and Voting Pool

Nominees for an Officer position (Chair-elect, Secretary, or Treasurer) shall 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.

Every effort shall be made to present at least two candidates for any Officer position. HL7 Headquarters shall provide the official Officer ballot to current individual members and designated voting representatives of current organizational and Affiliate members.

06.01.02.03 HL7 Director Nomination Criteria and Voting Pool

Nominees for HL7 Director shall 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, or TSC member. Service in like positions with another ANSI-accredited Standards Developer (ASD) or an organization with a Statement of Understanding ([SOU](#)) with HL7 may be accepted as equivalent experience.

All valid nominees for HL7 Director shall be placed on the ballot from which those voting will select the appropriate number of positions being filled. HL7 Headquarters shall provide the official HL7 Director ballot to current individual members and designated voting representatives of current organizational members of HL7 International.

06.01.02.04 Nomination and Election Process

Nomination packets shall be available on the first day of the nomination period and shall include instructions for the submission of a petition for nomination. The petition shall indicate the office being sought and include:

- a) a digital image (.jpg preferred) of the candidate
- b) a personal statement of goals and objectives if elected and information on HL7 leadership experience and years of participation
- c) a declaration that they personally have no proprietary interest in any organization currently represented on the Board

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.

All petitions must be submitted to HL7 Headquarters by the close of the nomination period. No nominations shall be accepted 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 Headquarters shall validate that all nominees are current members and contact the nominees to ensure that they:

- a) understand the obligations of serving on the Board of Directors (e.g., attending the Working Group Meetings, participating in Board meetings and monthly conference calls and attending the Board retreat);
- b) are willing to serve; and
- c) have sought and received any necessary endorsements from their respective organizations.

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At any point during the nomination period should the Nomination Committee note a lack of nominees for any given position they may recruit nominees for said position(s). Those nominees, if any, recruited by the Nomination Committee shall meet the criteria stipulated in the two paragraphs above specific to being considered "in nomination" and submission of petitions. In addition, a member of the Nomination Committee, should they be qualified, may resign from the Nomination Committee to seek election given that they subsequently meet the stipulated criteria for nomination.

The final slate shall be presented to HL7 Headquarters for preparation of the ballot at least five days prior to the start of the scheduled election period.

HL7 Headquarters shall provide the official ballots to the appropriate voting pool on the first day of the election period via electronic means. The ballots shall provide for write-in candidates. However, any write-in candidates shall be validated using the criteria stipulated above before their votes are tallied. If unable to respond electronically, members of the voting pool may submit their votes to HL7 Headquarters via letter or fax at any time during the election period.

At the conclusion of the election period the chair of the Nomination Committee 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. The winning HL7 Directors shall be those receiving the largest vote total. In the event of a tie there shall be a runoff election. Results of the election of Officers and HL7 Directors shall be announced by the HL7 Secretary at the Annual Business Meeting.

The results of the tally shall remain on file for one year and shall be produced upon submission of a written request by a current individual member or a voting representative of a current organizational or Affiliate member.

06.01.02.05 Appointment of an Interim HL7 Director to Fill a Vacancy

The Chair may choose to appoint an Interim HL7 Director to fill a vacancy until a duly elected HL7 Director is seated as a result of the next regularly scheduled election. 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 hierarchal and take into account 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. 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.

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Once appointed the Interim HL7 Director shall serve until a replacement HL7 Director is elected to serve the remainder of the term left vacant. The Interim HL7 Director shall be placed on the slate of candidates to be considered for the replacement HL7 Director. The duly elected replacement HL7 Director shall assume his or her seat immediately upon announcement of the results of the election as he or she shall be completing the term left vacant.

The newly elected HL7 Director shall be considered as completing a first term and shall be eligible for election to a second term. In the event that the term being completed would normally have ended the calendar year the election is held; the newly elected HL7 Director shall be considered to have been elected to a normal second term as the incumbent.

06.01.03 Nomination and Election of Affiliate Directors

Using the schedule specified in §06.01.02.01 a call for nominations shall be distributed to the Affiliate chairpersons via electronic means. This notice shall include the duties, obligations, and term of office of the Affiliate Directors. Nominees for Affiliate Director shall have been a designated voting representative of a current Affiliate of HL7 International for at least the last two years and shall have prior leadership experience in HL7 such as Affiliate Chair, committee or council chair, Work Group co-chair, or TSC member.

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. HL7 Headquarters shall contact all nominees to ensure that they

- a) understand the obligations of serving on the Board of Directors (e.g., attending the Working Group Meetings, participating in Board meetings and monthly conference calls and attending the Board retreat); and
- b) are willing to serve; and
- c) state that they personally have no proprietary interest in any organization currently represented on the Board

At the conclusion of the nomination period, HL7 Headquarters shall finalize the slate of nominees and prepare a ballot, which shall be distributed to the Affiliate chairpersons via electronic means. Each Affiliate is allocated a single vote for the Affiliate Director. HL7 Headquarters shall create a limited access web page to allow Affiliate chairpersons to submit their vote electronically. If unable to respond electronically, Affiliate chairpersons may submit their votes to HL7 Headquarters via letter or fax. All votes must be cast within the scheduled election period. The winner shall be the candidate with the largest vote tally. In the event of a tie HL7 Headquarters shall conduct a runoff election.

06.01.03.01 Appointment of an Interim Affiliate Director to Fill a Vacancy

The Chair may choose to appoint an Interim Affiliate Director to fill a vacancy until a duly elected Affiliate Director is seated as a result of the next regularly scheduled election. 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. 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.

Once appointed the Interim Affiliate Director shall serve until a replacement Affiliate Director is elected to serve the remainder of the term left vacant. The Interim Affiliate Director shall be placed on the slate of candidates to be considered for the replacement Affiliate Director. The duly elected replacement Affiliate Director shall assume his or her seat immediately upon announcement of the results of the election as he or she shall be completing the term left vacant.

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The newly elected Affiliate Director shall be considered as completing a first term and shall be eligible for election to a second term. In the event that the term being completed would normally have ended the calendar year the election is held; the newly elected Affiliate Director shall be considered to have been elected to a normal second term as the incumbent.

06.01.04 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.

06.01.05 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.

06.01.06 Travel for HL7 Board Functions

Selection by the Chief Executive Office as a candidate for the Board of Directors or nomination as an Officer, HL7 Director, or Affiliate Director 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. 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.

06.01.06.01 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.

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06.01.06.02 Attending 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.

06.02 Duties and Powers of the Board of Directors

The Board of Directors shall:

- a) Approve the contract for an organization to provide technical and administrative services for HL7 on such terms and conditions as it may deem advisable.
- b) 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.
- c) Provide for the development and maintenance of an HL7 strategic plan.
- d) Ratify recommended appointments for the chairmanship of councils and both *ad hoc* and standing committees.
- e) Review and approve the annual budget.
- f) Create advisory groups and councils as necessary to fulfill liaison with other organizations; and ratify the recommended appointments for representatives to those organizations.
- g) Report to the membership annually regarding the goals and objectives of the organization and other such matters as are necessary and advisable.
- h) 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.
- i) 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.

06.03 Board of Directors Meetings

- a) 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.
- b) 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.
- c) 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.
- d) 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.
- e) 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.

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- f) 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.
- g) 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.
- h) 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.
- i) 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.

06.03.01 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.

06.03.02 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.

06.04 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.

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06.04.01 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:

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

A financial interest is not necessarily a conflict of interest. Under §06.04.02.02 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.

06.04.02 Procedures

06.04.02.01 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.

06.04.02.02 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.

06.04.02.03 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.

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06.04.02.04 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.

06.04.03 Records of Proceedings

The minutes of the Board and Executive Committee shall contain:

- a) 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.
- b) 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.

06.04.04 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.

06.04.05 Annual Statements

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

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

06.04.06 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:

- a) Whether compensation arrangements and benefits are reasonable, based on competent survey information and the result of arm's length bargaining.
- b) 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.

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06.04.07 Use of Outside Experts

When conducting the periodic reviews as provided for in §06.04.06, 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.

06.05 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.

- a) They shall avoid situations in which they personally might profit or even give the appearance of profiting from their official HL7 activities.
- b) They shall not employ the name of HL7 in seeking or accepting payment for professional services.
- c) 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.
- d) They shall not use the HL7 name or its stationery for other than official HL7 business.
- e) 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.

06.06 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.

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All votes shall be submitted using “Reply All” to allow the members of the Board of Directors or Executive Committee to monitor progress. 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.

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.

06.07 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.

06.08 Fiscal Policy

06.08.01 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.

06.08.02 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.

06.08.03 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.

06.08.04 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.

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06.08.05 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:

- a) Coach class airfare
- b) Lodging
- c) Meals exceeding \$25
- d) Transportation
- e) Parking
- f) Telephone or communications charges, including Internet access
- g) Any other authorized expenditures

HL7 shall NOT reimburse:

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

06.09 Whistleblower Policy: Reporting Illegalities or Issues of Noncompliance

06.09.01 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 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.

06.09.02 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.

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06.09.03 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.

06.09.04 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.

06.09.05 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.

07 Officers

07.01 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 Executive Director, shall comprise the Executive Committee. Officers must be current members. 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.

07.02 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.

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07.02.01 Term of Office

The Chair shall serve for a term of two years, ascending from the Chair-Elect serving in odd-numbered years (term encompassing first the following even-numbered year, then the subsequent odd-numbered year).

07.02.02 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 [§10.08] 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.

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.

07.02.03 Reimbursing Expenses of the 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.

07.03 Chair-Elect

The Chair-Elect shall ascend to the Chair at the conclusion of the term of the then seated Chair. The Chair-Elect shall assist the Chair and develop the operating plan for the following year. The Chair-Elect shall be a member, *ex officio*, without vote, of all councils and committees including the Technical Steering Committee. The Chair Elect shall serve as Vice Chair of the Board of Directors.

07.03.01 Term of Office

The Chair-Elect shall be elected during the first year of the term of the then seated Chair and serve for a period of one year, coincident with the second year of the term of the then seated Chair.

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07.04 Immediate Past Chair

At the completion of their term the Chair shall assume the role of Immediate Past Chair. The Immediate Past Chair shall assist the incoming Chair in implementing their operating plan. The Immediate Past Chair shall be a member, ex officio, without vote, of all councils and committees including the Technical Steering Committee. The Immediate Past Chair shall serve as Vice Chair of the Board of Directors

07.04.01 Term of Office

The Immediate Past Chair shall serve for a period of one year, coincident with the first year of the term of the then seated Chair.

07.05 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:

- a) 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
- b) record and publish Board proceedings and motions
- c) create and distribute Board meeting and Working Group Meeting notices at least 30 days prior to such meetings
- d) create and distribute voting items and ballots as directed by the Board
- e) tally votes
- f) distribute Board agendas
- g) maintain the roster of Board members
- h) maintain this Manual and cause updates to be posted to the Web site
- i) establish and maintain appropriate archives and historical records of all official HL7 business
- j) maintain any other records required by law

07.05.01 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.

07.06 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. The Treasurer shall qualify for a fidelity bond procured by the Board of Directors.

07.06.01 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.

07.07 Individuals Appointed to Fill Vacant Officer Positions

An individual appointed to complete the term of a vacated Officer position, other than the Chair, pursuant to Bylaws §06.02.02 shall be considered to be serving a first term in the appointed position.

08 Appointed Positions

08.01 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.

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.

09.01 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. 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. The Chief Technology Officer (CTO) as well as the Chair and Vice Chair of the Architecture Review Board (ARB) shall be *ex officio* members with vote. The ARB Chair and Vice Chair shall share a single vote on formal motions.

Should the TSC identify an imbalance or the need for specific expertise, they may vote to include *ad hoc* members to correct the situation. The TSC shall elect its own chair from among current or former members; excluding *ex officio* members. 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:

- a) Establishing and maintaining an HL7 Architecture, development methodologies, and work processes to be used by The Working Group in developing HL7 protocol specifications
- b) Ensuring that the efforts of The Working Group to produce protocol specifications proceeds at a reasonable pace
- c) Ensuring that The Working Group collaborates smoothly and covers the scope of work in a consistent manner.
- d) 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.

09.01.01 TSC Elections

The election of TSC representatives shall be held prior to the annual plenary meeting with one of each of the steering division co-chairs and one of the two Affiliate representatives elected each year. The results of the election shall be announced during the plenary meeting with the representatives taking office the following January.

During the second WGM each year those SD co-chairs and the Affiliate representative 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 or, in the case of the Affiliate representative, the Affiliate chairs 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.

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09.01.01.01 TSC Chair

The TSC shall select its chair following the plenary meeting in odd numbered years from among those regular members currently seated or recently elected or qualified former members. The selected individual shall take office in January of the following even numbered year.

09.01.01.02 Steering Division Co-chairs

Adopting the schedule specified in §06.01.02.01, nominations for Steering Division (SD) co-chairs shall be accepted from the co-chairs of the Work Groups (WG) comprising the SD. The nominees must be current HL7 members and, although not required, should be either current or past co-chairs of one of the WG comprising the SD. It is felt that level of experience is necessary to be an effective member of the TSC. Service on the TSC requires a commitment of at least two hours a week.

HL7 staff will contact nominees to verify their willingness to stand for election, to confirm their commitment to participate as stipulated in §09.01.05, and to solicit a brief statement for distribution. Individuals who are nominated for more than one position (SD co-chair or Affiliate representative) will be asked to choose which nomination they wish to accept, thereby rejecting the other(s).

Votes shall be cast by the WG co-chairs in the SD, using their normal decision-making practices to assess their WG's preference. Write-in candidates shall be accepted on the ballot. The candidate receiving the most votes will be named the SD co-chair. Tie votes will be resolved by a runoff election. If this tally also results in a tie, the decision will be made by drawing lots, unless one of the candidates involved wishes to defer to the other.

09.01.01.03 Affiliate Representatives

An Affiliate representative shall be elected each year to serve a two year term. During a nomination period of at least 30 days, nominations for Affiliate representative shall be accepted from the Affiliate chairs. Nominees should be prepared to commit at least two hours a week to the TSC, if elected. HL7 staff will contact nominees to verify their willingness to stand for election, to confirm their commitment to participate as stipulated in §09.01.05, and to solicit a brief statement for distribution. Individuals who are nominated for more than one position (Affiliate representative or SD co-chair) will be asked to choose which nomination they wish to accept, thereby rejecting the other(s).

An election period of at least 30 days will follow the nomination period. Votes will be cast by the allotted voting representatives of the Affiliates, using their normal decision-making practices. Each Affiliate will vote for their candidate of choice. Write-in candidates shall be accepted on the ballot. The candidate receiving the most votes will be named the Affiliate Representative. Tie votes will be resolved by drawing lots, unless one of the candidates involved wishes to defer to the other.

09.01.02 Term of Office

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

09.01.02.01 TSC Chair

The TSC Chair shall serve a term of two years without term limits; the only criteria being current membership in the TSC. Should the TSC member selected to serve as the TSC Chair only have a year remaining of their term as an SD or Affiliate representative, and is not subsequently elected to another term, the second year of their term as TSC Chair shall be served as an *ad hoc* member of the TSC.

09.01.02.02 Elected Members

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

09.01.02.03 *Ad Hoc* Member

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

09.01.03 Vacancies

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

09.01.03.01 TSC Chair

Upon the resignation of the chair, the TSC shall select another member to fill the remaining term of office.

09.01.03.02 SD Co-chairs

Upon the resignation of an SD co-chair, the SD, following its decision making practices, shall appoint an interim co-chair pending the immediate nomination and subsequent election of another co-chair to complete the remaining term of office.

09.01.03.03 Affiliate Representative

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

09.01.04 Removal from Office

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

09.01.04.01 SD 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 Steering Division or TSC teleconferences held in the preceding calendar year; or
- failure to fulfill the responsibilities set forth in §09.01.01.02.

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.

The 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 § 09.01.03.02 to identify a replacement SD co-chair.

09.01.04.02 Affiliate Representative

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 TSC teleconferences held in the preceding calendar year; or
- failure to fulfill the responsibilities set forth in §09.01.01.03.

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.

The 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 § 09.01.03.03 to identify a replacement Affiliate representative.

09.01.05 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.

09.01.05.01 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.

09.01.06 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.

09.01.07 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.

09.01.08 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.

09.02 Work Groups

09.02.01 Establishing a Work Group

09.02.01.01 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:

- a) 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.
- b) The expressed need is within the scope of HL7 and creation of the proposed Work Group shall facilitate HL7 accomplishing its mission and objectives.

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- c) There are 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.

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.

09.02.01.02 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 Marketing Council 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.

09.02.02 Changing a Work Group Name or Mission/Charter

Given approval under the Work Group's documented decision making practices, the co-chairs shall present a 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 as 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.

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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.

09.02.03 Dissolution of a Work Group

Given approval under the Work Group's documented decision making practices, the co-chairs shall petition 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 petition 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 Dissolution Template 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 template.

The parent SD co-chairs shall distribute the template 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 template 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.

09.02.04 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 (WGM) with the actual number of co-chairs determined by majority vote of the Work Group. A decision by the Work Group to increase the number of co-chairs shall result in the subsequent call for nominations and an election for those positions at the next WGM. The Work Group may, using their decision making practices, designate an individual to fill the additional position interim to the next WGM who may be a candidate for said position.

09.02.04.01 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](#).

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09.02.04.02 Term of Office

Co-chairs shall serve two year terms without term limits. Terms shall commence upon validation of election results. 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.

09.02.04.03 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; or
- failure to fulfill the responsibilities set forth in §09.02.04.01.

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 1) that individual immediately stepping down from the position of co-chair; 2) removal of that individual from the list of co-chairs on the Work Group's web page; and 3) HL7 Headquarters scheduling a co-chair election for the next WGM. The Work Group may, using their decision making practices, designate an individual to serve as co-chair interim to the election who may be a candidate for said position.

09.02.04.04 Co-chair Vacancy due to Change in Membership Status

Should a seated co-chair experience 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 immediately step down from the position of co-chair. The Work Group shall notify HL7 Headquarters of the loss of a co-chair; request a co-chair election for the next WGM, and seek nominees for the position. Resolution of the individual's membership status would allow them to seek nomination for reelection 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 election who may be a candidate for said position.

09.02.04.05 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; request a co-chair election for the next WGM; and seek nominees for said position. The Work Group may, using their decision making practices, designate an individual to serve as a co-chair interim to the election who may be a candidate for said position.

09.02.04.06 Technical and Support Services Steering Division (T3SD) WG Co-chairs

The T3SD Work Groups, given the unique nature of their mission/chapter statements, have a special relationship with the Board. Therefore each T3SD Work Group shall select one co-chair to serve as liaison to the Board. The designated WG co-chair shall prepare a written status report for inclusion in the Board packet at each WGM and presentation to the T3SD co-chairs, who shall bring such reports to the attention of the TSC. The designated WG co-chair from each T3SD WG shall be prepared to present their WG's report to the Board in person, if requested to do so by the HL7 Chair or their designee. Should the designated WG co-chair not be available during the WGM, another WG co-chair may be asked to present the report to the Board.

09.02.05 Decision Making Practices

All HL7 Work Groups shall follow a documented set of decision-making practices. 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, this manual or the current edition of ANSI Essential Requirements. Working sessions of each Work Group shall be governed by the rules set forth in their decision-making practices. Meetings hosted jointly shall follow the practices 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 a Work Group's documented decision making practices, 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.

09.03 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. 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](#)

09.03.01 Composition

The ARB shall have a Chair and Vice Chair, who shall continue the business of the ARB in the Chair's absence, 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, ARB Chair and Vice Chair 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, ARB Chair and Vice Chair. 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.

09.03.02 Criteria for Membership

09.03.02.01 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:

1. 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.
2. HL7 "core infrastructure" components including complex data types, vocabulary binding, structured documents, methodology and modeling, infrastructure and messaging, implementation and conformance, etc.

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09.03.02.02 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:

- a. participate in 75% of weekly conference calls
- b. dedicate 6 - 10 hours each week, in addition to conference calls, to ArB deliverables
- c. attend at least two of the three Working Group Meetings each year

09.03.02.03 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, ARB Chair or Vice Chair.

09.03.03 Term of Membership

The CTO, ARB Chair and Vice Chair shall consider staggering appointments to the ARB to ensure continuity of knowledge of recent history and ongoing goals and objectives of the ARB.

09.03.03.01 ARB Chair and Vice Chair

There shall be no limit on the duration of service of the ARB Chair and Vice Chair subject to the approval of the TSC.

09.03.03.02 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, ARB Chair and Vice Chair with the approval of the TSC.

09.03.03.03 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, ARB Chair and Vice Chair prior to making their recommendations on renewal to the TSC.

09.03.04 Change of Member 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.

09.03.05 Removal of Member

Any ARB member who – in the opinion of the CTO, ARB 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 TSC, be removed from the ARB at any point during their term.

09.03.06 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.

09.04 HL7 Terminology Authority (HTA)

In support of the agreement between HL7 and IHTSDO, the HTA is established to be 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 continuous maintenance of the HL7 RIM (Harmonization). The HTA shall work through the TSC to implement any processes or policies that impact the Working Group.

09.04.01 Purpose

The HTA, as a representative body of HL7 International, shall ensure that HL7 provides timely and high quality terminology products and services to meet its business needs. The HTA shall serve as the single point of contact with any external terminology standards development organizations (SDO) with which HL7 has established, or in the future shall establish, formal relationships.

09.04.02 Scope

The HTA is exclusively focused on the content of Value Set Expansions derived from external terminology SDO code systems. Responsibilities include:

1. Develop and maintain quality processes and measures related to HL7 terminology derived from external terminology SDO
2. Provide advice, where needed, on the acceptability of external vocabulary proposed for inclusion in HL7 terminology (NOTE: this does NOT refer to “infrastructure controlling” vocabulary, e.g. the CS data type)
3. Maintain relationships with external terminology SDO to ensure legal use of their products.

09.04.03 Participation in the Harmonization Process

The HTA shall be in an advisory capacity relevant to the harmonization process, which shall continue to be the final authority for terminology decisions. Vocabulary facilitators, in response to requests for new coded content, may submit requests to the HTA for consideration as to whether content coverage requested is provided by an external terminology. If deemed appropriate for derivation from or addition to an existing 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 SDO.

The HTA may engage the harmonization process:

1. During vocabulary proposal development when vocabulary facilitators should decide whether the concepts resulting from the expansion of the value set definition may be derived from an external terminology and whether all of the concepts to support the proposal exist in said terminology. The HTA should have the opportunity to review such proposals prior to submission
2. During harmonization where a HTA representative should:
 - a. Participate as a voting member on those proposals where external terminologies are being considered
 - b. Be prepared to answer questions concerning the use of external terminologies
 - c. Hold “steward” status on those proposals for implementation of external terminologies
 - d. Accept those content requests for submission to external terminology SDO assigned during the meeting
3. Following harmonization when the HTA shall review the minutes for any assigned action items; any resulting new content or assigned identifiers being returned for harmonization

09.04.04 Composition

The HTA shall be composed of five current members of HL7 appointed by the Board of Directors including one Vocabulary WG co-chair and at least two Affiliate members. 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.

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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 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.

09.04.05 Criteria for Membership

09.04.05.01 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:

1. 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.
2. Good terminology practices as defined by the Cimino desiderata coupled with in depth knowledge of the HL7 core principles for terminology
3. 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.
4. Realizing the implications of developing and managing an extension to one or more of the large scale reference terminologies cited

09.04.05.02 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:

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

09.04.05.03 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.

09.04.06 Term of Membership

Members of the HTA shall serve a two year term from their date of appointment, with two 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.

09.04.06.01 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.

09.04.07 Change of Member 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.

09.04.08 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.

09.04.09 Conduct of Meetings

Quorum shall be met when at least 3 members are in attendance whether physically or virtually, including either the chair or vice chair each of whom shall have a vote. All issues before the HTA shall be resolved by simple majority. A tie vote may result in an item being tabled for consideration at a later meeting.

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 Committees and Councils

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 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.

10.02 International Council

The International Council shall be the collective leadership of the Affiliate members. The International Council shall elect its own leadership. It 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.

10.02.01 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.

10.03 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 **§06.01.01 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. It shall be responsible for reviewing the annual audit of HL7 financial records. Should the auditor raise serious 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.

10.04 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 will comprise the Governance and Operations Committee (GOC), which shall be responsible for maintenance of this manual as defined in §17.

10.05 Membership and Strategic Resources Committee

The Membership and Strategic Resources Committee (MSRC) shall consist of a chair appointed by the HL7 Chair with the concurrence of the Board and up to eight (8) other members nominated by the appointed chair and approved by the Board; said members to be representative of the various stakeholder groups active within HL7 including two (2) representatives from amongst the Affiliate membership. The HL7 Director of Membership Services shall be a member *ex-officio* with vote. The HL7 CEO, the HL7 Executive Director, and the HL7 Associate Executive Director shall be members *ex officio* without 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 HL7 Chair at his or her discretion may, with the approval of the Board, fill any opening on or replace any member of this committee.

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The MSRC shall advise the Board in four broad areas:

1. Mechanisms to retain current and recruit new members of HL7 International including new or expanded membership benefits
2. Models for expanding member categories, activities, meetings, and conferences beyond the technical processes specific to standards development and maintenance
3. New revenue opportunities other than membership
4. Development of a functional framework defining the relationship between Affiliate Members and HL7 International

10.06 Nomination Committee

A Nomination Committee shall be convened during the first Working Group Meeting of each year to oversee the nominations process for the Board of Directors; collect and validate petitions of nomination; actively recruit, if necessary, to ensure a viable, balanced slate of candidates; and prepare the slate for ballot.

10.06.01 Composition

The Nomination Committee shall consist of:

- a) Up to four representatives, who meet the criteria for participation, elected from amongst current individual members or designated voting representatives (HL7 Bylaws §03.02.03) of current organizational members
- b) Up to two representatives selected by the Technical Steering Committee
- c) Up to two representatives, who shall be designated voting representatives of current Affiliate members, selected by the International Council
- d) The Advisory Council may select one representative, if it so chooses.
- e) The Board of Directors may select one representative, if it so chooses.
- f) The Executive Director shall be an ex officio member with vote and shall appoint an HL7 staff member to support the committee

10.06.01.01 Elected Representatives

A four week nomination period for member candidates seeking a seat on the Nomination Committee, to start the second Monday following the close of the third Working Group Meeting, shall be announced during the Tuesday general session of the third Working Group Meeting of each year. Any current individual member or voting representative of a current organizational member of HL7 may submit a nomination which shall be validated against HL7 membership rolls to ensure that the nominee has completed at least two years of active participation. There shall be no prohibition to self-nomination. If there are four or fewer validated candidates, they shall be accepted as selected by acclamation.

If there are more than four validated candidates, HL7 Headquarters shall prepare a ballot containing all validated candidates for release to current individual members and the voting representatives of current organizational members by the second Monday following the close of the nomination period. The ballot shall be open for thirty days. HL7 Headquarters shall tally the vote. The four candidates receiving the most votes shall be the membership representatives on the Nomination Committee. A tie vote impacting the fourth position shall be resolved by a run off ballot of two weeks duration to be initiated the second Monday following the close of the initial ballot.

10.06.01.02 Selected Representatives

The Advisory Council, Board of Directors, International Council, and the TSC shall, if they so choose, select their representatives at least one month prior to the start of the first Working Group Meeting of each year.

10.06.02 Announcement

The members of the Nomination Committee shall be announced via the HL7 list server at least one week prior to the opening of the first Working Group Meeting of the year.

10.06.03 Selecting a Chair

The Nomination Committee shall elect its own chairperson, who shall not be the Advisory Council, International Council or Board of Directors representatives if present.

10.06.04 Term of Service

The Nomination Committee shall serve through the nomination period, being disbanded on or before the start of elections subject to recall in the event of a special election for HL7 Chair.

10.07 Organizational Relations Committee

The Organizational Relations Committee shall consist of a chair appointed with the concurrence of the Board and at least two (2) other members. The CEO shall be an *ex-officio* member. 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 Organizational Relations Committee shall be responsible for initiating and/or managing, under the direction of the CEO, the relationship between HL7 and various other organizations, associations, and consortia. The Organizational Relations Committee shall draft appropriate statements of understanding (SOU) and associate charters addressing these relationships. Whenever possible, these documents shall name those individuals being proposed as liaisons. The CEO shall bring these documents before the Board for consideration and approval.

10.08 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. The PAC shall review and comment on any statements, written or oral, espoused as representing an HL7 position [§07.02.02] prior to the submission of such statements to the Executive Committee for approval.

10.09 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.

11 Conferences, Meetings, and Educational Programs

11.01 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.

11.02 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.

1. The HL7 Executive Committee approves the request.
2. The purpose of the proposed meeting is one of the following:
 - a. To jointly develop standards
 - b. To coordinate with HL7
 - c. To share in educational opportunities
3. 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:

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

11.03 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 Work Group during the WGM that precedes their occurrence.

Proposed tutorials should meet the following criteria:

- a) The topic should be of broad interest to the Working Group or to one of its Work Groups
- b) The topic should be of interest to all classes and types of HL7 members
- c) 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 Work Group for recommendation. The Education Work Group will promptly review and make a recommendation on the proposal, presenting it to the Executive Committee 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.

11.04 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., a 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 sufficiently in advance to allow for a decision by the TSC and still accommodate the required thirty days prior notice. Proposals will include:

- a) The purpose of the meeting
- b) Expenses to be borne by HL7, if any
- c) The name of the individual(s) in charge of the meeting
- d) 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:

- a) Until the series is completed, or
- b) Until the receipt by HL7 Headquarters of a statement that such special meetings are no longer necessary, or
- c) Until the sponsoring group is disbanded, or
- d) 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 Electronic Ballots

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

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

12.01 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.

12.02 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

12.02.01 Constructing V2.x Ballot Protocol Specification Names

The naming convention for a normative iteration of Version 2 shall be:

HL7 Standard Version 2.[release number]: An Application Protocol for Electronic Data Exchange in Healthcare Environments

The naming convention for Version 2 implementation guides shall be:

HL7 Version 2.[release number]: Implementation Guide: [Work Group name]; [application name]; Release [IG release number]

12.02.02 Constructing Other HL7 Ballot and Protocol Specification Names

The full document name shall begin with a document type classification followed by a descriptive document title indicating the contents/use of the document and its realm of applicability; further, the title should avoid the use of acronyms wherever possible. The full name should end with a release identifier.

12.02.02.01 Document Type Classification

The document type classification generally consists of:

- An Organizational Identifier(s)
 - ANSI/HL7 indicating an HL7 document that is an ANSI-approved normative standard
 - HL7 indicating an HL7 document other than an ANSI-approved normative standard
 - HL7/Other [such as NCPDP] indicating an HL7 document published in conjunction with another organization
- A Standard Family or Product Identifier such as Version 3 or CDA Release 2; where a document includes reference to two or more Families or Products it may be identified as Cross-paradigm. Certain Family or Product Identifiers such as CCOW and Arden Syntax followed by a release identifier provide a sufficient and complete full document name.
- A Document Classifier such as Standard or Implementation Guide

12.02.02.02 Document Title

The document title shall be descriptive and avoid the use of acronyms wherever possible. In general, a title should indicate not just a broad topic area but also a specific area of applicability or relevance within that topic area. For Version 3 documents, common practice is to begin the title with the domain name or realm and then, if needed, indicate the topic (preceded by a semicolon).

12.02.02.03 Release Identifier

All document names shall conclude with a release identifier. Release identifiers shall consist of only the word "Release" followed by the release number. The use of alternate terms for release (e.g. "Version", "Iteration", etc.) is discouraged. In addition, release numbers should be whole numbers; the use of sub-numbering (e.g. 1.1, 1.2, etc.) is discouraged.

12.02.02.04 Punctuation

For simple document names, the document type classification is separated from the document title by a colon, and the release number is separated from the document title by a comma, for example:

- HL7 Version 3 Standard: Claims and Reimbursement, Release 3
- HL7 CDA Release 2 Implementation Guide: Healthcare Associated Infection Reports, Release 1

When a domain name or realm is included in the document title, the two are separated by a semicolon, for example:

- HL7 Version 3 Standard: Care Provision; Allergy and Intolerance, Release 1
- HL7 Version 3 Standard: Clinical Genomics; Pedigree, Release 1

12.02.03 Approving HL7 Ballot and Protocol Specification Names

Normative Material, Informative Documents and DSTU:

The Work Group proposing a new document title, or a change to an existing document title, shall obtain approval from the TSC prior to the document moving to ballot.

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.

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.

13 Review Ballots

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

13.01 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 shall 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.

13.01.01 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.

13.01.02 Forming the Consensus Group

All current members shall be notified of the intent to form a consensus group and ballot an informative document. 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.

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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.

13.01.02.01 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.

13.01.03 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.

13.01.04 Handling Comments

At the close of the ballot the responsible Work Group (WG) shall capture all comments using the HL7 Ballot Spreadsheet 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 Spreadsheet 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; however, an agreement that the negative comment is persuasive, resulting in change to the subject matter, will most likely result in the submitter changing their ballot to affirmative which may affect the outcome of the ballot.

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.

13.01.05 Approval

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.

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Upon approval the responsible Work Group shall submit a [Request for Publication of an Informative Document](#) form 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.

An approved informative document may, with the approval of the TSC, be registered with ANSI as a Technical Report. While registering the document with ANSI does not infer any status on the document, it does ensure notification of the availability of the informative document to a broad audience.

13.01.06 Errata

A request to publish errata to an informative document shall be accompanied by a draft cover letter citing the rationale supporting such a request and shall be submitted to the Chief Technology Officer (CTO) for approval.

An example of an informative document errata cover letter may be found embedded in the following document file: [V251 IG SIF LABRESULTS DSTUR1 2012JUL.zip](#)

13.01.07 Registration as an ANSI Technical Report

HL7 develops materials that are useful in conjunction with American National Standards. These mainly take the form of informative documents and give methods for application of an American National Standard. Registration of such documents with ANSI is undertaken to encourage widespread use and acceptance, not only of the Technical Report, but also of the related American National Standard. However, nothing precludes a standards developer from developing, approving and disseminating its own reports or other publications.

All material contained in a Technical Report that has been registered with ANSI is informational in nature. Technical reports may include, for example, reports of technical research, tutorials, factual data obtained from a survey carried out among Standards Developers and/or National Bodies, or information on the "state of the art" in relation to standards of National or International bodies on a particular subject. Technical reports may not be used as a way to circumvent the regular consensus process for approval of an American National Standard.

13.01.07.01 Criteria for Registration

To be registered as a Technical Report a document shall be entirely informative in nature and shall not contain information implying that it is a standard. It shall clearly explain its relationship to aspects of the subject that are, or will be, dealt with in related American National Standards. All Technical Reports registered with ANSI must be in compliance with the ANSI Patent Policy.

13.01.07.02 Required Foreword

When a document that has been registered as a Technical Report with ANSI is published, the following text shall be included in the foreword. "Publication of this document that has been registered as a Technical Report with ANSI has been approved by Health Level Seven International (HL7), 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104-4261. This document is registered as a Technical Report according to the Procedures for the Registration of Technical Reports with ANSI. This document is not an American National Standard and the material contained herein is not normative in nature. Comments on the content of this document should be sent to HL7, 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104-4261 or [appropriate email address]." In addition, the foreword should include a rationale for the publication of the document registered as a Technical Report with ANSI.

13.01.07.03 Procedures for Approval and ANSI Registration

The decision to publish a document as a Technical Report that is registered with ANSI (or as a Supplement to a currently registered Technical Report) shall require approval by the TSC using its own procedures and the procedures stipulated by ANSI as well as compliance with **§13.01**

Informative Documents. HL7 assumes responsibility for assuring that policies and procedures are followed in the development and approval of a Technical Report that is registered with ANSI. At the time of the submittal of the technical report for registration, HL7 shall certify that it has complied with its own and ANSI procedures.

Technical Reports that are registered with ANSI need not be subjected to consensus by public review before approval action is taken by HL7. In addition, no approval by ANSI's Board of Standards Review, the Executive Standards Council, or any other ANSI body is required prior to registration of the Technical Report with ANSI; however, ANSI reserves the right to deny registration of any Technical Report, for legal reasons, upon advice of its counsel, or where it is shown that publication of the Technical Report is contrary to the public interest.

Prior to registration of the Technical Report with ANSI, a 30-day announcement of the intent to register said report shall be placed in *Standards Action*. Parties interested in further information will be instructed to contact HL7. Immediately following the close of the announcement of the intent to register, the technical report shall be registered with ANSI. A PSA-01 form shall be used to initiate both the announcement in *Standards Action* and ANSI registration. An Accredited Standards Developer may choose, at any time, to issue a supplement to a Technical Report that has been registered with ANSI. The issuance of a supplement to a Technical Report that has been registered with ANSI shall require adherence to the same procedures as for registration of a Technical Report with ANSI.

Each Technical Report (with any supplements) registered with ANSI is subject to review by the responsible Accredited Standards Developer, following its own procedures. Reaffirmation, revision or withdrawal of a Technical Report that is registered with ANSI is determined by the responsible Accredited Standards Developer and the results of this determination are transmitted to ANSI for registration and publication action, as appropriate. Any Technical Report that has not been reaffirmed, revised or withdrawn by the tenth anniversary of its registration will be withdrawn administratively and a notice of same placed in *Standards Action*.

13.01.07.04 Designation and Publication

A document that has been registered with ANSI as a Technical Report shall have its cover or title page marked with the words "a Technical Report prepared by Health Level Seven (HL7) and registered with ANSI". The words "an American National Standard" shall not be used on any Technical Report. The date of registration shall be included in the published Technical Report, preferably on the cover. A Technical Report registered with ANSI shall be identified by a unique alphanumeric designation that shall include: (1) a Technical Report Identifier of HL7 TR and (2) a designation assigned by the HL7 and registered with ANSI such as HL7 TR 1-2008.

Technical Reports that are registered with ANSI shall be published and made available within three months of registration, if possible. In no case shall publication take longer than six months. HL7 shall publish the Technical Report or shall arrange for publication by another entity.

13.01.07.05 Challenging the Registration of a Technical Report

Developers of Technical Reports that are registered with ANSI shall establish and adhere to procedures that afford materially affected interests the opportunity to challenge the decision to register a technical report with ANSI. Materially affected interests wishing to initiate such a challenge at ANSI shall first exhaust all methods of challenge at the Accredited Standards Developer's level prior to submittal to the ANSI Appeals Board.

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The only basis upon which such a challenge shall be filed is failure of HL7 to follow either its own procedures or any other provisions contained in the *Procedures for the Registration of Technical Reports with ANSI*. The burden of proof shall be on the challenger. An announcement regarding the challenge will appear in *Standards Action*. There will be no suspension of the registration of the document with ANSI as a Technical Report during the challenge process.

Materially affected interests shall deliver their challenge including all appropriate contact information to the HL7 business office (§01.02) addressed to the attention of the Associate Executive Director. Upon receipt the Associate Executive Director shall immediately notify the Executive Committee of the submission of a challenge by providing them a copy of the correspondence. The Executive Committee shall identify a disinterested third party, who may or may not be a member of HL7, and instruct them to conduct an audit of the process and records related to the publication being challenged. The individual conducting the investigation shall prepare a report for the consideration of the Executive Committee, who shall resolve the challenge. The challenger may appeal the decision of the Executive Committee to ANSI.

13.01.08 Withdrawal of an Informative Document

A Work Group that, through its decision making practices, identifies a non-normative HL7 Protocol Specification [§02.02] to be withdrawn shall initiate a project for that purpose and request that a Comment-only Ballot be undertaken to assess the impact of the withdrawal of the subject protocol specification. The content of said Comment-only Ballot shall identify the subject protocol specification and request input on the decision to withdraw the document. The ballot instructions shall clearly state that the intent of the ballot is to assess the impact of the withdrawal of the document; not to collect comments on the contents of the subject protocol specification.

Should the TSC, considering the results of the Comment-only ballot, support the withdrawal of the subject protocol specification, a notice of withdrawal shall be published in both the HL7 Newsletter and the HL7 Technical Newsletter citing the date of withdrawal. If the document to be withdrawn has been registered with ANSI as a Technical Report, the decision to withdraw the document will be reported to ANSI for publication in *ANSI Standards Action*. The proposed date of withdrawal shall allow sufficient time to address any public comments that may be received.

13.02 Draft Standards

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 draft standard and its release for trial use to establish interoperability. While there is no ANSI requirement for due process regards a draft standard, given that the ultimate objective is the creation of a normative standard it is appropriate to validate the content of the draft standard by subjecting it to review prior to its release for trial use. Should the content of the proposed draft standard not be approved, for whatever reason, it may simply be withdrawn from consideration. Following a successful review the draft standard, in the appropriate form, may be presented to the TSC for release as a Draft Standard for Trial Use (DSTU).

13.02.01 Initiation

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

13.02.02 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 draft standard. 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 Draft Standard 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.

13.02.03 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.

13.02.04 Handling Comments

At the close of the review ballot the responsible Work Group (WG) shall capture all comments using the HL7 Ballot Spreadsheet 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 draft 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 Spreadsheet 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. Nevertheless, the responsible Work Group is expected to annotate each negative comment on the reconciliation spreadsheet with a disposition of "Persuasive", "Not Persuasive", 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). There is no requirement to resolve negative comments and seek withdrawal of the negative; however, notification that the negative comment is persuasive, resulting in change to the subject matter, will most likely result in the submitter changing their ballot to affirmative which may affect the outcome of the ballot.

The issue of substantive change shall not be applicable to a proposed draft standard. In the instance of an approved draft standard 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 draft standard for trial use.

13.02.05 Approval

The proposed draft standard shall be considered approved if sixty percent (60%) of the combined affirmative and negative votes cast by the review group are affirmative. Upon approval the responsible Work Group shall submit a [Request for Publication of DSTU](#) form 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.

If the proposed draft standard 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.

13.02.06 Errata

A request to publish errata to a Draft Standard for Trial Use (DSTU) shall be accompanied by a draft cover letter citing the rationale supporting such a request and shall be submitted to the Chief Technology Officer (CTO) for approval.

Examples of Draft Standard errata cover letters may be found embedded in the following document files:

[CDAR2IG QRDAI DSTUR2 Errata 2014JUN.zip](#) and
[CDAR2IG QRDAIII DSTUR2 Errata 2014JUL.zip](#)

13.02.07 Trial Use

Once approved a draft standard shall be released for trial use to refine and enhance its content through demonstrations of interoperability. The length of the trial use period is at the discretion of the responsible Work Group. Due consideration should be given to the need for timeliness in moving the draft standard 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 up to one year for trial use and comment which should be followed by one year or less for completion of the normative ballot period. The draft standard 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.

13.02.07.01 Draft Standard for Trial Use (DSTU) Front Matter

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

"Publication of this draft standard for trial use and comment has been approved by Health Level Seven International (HL7). This draft standard is not an accredited American National Standard. The comment period for use of this draft standard 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/dstucomments/index.cfm>.

Following this *[the number of months shown above]* month evaluation period, this draft standard, revised as necessary, will be submitted to a normative ballot in preparation for approval by ANSI as an American National Standard. Implementations of this draft standard 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 DSTU is strictly prohibited and at no time shall the DSTU be referred to as a Draft American National Standard for Trial Use.

13.02.07.02 Extending the Trial Use Period

A Work Group may petition the TSC to extend the trial use period of a draft standard for up to one year from the end of the existing period. 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 regards the approval and length of an extension is final.

13.02.08 Results of the Trial Use Period

Where the evaluation and comment period results in a need for substantive changes to the draft standard, the resulting content for normative ballot may embody such changes or a revised draft standard 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 draft standard is not bound to maintain compatibility with the initial draft standard. Under such circumstances, given that the intent of a draft standard 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 draft standard.

13.02.09 Backwards Compatibility to Base American National Standard

Typically a DSTU is used to prototype a new artifact and would therefore not be a candidate for backwards compatibility. However, should a Work Group use DSTU 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.

Within the context of the DSTU itself, there is no requirement that the final specification brought to normative ballot be backwards compatible to the initial release of the draft standard. 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).

13.03 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.

13.03.01 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.

13.03.02 Forming the Consensus Group

All current members shall be notified of the intent to form a consensus group for comment-only review not less than two weeks 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.

13.03.03 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.

13.03.04 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 Spreadsheet 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.

The Work Group shall post the results of their consideration of the comments submitted as recorded on the Ballot spreadsheet 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.

14 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*.

15 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*.

16 Intellectual Property

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.

16.01 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 publically 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**.

16.01.01 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.

As an ANSI accredited standards developer (ASD) for health care related electronic data interchange, HL7 is responsible for assuring that the HL7 Protocol Specifications remain accurate and their integrity is maintained. This duty is consistent with the mandate of a standard making organization to assure that the emerging standard is consistently presented and its evolution fully documented.

Copyright secures to its owner the exclusive right to authorize certain uses of the copyrighted material. HL7's objective in asserting and enforcing copyrights in the HL7 Protocol Specifications is to assure that the public and end-users of the HL7 Protocol Specifications may rely upon HL7 to be an official source of the most current and accurate versions of the HL7 Protocol Specifications.

To achieve the twin objectives of 1) assuring the integrity of the HL7 Protocol Specifications, and 2) 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.

16.01.02 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:

- (a) incorporate any contributions regardless of media or form, and any subsequent modifications thereof, in the creation or maintenance of HL7 Protocol Specifications;
- (b) copyright in HL7's name any Protocol Specification even though it may include portions of said contributions; and
- (c) 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.

16.01.03 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.

16.01.04 Independently Developed Specifications

The submission of independently developed specifications for consideration as a potential HL7 Protocol Specification (§02.02) 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.

16.01.05 Negotiated Use of HL7 Copyrighted Material

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.

16.01.06 Academic Access to HL7 Copyrighted Materials

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. 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.

16.01.07 Use of HL7 Copyrighted Materials in Other Educational Scenarios

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.

16.01.08 Public Access to HL7 Copyrighted Vocabulary Tables

The content of HL7 Version 2 and Version 3 Vocabulary Tables will be made available free for use electronically. HL7 reserves the copyright on all vocabulary content, but allows its use and distribution subject to the provisions of the licensing agreement shown in Addendum A. The codes and text may be used without further license in all applications, databases, and derivative works except those that seek to circumvent, compete with or replace the HL7 Vocabulary table values.

HL7 shall provide the capability to download the HL7 Vocabulary Tables via the HL7 Web site. Electronic media distribution of the HL7 Vocabulary Tables will be made available for a nominal handling fee, initially set at \$50. The Executive Committee shall periodically reassess the reasonableness and viability of the handling fee.

16.01.09 Use of HL7 Copyrighted Material 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.

16.02 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.

16.03 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.

16.03.01 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) 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
- (b) 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.

16.03.02 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 (§02.02). 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:

- (i) 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
- (ii) the implementation of other published standards developed elsewhere and merely referred to in the body of the HL7 Protocol Specification, or
- (iii) 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.

16.03.03 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 §03.04, the commitments of the withdrawing or terminating member stipulated under §16.03.01 shall survive, but only with respect to (1) any HL7 Protocol Specification (§02.02) adopted by normative ballot within 60 days after notice of withdrawal or effective date of termination, and (2) any contribution of that member that has been, or that later is, incorporated in any HL7 Protocol Specification by normative ballot.

16.03.04 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.

16.04 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.

17 Maintenance

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.

17.01 Membership Participation

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

- a) a GOM suggestion box on the registration/information desk at each Working Group Meeting (WGM)
- b) an open forum at each WGM to collect comments and recommendations for maintenance of the GOM,
- c) an email address [goc@hl7.org] for the submissions of comments and recommendations for maintenance of the GOM interim to the WGM, and
- d) peer review of all proposed revisions to the GOM

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 the Working Group Meeting (WGM).

On either Tuesday or Wednesday of the WGM, the Governance and Operations Committee (GOC) shall conduct an Open Forum of one quarter duration. GOC members will be available during the open forum to:

- a) Answer any questions related to those revisions to the GOM announced at that WGM
- b) Capture issues for work item proposals to be considered by the Executive Committee

17.03 Concurrent Processes Interim to Working Group Meetings

17.03.01 Developing the GOM Revisions

The GOC shall prepare documentation with markup reflecting the proposed revisions identified in the work item list. This documentation shall be submitted to a peer review process. While a particular revision may dictate additional peer review resources such as the Co-chairs list for revisions to §09.02 or such sections as directly affect the ballot process, generally peer review will engage the following HL7 member lists: Board of Directors, Affiliate Chairs, Technical Steering Committee (TSC), 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 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 Work Item Requests

Exceptional work items may result from ongoing process review or the comments received during the peer review of work items ratified for the current revision cycle. The GOC shall assess the criticality of the exceptional work item 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 work item shall become a candidate for the next revision cycle.

17.03.03 Developing the Work Item List for the Next Cycle

Following any given WGM, the GOC shall consolidate all comments and recommendations collected during the previous WGM or received via email since the last revision cycle into an issues list for consideration for adoption as work items by the Executive Committee. There shall be standing work items to capture correction of any typographical or other trivial errors; any items addressing ANSI audit reports; and any items resulting from changes to *ANSI Essential Requirements*. Any issues not

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adopted as work items by the Executive Committee will be reworked for consideration in the next revision cycle or, if so directed, removed from the list and not further considered.

17.04 Executive Committee Action

Following any given WGM, the GOC shall prepare a motion for the Executive Committee to consider those issues capture by the GOC in the current revision cycle for adoption as work items. 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 work items in the current revision cycle. The Executive Committee proceedings shall include notice of those revisions subsequently adopted. Those revisions not adopted may be returned to the GOC for additional work during the next revision cycle.

17.05 Effective Date of Revision or Addition

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.

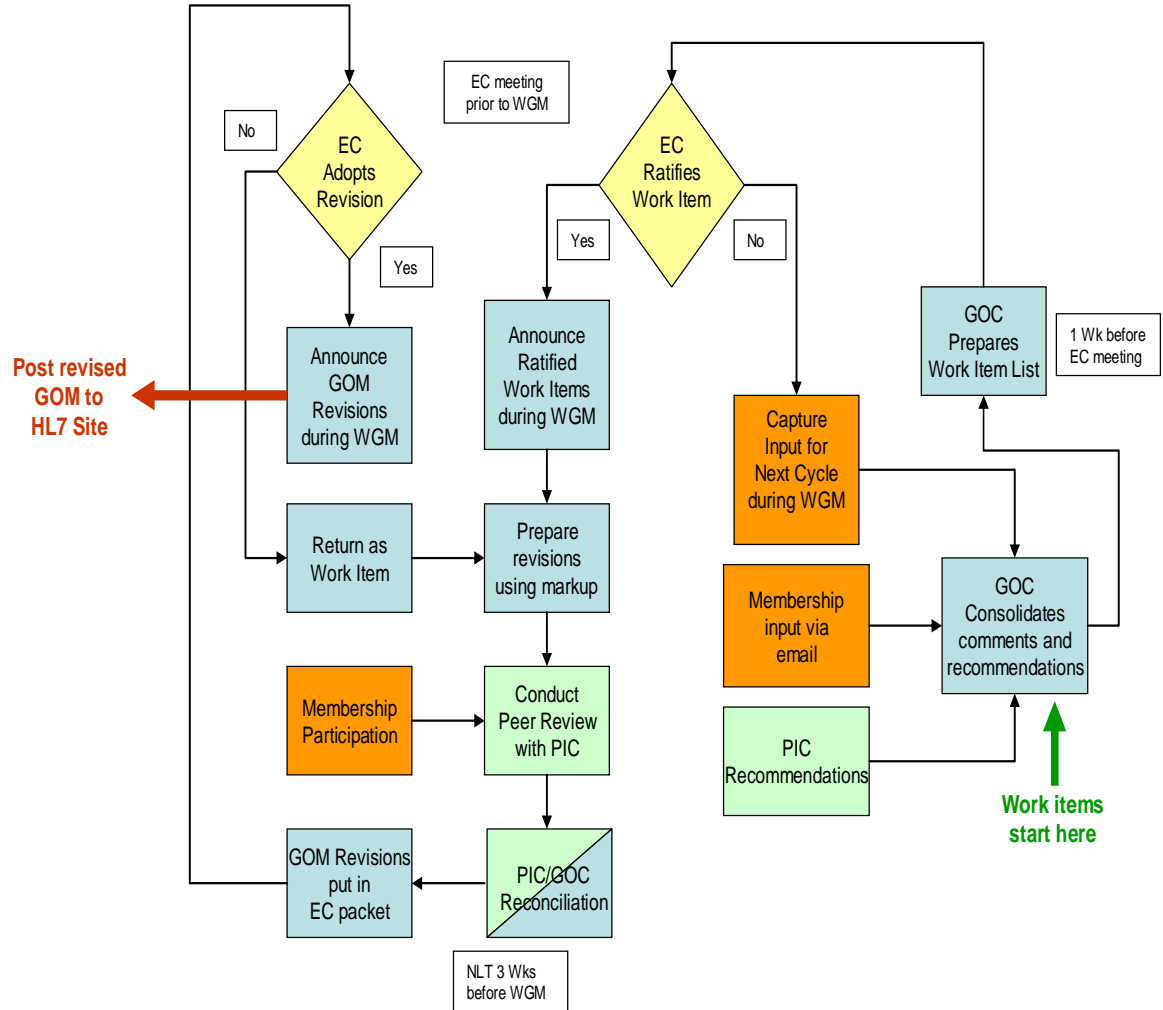
17.06 Periodic Adoption in its Entirety

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:

- 1) The GOM shall, within ten working days, be posted with an adoption date reflecting the decision of the EC and with all notation of addition or revision removed
- 2) 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.

17.07 Process Flow Chart

GOM Maintenance Process



18 Externally Developed Implementation Guides

HL7 may choose to either endorse or adopt an externally developed implementation guide (IG). In either case the IG must be in the HL7 standard template for implementation guides and adhere to the style guide developed by the Publishing Committee.

18.01 Endorsement

If HL7 elects to endorse an externally developed IG and the developer is an accredited standards development organization, both HL7 and the developer may release their own version of the IG under separate copyright; otherwise the IG will be released by HL7 under joint copyright should the developer prefer to retain copyright. If a previously endorsed IG released under joint copyright is revised, updated, or otherwise changed from the original distribution it shall be resubmitted to HL7 for endorsement.

18.02 Adoption

If HL7 elects to adopt an externally developed IG, the document shall become the property of HL7 and be released under an HL7 copyright. Once adopted, the IG shall be updated, enhanced, and generally maintained as HL7 intellectual property.

18.03 Process

The Technical Steering Committee (TSC) shall identify the appropriate Work Group to process the IG. Representatives of the developing organization shall meet with the Work Group to develop a project plan that adheres to HL7 project initiation requirements, is consistent with the Work Group's mission and charter, and falls within the Work Group's scope. The Work Group will ensure that copyright and distribution rights are understood; which may include obtaining a release from the developing organization.

If deemed critical to the success of the project, the Work Group shall designate an HL7 member to serve as liaison to the developing organization. The Work Group shall ensure, to the satisfaction of the HL7 Project Management Office (PMO), that the following roles are filled by HL7 members, representatives from the developing organization, or consultants provided by HL7 or the developing organization:

- a) Project Manager/Facilitator
- b) Publication Facilitators, one of whom must be an HL7 member
- c) Document Editor
- d) Reconciliation committee members, with at least two from the developing organization and two from HL7 with HL7 representatives being the majority

The Work Group shall, with the concurrence of the TSC and following review and, if necessary, revision, submit the IG to ballot. The type of ballot chosen will determine process and approval requirements; however, in every case 60% of those participating and submitting a ballot for an externally developed IG must be HL7 members. Nonmembers may participate in the ballot subject to an administrative fee, which entitles them to a copy of the document upon completion of the ballot process.

18.04 Associated Fees

Typically fees are associated with accelerating the process of endorsement or adoption, not to be confused with fees associated with participating in a ballot. The developing organization may be assessed such a fee by the HL7 Executive Committee. The amount of the fee shall depend on negotiations between the developing organization and an individual designated by the Executive Committee to include consideration of:

- a) Whether the process will require resources beyond those provided by current HL7 volunteers and project support provided by the developing organization.
- b) That portion of the fee, if any, to be paid to HL7 members acting as project managers/facilitators, publishing facilitators, document editors, or members of the reconciliation committee. Such fees may be offset by resources in kind from the developing organization.

- c) That portion of the fee, if any, to offset expenses for HL7 members to maintain an ongoing presence at meetings of the developing organization to ensure adoption or endorsement of the IG.
- d) The costs of publication and distribution.

18.05 Distribution

Once approved the IG shall be processed through normal HL7 distribution channels. If the developing organization is an organizational member of HL7, they are entitled to all the rights of distribution granted to that member category. If the developing organization is a US government agency, they may choose to negotiate with HL7 for distribution of the IG via a public access .GOV web site.

18.05.01 Dependence on a Base Specification

The distribution of an externally developed IG does not imply, nor shall it include, the distribution of any underlying specifications or documents; e.g. the Clinical Document Architecture or some version of an HL7 Protocol Specification (§02.02). HL7 members have access to the various HL7 Protocol Specifications; others must acquire the underlying documentation from HL7.

19 User Groups

19.01 Criteria for Establishing a User Group

Individual(s) interested in establishing a User Group shall ensure the proposed User Group conforms to the following criteria:

1. There is a demonstrated interest in the creation of a User Group by at least five HL7 members who have agreed to actively participate and possess the necessary expertise and commitment to accomplish its stated goals
2. The stated goals or focus of the User Group is within the scope of HL7 and creation of the proposed User Group shall facilitate the accomplishment of HL7's mission and objectives

19.02 Process for Establishing a User Group

The individual(s) proposing the formation of a User Group shall complete a [New User Group Formation Template](#) and submit it to the chair of the Membership and Strategic Resources Committee (MSRC) who shall distribute it to MSRC members. Within 30 days of receipt of the formation template, the MSRC shall for the purpose of accepting or rejecting the proposal either:

1. Convene a conference call with the individual(s) proposing formation of a User Group OR
2. Conduct an eVote on said proposal

The proposal shall be moved to the Executive Committee (EC) for consideration upon approval by a majority vote of the MSRC members. Failure to achieve quorum (60%) on either the MSRC call or eVote considering the proposal shall result in the proposal and record of votes cast moving forward to the EC for final approval. Given quorum, failure to receive approval by a majority vote shall cause the proposal to be rejected. A rejected proposal may be appealed to the EC up to thirty days from the date of rejection. The EC shall resolve an appeal within thirty days of submission. The decision of the EC shall be final. The EC shall review the proposal within thirty days of receipt from the MSRC. If approved, staff shall inform the Board of the creation of a new User Group and initiate all necessary infrastructure activity appropriate to the creation of a new User Group, including:

1. Creation of a public page on the HL7 website
2. Creation of a closed listserv for User Group members
3. Creation of a closed wiki site for User Group members
4. Creation/distribution of press releases and other marketing/promotional outreach

19.03 User Group Co-chairs

Each User 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 User Group call or meeting with the actual number of co-chairs determined by majority vote of the User Group. Upon formation of a new User Group, the two co-chairs identified on the User Group Proposal Template shall serve until such time that a 30-day call for nominations and a 30-day election can be scheduled. A decision by the User Group to increase the number of co-chairs shall result in the subsequent call for nominations and an election for those positions within 90 days. The User Group may designate an individual to fill the additional position interim to the election.

19.03.01 User Group Co-chair Responsibilities

User Group co-chairs are responsible for the smooth operation of the User Group including:

1. Scheduling and running GoToMeeting calls
2. Developing and posting agendas to both the User Group public website and private wiki
3. Ensuring that the minutes of each User Group call/meeting are recorded and posted, along with any presentations, to the User Group wiki
4. Arranging for any needed speaker(s) for any given call/meeting

19.03.02 User Group Co-chair Term of Office

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

19.03.03 Removal of User Group Co-chair from Office

At any time, a User Group that judges the performance of a co-chair egregious may, by majority vote, forward a motion to remove an offending co-chair from office to the MSRC. Criteria for removal shall include:

1. Failure to attend two consecutive User Group Meetings without notice or the subsequent presentation of mitigating circumstances; or
2. Failure to participate in at least 60% of the User Group teleconferences held in the preceding calendar year; or
3. Failure to fulfill the responsibilities noted above

Upon receipt of a motion for removal of a User Group co-chair the MSRC 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 from office shall result in:

1. That individual immediately stepping down from the position of co-chair
2. Removal of that individual from the list of co-chairs on the User Group's web page
3. HL7 Headquarters scheduling a co-chair election to fill the vacant positions. The User Group may, by majority vote, designate an individual to serve as co-chair interim to the election who may be a candidate for said position

19.03.04 User Group Vacancy due to Change in Membership Status

Should a seated User Group co-chair experience a change in membership status due to loss of HL7 membership or failure to pay the User Group fee he or she shall immediately step down from the position of co-chair. The User Group shall notify HL7 Headquarters of the loss of a co-chair; request a co-chair election, and seek nominees for the position. Resolution of the individual's membership status would allow them to seek nomination for reelection as a co-chair. The User Group may, by majority vote, designate an individual other than the individual who stepped down to serve as a co-chair interim to the election who may be a candidate for said position.

19.03.05 Voluntary User Group Co-chair Vacancy

Should a seated User Group co-chair voluntarily vacate their position, for whatever reason, the User Group shall notify HL7 Headquarters of the loss of a co-chair; request a co-chair election; and seek nominees for said position. The User Group may, by majority vote, designate an individual to serve as a co-chair interim to the election who may be a candidate for said position.

19.04 Changing a User Group Name or Mission/Charter

Given approval of a majority of the User Group's documented members, the co-chairs shall present a request to change the name of the User Group or revise its mission and charter to the MSRC. Upon approval by the MSRC, the revised User Group charter shall be distributed to the Executive Committee for final approval. Given Executive Committee approval, HL7 staff shall initiate all necessary changes to the infrastructure to reflect the User Group's new name, mission, and charter.

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

19.05 Dissolution of a User Group

Given approval by a majority of the User Group's documented members for dissolution, the co-chairs shall complete and submit the User Group Dissolution Template to the MSRC. 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 User Group. The MSRC may propose and seek alternatives to dissolution. Upon approval by the MSRC, the petition for dissolution shall be forwarded by the MSRC co-chair to the Executive Committee, which shall address the request to dissolve. Upon approval, the Board Chair shall notify the Board of the dissolution of a User Group and HL7 staff shall take the appropriate actions to effectively remove the User Group from the organization. The MSRC may, at its discretion, dissolve a User Group that is, in their opinion, inactive.

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