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

DRAFT CHARTER
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1. 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 would interact in a Nationwide Health Information Network 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 stand up and maintain an entity capable of achieving readily-implemented, consensus-based outcomes.

2. 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 shall 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.
- Consensus. Decisions are reached through a use-case driven process that encourages consensus among those affected.

- Performance-based. Standards specify essential characteristics rather than detailed designs where possible.
- Coherence. The process encourages coherence to avoid overlapping and conflicting standards.
- Consistency. Where business conditions dictate that different standards transmit the same information, the process assures consistency in the representation of this information in the different standards.
- Due Process. Decisions include due process so that all views are considered and a dispute resolution process exists.
- Timely. Decisions are reached in a timeframe that meets market 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.

3. 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 of healthcare information throughout the healthcare spectrum. It is use-case driven, with decision making based on industry needs. Utilizing information from stakeholders, the Panel will facilitate the development of harmonized implementation guidelines and information policies, including SDO work products (e.g. standards, technical reports). These policies, profiles and work products are essential for establishing privacy, security and interoperability among healthcare software applications.

In conducting its work, the Panel, as appropriate, will coordinate with other national, regional and international groups addressing healthcare informatics with the goal of realizing globally relevant standards.

The Panel and all sub-groups shall operate in accordance with approved operating procedures.

4. Healthcare Information Technology Standards Panel (HITSP)

4.1 Panel Members

Membership in the Panel is open to all affected parties. Membership in the Panel shall be by organization and consist of four categories:

- Standards development organizations (SDOs) which shall be defined as SDOs accredited by ANSI in health informatics and implementation of EHR systems; SDOs or other organizations responsible for the standards chosen by the Consolidated Health Informatics (CHI) initiative; SDOs or other organizations put forth by the respondents to the November 2004 HHS RFI on the development and adoption of a NHIN; SDOs under the Institute of Electrical and Electronics Engineers-Standards

Association (IEEE-SA) with a focus on health care and health informatics; SDOs that serve as US Technical Advisory Group (TAG) Administrators under the International Organization for Standardization (ISO) and/or the International Electrotechnical Commission (IEC) with a focus on health care and health informatics; and other SDOs nominated by expert cross-agency sources in the Federal government; It shall be the objective of the Panel over the term of this contract to ensure that at least two-thirds of those eligible to join the Panel in the SDO category do so.

- Non-SDO stakeholder organizations which shall be defined as: recognized national associations or other similar types of organizations that have broad national membership constituencies of clinicians and 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; health care purchasers or employers and their representative organizations; health care payers or health insurance companies and their representative organizations; public health agencies 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' representative organizations;

- Governmental bodies which shall be 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; and

- Consumers who shall be identified as: consumer organizations with an interest in health information technology standards; and any other United States citizen interested in the development of health information technology standards or related activities, who is not eligible for membership under any other membership category.

4.2 Officers:

ANSI shall appoint a non-voting Chair subject to approval by the Office of the National Coordinator (ONC) and the ratification of a majority vote of the HITSP. If a Chair candidate either is not approved by ONC or not ratified by the Board, ANSI shall submit a new candidate for ratification.

The Chair shall facilitate Panel meetings and shall represent the Panel to the external community, including AHIC, and convene Board meetings.

The Chair shall appoint Committee chairs subject to ratification by Committee members.

The Chair may call at his or her discretion an executive session open to only Board members. It is understood that executive session is for discussion only and that no formal decisions will be taken during an executive session. Agenda items for executive session shall not include topics which are subject to Board and/or Panel votes.

The Board shall nominate several candidates for Vice Chair from its members, one of whom shall be appointed by ANSI as Vice Chair. The Vice Chair shall assume the role of Chair in the Chair's absence.

Both the Chair and Vice Chair shall serve two-year terms and may be re-ratified for one additional two-year term.

4.3 Panel Responsibilities

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. Approve and ratify all Panel governance documents and operating procedures;
   e. Ratify and adopt HITSP committee deliverables such as: use case recommendations, gap and duplication analyses, evaluation of relevant standards to meet use case requirements, a standards change management process, and implementation guidelines;
   f. Recommend priorities to AHIC among proposed use cases to solve health information exchange issues and implement AHIC decisions in these matters;
   g. Ratify a self-sustaining business model presented by the Board that ensure the ongoing viability and financial sustainability of the Panel beyond the contract;
   h. Do and perform all other acts as may be necessary or appropriate to the conduct of the Panel's activities.

4.4 Panel Voting Requirements

HITSP membership is organizational. Each organizational member has one vote.

Voting in person, electronically or other such approved means shall require a quorum of 33% of Panel members voting, including abstentions. Prior to a formal vote, there shall be a 5-day review and comment period for all members.[1] All votes shall be open, and the results of the voting shall be available to all Panel organizational members.

Panel members elect the Board. HITSP Board members are elected by a majority of those voting.

For all other votes, approval is determined by no less than a 66% affirmative vote of those voting.

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[1] Voting requirements associated with the Panel's inaugural meeting may be modified due to time constraints resulting from deadlines imposed through the Panel's initial federal contract. For votes to be taken at the Panel's first meeting, the review period may be reduced to no less than 10 days. However, the votes taken with the shortened review period shall be limited to organizational issues (election of the Board, approval of operating procedures, and similar types of matters).

5. HITSP Board

5.1 HITSP Board Membership

The HITSP Board (the Board) shall be the governing body of the Panel.

The Board shall consist of the following voting members, who shall be elected from the members of the Panel:

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

- A minimum of one (1) representative from each of the eight (8) following non-SDO stakeholders: recognized national associations or other similar types of organizations that have broad national membership constituencies of clinicians and 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; health care purchasers or employers and their representative organizations; health care payers or health insurance companies and their representative organizations; public health agencies 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' representative organizations; and

- Two (2) representatives, appointed by ONCHIT, from either government agencies or coordinating bodies representing various government agencies;

- A minimum of one (1) healthcare consumer representative;

- One (1) ex-officio member appointed by ONCHIT;

The SDO representatives shall be elected for two-year, staggered terms by majority vote of the SDO members; the non-SDO representatives shall be elected for two-year, staggered terms by majority vote of the non-SDO members and consumer organization members; and the government representatives shall be elected for two-year, staggered terms by majority of the participating government agencies. Board members are limited to three consecutive terms. SDO representatives must be endorsed by their respective SDO. Non-SDO stakeholders must be endorsed by their respective national association or organization.

If a Board member is unable to complete his or her term of office, his or her organization is to, within 30-days, appoint a replacement for the remainder of the term.

To ensure that there is both the infusion of new thought leaders and adequate leadership to maintain momentum and continuity, the 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.

The Board shall be solely responsible for any changes in its operations and may make modifications based upon experiences in its operations as long as the principles of the Panel are not violated or compromised.

5.2 <u>HITSP Board Responsibilities</u>

The Board shall have responsibility for governing the Panel's activities. These activities shall include, but not necessarily be limited to:

    a. Development of operating guidelines and other such operating procedures necessary to perform its work as long as they are consistent with the principles of this Charter;
    b. Recommend governance changes to the Panel for ratification;
    c. Ensure that the principles of this Charter and governance documents are upheld and maintained;
    d. Provide direction and guidance for the development of use case recommendations;
    e. Attempt to resolve or mediate conflicts among standards-related and standards-impacted organizations and take appropriate follow-up action or make appropriate recommendations to involved parties;
    f. Formation of Panel committees of sufficient number to accomplish the work of the Panel, and provide direction and guidance for their work;
    g. Approve the dissolution of Panel committees at the conclusion of their tasks;
    h. Ensure the coordination of Panel committee activities;
    i. Appoint task groups as needed;
    j. In the event that a Panel committee is unsuccessful in minimizing duplication or conflict in a standard or standards, the Board will make a concerted documented effort to achieve a harmonized outcome;
    k. Within one year of the contract awarded by the Department of Health and Human Services, the Board shall recommend a self-sustaining business model to ensure the on-going viability and financial sustainability of the Panel beyond the term of the contract;
    l. 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
    m. Do and perform all other acts as may be necessary or appropriate to the governance of the Panel's activities.

5.3 HITSP Board Voting Requirements

Voting approval is determined by no less than a 66% affirmative vote of those voting. In person meetings and electronic votes shall require a quorum of 50% of the voting Board members, including abstentions. Prior to a formal vote, there shall be a 15-business-day review and comment period for all Board members. All votes shall be open, and the results of the voting shall be available to all Panel members.

5.4 HITSP Board Meetings

There shall be established regularly scheduled Board meetings. In the event of an emergency Board meeting, notice shall be given with at least 5 days advance notice provided to all members for in person meetings and at least 3 days advance notice provided to all members for conference calls. All meetings of the Board shall be open to all Panel members.

6. Committees:

Through formation by the Board, Committees shall be organized by specialty domains, be assigned approved use cases if appropriate, and consist of representation from Panel members. When appropriate, Committees will work with a specific use case from development through standards gap analysis and through standards development coordination and implementation. Committee membership is open to all interested Panel members. All committee meetings and conference calls shall be open to all Panel members and posted in advance. The committee chair can appoint task groups as needed.

6.1 Committee Voting Requirements:

For voting, approval is determined by no less than a 66% affirmative vote of those voting. In person meetings and electronic votes shall require a quorum of 50% of the voting committee members, including abstentions

All votes shall be open, and the results of the voting shall be available to all Panel members.

6.2 Committee Responsibilities

Committees ratify Committee Chairs appointed by the Board Chair.

Committees have responsibility for initiating and implementing the Panel's activities. Each Committee will have its own charter. 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.

7. <u>Secretariat Responsibilities:</u>

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

- Provide all administrative support services to the 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
- Provide accounting, billing and other such services except for those handled elsewhere by contract.

ANSI, as secretariat, shall have no vote at either the Panel or Board level.