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American National Standards Institute Healthcare Information Technology Standards Panel (HITSP)

CHARTER

§ I. Mission

Organizations participating in the Healthcare Information Technology Standards Panel (HITSP) (referred to as the "Panel") agree to serve as a cooperative partnership between the public and private sectors for the purpose of achieving a widely accepted and useful set of standards specifically to enable and support widespread interoperability among healthcare software applications, as they will interact in a local, regional and nationwide health information network (NHIN) for the United States.

The HITSP is established under the sponsorship of the American National Standards Institute (ANSI) and endorsement of the Healthcare Information and Management Systems Society (HIMSS). The Panel intends to ensure the broadest possible participation of all affected parties in order to establish and maintain an entity capable of achieving readily-implemented, consensus-based outcomes.

§ II. Principles

This Panel shall serve the public good by working to ensure that the harmonized work of various healthcare information standards development organizations is broadly deployed and supports interoperability, accurate use, access, privacy and security of shared health information. It shall be representative of all organizations and stakeholder groups in order to ensure that it operates under the following principles:

• Transparency. Essential information regarding governance, activities and decisions of the Panel is accessible to all parties on a timely basis.

• Openness. Participation on the Panel is open to all affected interests.

 Stakeholder Representation. The governance and all activities of the Panel include broad representation from stakeholders without regard to ANSI membership or accreditation.

• Impartiality and Balance. No one interest dominates the process or is favored over another among competing interests and various stakeholders.

 Effectiveness and Relevance. Decisions are relevant and effectively respond to regulatory and market needs, as well as scientific and technological developments.

• Performance-based. Standards specify essential interoperability characteristics rather than detailed application designs (wherever possible).

- Harmonization. The process encourages harmonization to avoid overlapping and conflicting standards.
- Consistency. Where business conditions dictate that information is transmitted under different standards, the process assures consistency in the representation of this information.
- Due Process. Decisions are arrived at by procedures that assure all views are considered and a dispute resolution process is provided.
- Timely. Decisions are reached in a timeframe that meets stakeholders' expectations.
- Flexibility. Decision making may incorporate variation in process to meet the needs of differing sectors, so long as the other principles are not compromised.
- Competition. Recognizing that the membership of the Panel includes many business organizations that compete directly with one another, normal considerations of appropriate legal boundaries, including antitrust, where appropriate, will be observed.

2.1 <u>Operation by Consensus</u>: Acceptance of recommendations by unanimous consent of the Panel will be the default operating procedure, with recorded votes of the Panel resorted to only where significant division within the Panel and in the working group process is apparent to the Chair.

It is the overriding objective of policy development in the HITSP to enable a functional National Health Information Network, available to all Americans. Accordingly, the complex issues of health information technology standardization being addressed in the HITSP process must be resolved in a manner most likely to be accepted and deployed by a diverse community of health sector stakeholders, beyond those comprising the HITSP itself. Decisions regarding health information policy adopted by the HITSP must not only be the product of a process reflecting the principles set out above, but must be supported by as strong a majority of participants as possible.

Accordingly, while the working groups, Board and other operating committees of the HITSP, as well as the Panel itself, will rely on time-tested parliamentary procedures whenever formal decision-making is required, it is the firm intention of the sponsoring organizations that the HITSP reach its conclusions of policy and practice through a consensus process, reflecting deliberations that thoroughly review all competent positions, and protect the views of minority positions whenever substantial differences persist.

§ III. Scope

The Panel is a multi-stakeholder coordinating body designed to provide the process within which stakeholders identify, select, and harmonize standards for communicating and encouraging broad deployment and exchange of healthcare information throughout the healthcare spectrum. The Panel's processes are business process and use-case driven, with decision making based on the needs of all NHIN stakeholders. Utilizing information from stakeholders, the Panel will facilitate the development of harmonized

implementation guides and information policies, including SDO work products (e.g. standards, deployment guidance, and technical reports). These policies, guides and work products are essential for establishing privacy, security and functional and semantic interoperability among healthcare community organizations and the software applications they utilize.

In conducting its work, the Panel, as appropriate, will coordinate with other national, regional and international groups with due regard to existing policy and regulatory frameworks addressing healthcare informatics with the goal of implementing globally relevant standards.

The Panel and all sub-groups shall operate in accordance with approved operating procedures set out in this document or its successors.

§ IV. Healthcare Information Technology Standards Panel (HITSP)

4.1 Panel Members

Membership in the Panel is open to all parties with an institutional interest in or affected by the national healthcare delivery system, Membership in the Panel shall be by organization and consist of four categories. Organizations that could be categorized in more than one group must choose a single affiliation for voting purposes.

(a) "Standards development organizations" (SDOs) (1) which are entities whose processes are accredited by ANSI and which create standards in health informatics and implementation of electronic health record systems; (2) SDOs or other organizations responsible for the standards chosen by the Consolidated Health Informatics (CHI) initiative; (3) SDOs or other organizations put forth by the respondents to the November 2004 Health and Human Services RFI on the development and adoption of a NHIN; (4) SDOs under the Institute of Electrical and Electronics Engineers-Standards Association (IEEE-SA) with a focus on healthcare and health informatics; (5) SDOs that serve as U.S. Technical Advisory Group (TAG) Administrators under the International Organization for Standardization (ISO) and/or the International Electrotechnical Commission (IEC) with a focus on healthcare and health informatics; and (6) other SDOs nominated by expert cross-agency sources in the Federal government. It shall be the objective of the Panel to ensure that at least two-thirds of those organizations eligible to join the Panel in the SDO category do so.

• (b) "Non-SDO stakeholder organizations" including: clinicians and their representative organizations; providers and their representative organizations; safety net providers and their representative organizations; vendors that develop, market, install, and support health IT products and their representative organizations; healthcare purchasers or employers and their representative organizations; healthcare payers or health insurance companies and their representative organizations; public health professionals and their representative organizations; national organizations with a broad representation of stakeholders with an interest in healthcare information

technology standards; and clinical and health-services researchers and their representative organizations.

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• (c) "Governmental bodies" defined as: Federal, state, and local agencies; and coordinating bodies with responsibilities for and/or a relationship to healthcare information technology used in the public sector.

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• (d) "Consumers" represented by: consumer-representative organizations with an interest in health information technology standards.

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4.1.1 Open Meetings; Notice: Panel meetings and minutes are open and available to the public. Meetings of the Panel, including the annual meeting, shall be announced not less then 15 days prior to the meeting by email notice to Panel membership and posting on the Panel web site.

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4.1.2 Attendance: Attendance at Panel meetings is an obligation of membership. The
Secretariat shall record the presence of the principal or designated alternate representative
of each Member at each Panel meeting at which a vote is taken pursuant to prior Notice
as provided in section 4.1.1. It shall be the responsibility of Panel Members to make their
attendance at Panel meetings known to the Secretariat.

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4.1.2.1 <u>Absence</u>; <u>Restoration of Voting Privilege</u>: Any Member who is absent for two successive Panel meetings at which a vote is taken shall forfeit the privilege of voting on any Panel matter. The Secretariat shall inform the Chair of any Member that has been absent for two successive Panel meetings, and a notice shall be transmitted to the Member's principal and alternate representative, declaring the Member's privilege of voting suspended. A Member whose voting privilege is suspended shall have its voting privilege restored upon and at its attendance at two successive Panel meetings.

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4.1.3. <u>Voting by newly affiliated Members</u>: A Member other than a founding Member present at the Panel Meetings of September 2005 and January 2006 shall be entitled to vote as a Panel Member on a matter put before the Panel for a decision upon and at its attendance by a designated representative at two successive Panel meetings, as recorded by the Secretariat.

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4.2 Officers

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4.2.1 <u>HITSP Chair</u>: The activities of the Panel and Panel meetings shall be presided over by the HITSP Chair.

- 4.2.1.1 <u>Appointment of HITSP Chair</u>: ANSI shall appoint a non-voting Chairperson,
- subject to approval by the Office of the National Coordinator (ONC) and the ratification
- of a majority vote of the HITSP Panel. If a Chair candidate either is not approved by
- ONC or not ratified by the Board, ANSI shall submit a new candidate for ratification.
- ANSI's selection and criteria shall be communicated to the Panel.

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 186 4.2.1.2 <u>Duties of the HITSP Chair</u>: The Chair shall facilitate Panel meetings and shall
 187 represent the Panel to the external community, including the American Health
 188 Information Community (AHIC), and convene and preside over all Board meetings.

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4.2.1.3 <u>Term of Service</u>; <u>Vacancy of the Chair</u>: Both the Chair and Vice Chair shall serve two-year terms and may be re-appointed for one additional two-year term. If the Chair is unable to complete his/her term of office, ANSI shall select a successor by following the process for appointing a Chair set out in §4.2.1.1.

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195 4.2.2 HITSP Vice Chair; Succession: The Board shall nominate several candidates for 196 Vice Chair from its members, one of whom shall be appointed by ANSI as Vice Chair. 197 The Vice Chair shall assume the role of Chair in the Chair's absence; however the Vice 198 Chair will not automatically become Chair, should the Chair be unable to serve. ANSI's 199 selection criteria and process shall be communicated to the Panel. Designation as Vice 200 chair shall have no impact on the selected Board member's voting status unless serving as Acting Chair in the absence of the HITSP Chair, in which case the Vice Chair may cast a 201 202 vote only to break a tie in a Board vote.

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4.3 <u>Committee Conveners</u>: The HITSP Chair shall appoint initial Committee conveners subject to ratification by Committee members. See §6.5.

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- 4.4 <u>Panel Responsibilities:</u> The responsibilities of the Panel shall include, but not necessarily be limited to:
 - a. Facilitate the timely development and harmonization of standards responsive to identified use cases;
 - b. Elect HITSP Board members;
 - c. Ratify Panel Chairperson;
 - d. Recommend creation or dissolution of committees;
 - e. Approve and ratify all Panel governance documents and operating procedures;
 - f. Ratify and adopt all final HITSP work products, such as, but not limited to: use case recommendations, gap and duplication analyses, evaluation of relevant standards to meet use case requirements, a standards change management process, use case related implementation guides, and use case testing;
 - g. Employ existing harmonization processes as appropriate.
 - h. Activate a conflict resolution mechanism as needed.
 - i. Recommend priorities to AHIC among proposed use cases to solve health information exchange issues and implement AHIC decisions in these matters;
 - j. Ratify a self-sustaining business model presented by the Board that ensures the ongoing viability and financial sustainability of the Panel;
 - k. Perform all other acts necessary or appropriate to the conduct of the Panel's activities and achievement of the Panel's Mission.

4.5 <u>The Consensus Process</u>: In order to foster the collegial processes of the Panel and to fully achieve the Principles of Consensus set out in § 2.01, the Panel will base its conduct of business on the following consensus protocol:

The HITSP Consensus process shall be directed by the HITSP Chair. The achievement of consensus shall be based on thorough examination of issues, including the discussion of dissenting opinions and the resolution of disagreements. Consensus shall be preferred to resolve all issues brought before the Panel except those for which a vote is prescribed by this Charter, or those for which a vote is called at the discretion of the Chair.

There must be a quorum (See §4.6.1) at any Panel meeting at which consensus may be declared on an issue. Points made during discussion will be recorded by the Secretariat in minutes.

The HITSP Chair shall have authority to table or terminate discussion, call for affirmation of consensus, mediate with dissenting parties or recommit a matter to committee for further action consistent with § 6.6.

4.6 <u>Panel Voting Requirements</u>: HITSP membership is organizational. Each organizational Member has one vote in plenary sessions of the Panel, and in any working group or committee in which it may participate. In the event the principal representative of a Panel Member is absent, a previously designated alternative may vote on behalf of the Member. For all Panel votes, approval is determined by the affirmative vote of not less than 66% of those voting.

4.6.1 Quorum of the Panel: A Quorum of the Panel is defined as 50% of eligible Panel members voting in person, electronically or other such approved means as declared by the HITSP Chair and announced in the Notice of the Panel meeting required by § 4.6.2. In establishing a quorum, a Panel member shall be eligible to be counted as part of the quorum if it is present and eligible to vote.

4.6.2 Notice of Panel meetings; Prior publication and review of Panel matters: Announcements of Panel meetings as required by §4.1.1 shall include the date and time set for the meeting, the subject matter and agenda of the meeting and the present membership level of the Panel and a declaration of the number of Panel Members that constitute a quorum for the purpose of any votes. A description of any matter to be put to a vote of the Panel shall be included in the Notice, including the recommendation of the working group and any working papers. Prior to any formal vote on any matter recommended to the Panel by a working group, there shall be at least a 5-business day review and comment period for all Members.

4.6.3 <u>Publication of results of Panel votes</u>: When voting on candidates for leadership positions only the final results will be made public. In all other cases, votes shall be open, and the results of the voting shall be available to all Panel organizational Members.

§ V. HITSP Board

- 276 <u>5.1 HITSP Board Functions</u>: The HITSP Board (the Board) shall be the governing body
 277 of the Panel. The Panel may delegate a decision on any matter, including any matter
 278 enumerated in §4.4, to the Board for action, except for:
 - a. election of the HITSP Chair;
 - b. election of a Board member;
 - c. expulsion of a Panel Member;
 - d. amendment of the charter document.

Any matter so delegated by the Panel may be referred back to the Panel by the Board upon review. Such referral back shall be final.

5.2.<u>Board Membership Categories</u>: The Board shall consist of twenty-three (23) voting members, who shall be elected or appointed by the Members affiliating with the following categories of membership of the Panel:

(a) Eight (8) representatives elected by the standards development organizations from the SDO membership of the Panel (but no more than one representative from any one SDO); and

• (b) One (1) representative from each of the nine (9) following non-SDO stakeholders, elected by the non-SDOs as a group: recognized national associations; other similar types of organizations; or other organizations of: clinicians and their representative organizations; providers and their representative organizations; safety net providers and their representative organizations; vendors that develop, market, install, and support health information technology products and services and their representative organizations; healthcare purchasers or employers and their representative organizations; healthcare payers or health insurance companies and their representative organizations; public health professionals and their representative organizations; national organizations with a broad representation of stakeholders with an interest in healthcare information technology standards; and clinical and health services researchers and their representative organizations; and

(c) Four (4) representatives, appointed by ONCHIT, representing government agencies or coordinating bodies representing various government agencies; and

(d) Two (2) representatives of healthcare consumer representative organizations, in addition to any organization representing consumers that may be included among § 5.2 (b).

5.2.1 <u>Board Terms</u>: Board members elected in the normal course shall serve a twoyear term. The initial terms of the Board members will be staggered to ensure that no more than one half of the Board members will be replaced in any given year. By lot one half of all initial Board members will be designated to 321 serve only one year, and their seat shall be vacant and subject to replacement 322 for a full two-year term by their constituency after that year. 323 324 5.2.2 Board members are limited to three consecutive terms. If a Board member is 325 unable to complete his or her term of office, his or her category (e.g. SDO, 326 non-SDO, or consumer organization) is to, as soon as possible, elect a 327 replacement for the remainder of the vacant Board term. 328 329 5.3 HITSP Board Responsibilities 330 331 The Board shall have responsibility for governing the process of the Panel's activities. 332 These activities shall include, but not necessarily be limited to: 333 334 a. Development of operating guidelines and such other operating procedures 335 necessary to perform its work, consistent with the principles of this Charter; 336 b. Recommend governance changes to the Panel for ratification; 337 c. Ensure that the principles of this Charter and governance documents are upheld and maintained; 338 339 d. Provide direction and guidance for the development of use case 340 recommendations; 341 e. Formation of Panel committees of sufficient number to accomplish the work 342 of the Panel, and provide direction and guidance for their work; 343 f. Approve the dissolution of Panel committees at the conclusion of their tasks; 344

g. Ensure the coordination of Panel committee activities;

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- h. In the event that the Panel or a committee is unsuccessful in minimizing duplication or mediating conflict, the Board will make a concerted documented effort to achieve a harmonized outcome, consistent with the HISTSP Consensus process set out in §4.5;
- i. Within one year of the contract awarded by the Department of Health and Human Services, the Board shall recommend a self-sustaining business model and may preside over creation of a legal entity to ensure the ongoing viability and financial sustainability of the Panel beyond the term of the contract;
- Upon enactment of the self-sustaining business model, ensure the fulfillment of fiduciary responsibilities of the Panel; and monitor the Panel budget within the limitations of and in coordination with outside funding (e.g. federal contracts); and
- k. Do and perform all other acts as may be necessary or appropriate to the governance of the Panel's activities.
- 5.3.1 The Board shall be solely responsible for recommending any changes in its operations as set out in these rules and may recommend modifications, as set out in § 9.1 based on its experience as long as the principles of the Panel are not violated or compromised.
- 5.4 HITSP Board Voting Procedure: The Board shall seek to reach a consensus on any matter before it for decision. When a matter is put to a recorded vote, approval requires

the affirmative vote of no less than 66% of those voting. When voting on candidates for leadership positions, only the final results will be made public. In all other cases, votes shall be open, and the results of the voting shall be available to all Panel Members.

5.4.1 <u>Board Quorum</u>: In-person meetings and electronic votes shall require a quorum of
 50% of the voting Board members eligible and present.

5.5 <u>HITSP Board Meetings</u>: All meetings of the Board shall be open for attendance to all Panel Members. The Board shall establish a regular schedule of meetings, and in no event shall it meet any less frequently than quarterly.

5.5.1 Prior Notice of Board Meetings: Board meetings shall be announced to the Panel by electronic mail and posting on the Panel Web site. In the event of an unscheduled Board meeting, notice shall be given at least 5 days in advance for in person meetings and at least 3 days in advance for conference calls. Notice shall include the date and time of the meeting, telephonic access information and an agenda indicating the subject(s) to be addressed.

 5.5.2 <u>Prior Publication and Review of Board Agenda</u>: In the event a Board meeting is expected to act on any recommendation, prior to a formal vote on any matter by the Board, such a decisional matter is subject to a 5-business-day review and comment period for all Board members. Publication of working group recommendations and any working papers shall be made to the Panel by electronic mail and posting on the Panel Web site.

5.6 <u>Executive Session</u>: The Chair may call at his or her discretion an executive session open to only Board members. Executive sessions shall be called for discussion only and no formal decisions will be taken during an executive session. Agenda items for executive sessions shall not include topics which are subject to Board and/or Panel votes.

5.7 <u>Absence from Board meetings</u>: In the event a Board member shall be absent from 2 successive properly noticed Board meetings without good cause, the Chair shall order a notice to the Board member, the sponsoring Panel Member and the other Board members representing the absent Member's voting sector, declaring the Board Member to be subject to removal from the Board upon a subsequent successive absence.

In the event of such subsequent absence, the Chair shall declare the absent Member's Board seat to be vacant, and, in the case of an elected Board seat, a special election of the sector constituency shall be held to elect a successor, who shall serve for the remainder of the vacant seat's term, or, on the case of an appointed Board member, the appointing authority shall designate a successor who shall serve for the remainder of the vacant seat's term. A constituency election by a membership sector to fill a vacant Board seat may be conducted by electronic mail ballot, at the discretion of the HITSP Chair.

§ XI. Committees

The Panel will conduct its activities through Committees comprised of representatives of Panel Members.

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- 416 6.1 <u>Membership of Committees</u>: Committee membership is open to all interested Panel
- 417 Members and their staff and shall be representative of affected stakeholders. All
- 418 committee meetings and conference calls shall be open to all Panel Members and posted
- in advance. The committee chair can appoint subordinate working groups as needed.

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421 6.2 Operation of Committees: Upon approval by the Board, a Committee shall (1) be 422 organized by specialty domain or subject matter, and (2) be assigned approved use cases 423 if appropriate.

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6.3 <u>Committee Voting Requirements:</u> Approval of a matter before a Committee shall be achieved by consensus; when a matter is put to a record vote, approval is determined by no less than a 66% affirmative vote of those voting. All Committee votes shall be open, and the results of the voting shall be available to all Panel Members.

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430 6.4 <u>Committee Quorum</u>: In person meetings and electronic votes shall require a quorum of 50% of the voting committee members.

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- 433 6.5 Committee Responsibilities; Minutes: Committee members select Committee Chairs.
- Committees can choose to recommend a Co-chair for appointment. Committees have
- responsibility for initiating and implementing the Panel's activities. Each Committee will
- have its own terms of reference. Committee Charters will be approved by the Board.
- Committee Chairs will be responsible for ensuring consistency in all methodologies used
- in committee work in accordance with the principles of this Charter. Each Committee
- shall establish a procedure for recording minutes of its proceedings pursuant to a template
- furnished by the Secretariat and publish them in a timely manner to the entire Panel;
- publication may consist of posting to the Panel Web site.

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6.6 Recommittal to Achieve Consensus

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6.6.1 <u>Declaration of Minority Position of Panel</u>: In the event more than one position on a recommendation subject to a vote receives substantial support among the Panel, the Chair may in its discretion order the declaration of "majority" and "minority" positions of the HITSP.

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450 6.6.2 <u>Recommittal of a Matter to Working Groups</u>: Recommittal of a matter to the 451 recommending working group is to be preferred whenever a consensus may be achieved, 452 rather than reporting a recommendation with majority and minority positions.

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§ VII. Secretariat Responsibilities

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456 ANSI staff shall serve as Secretariat to manage the business affairs of the Panel and shall:

- (a) Provide all administrative support services to the Panel, Board, membership and other such groups as created by the Board including but not limited to: scheduling meetings, notifying Members of Panel meetings, preparing agendas, issuing minutes, staffing committees (except as agreed to with HIMSS for the Use Case Committees); and
 (b) Provide accounting, billing and such other services not elsewhere handled by
 - (b) Provide accounting, billing and such other services not elsewhere handled by contract.

ANSI, as Secretariat, shall have no vote at either the Panel or Board level. ANSI subject matter experts may participate in Committees and working groups by consent of a Committee chair, but shall have no vote.

§ VIII. Robert's Rules of Order

 All questions of parliamentary procedure not addressed in this Charter shall be resolved according to <u>Robert's Rules of Order</u> (10th edition). The Panel Chair may select a Parliamentarian to interpret procedural rules and advise the Chair on procedural issues; the Secretariat may fill this responsibility.

§ IX. Charter Ratification

<u>Amendment of Charter</u>: Amendment of the Charter may be done only by a vote of the Panel, and may be accomplished by:

1. Publication of a proposed amendment to the Panel by email and posting to the Panel Web site at least 30 days prior to the date of a Panel meeting;

 2. Review by the Board with a recommendation to the Panel endorsing or opposing the Charter amendment; and

3. A vote by the Panel at a Panel meeting at which personal attendance by a majority of Members is recognized by the Panel Chair. Approval of an amendment requires an affirmative vote of 66% of eligible Members.