

HEALTH POLICY AND REGULATORY AFFAIRS COMMITTEE (HPRAC) CHARGE

Number of Members 12-16

Composition

Members shall include the Chair and a Vice Chair, up to 8 ex officio members as described below, and 1-5 additional members. The Chair may invite guests as needed to expedite information sharing.

Ex officio members serve automatically. Ex-officio members will include

- President
- President-elect
- Up to 2 AMA RUC Advisors
- Up to 2 AMA CPT Advisors
- Up to 2 AMA HOD Delegates

Up to five at large members also will be appointed.

Method of Appointment

The Committee Chair and Vice-Chair and at-large members shall be appointed by the President-Elect, in consultation with the President and the Chief Executive Officer.

Term of Office

At-large members shall serve a term of one year, with reappointment possible of two additional, consecutive one-year terms.

Accountability

Reports to: Board of Trustees

Key Relationships: Executive Committee, Scientific and Clinical Documents Committee,

Quality Improvement Committee

Purpose

To promote high quality patient care and represent the legal, advocacy, regulatory, and clinical goals of heart rhythm specialists.

Responsibilities

- Set annual objectives and deliverables.
- Ensure accountability to the Board and meet the Committee's priorities and timelines.
- Maintain open communications with stakeholders, including providing regular reports to the Board and Executive Committee.
- Refer matters to the Board or Executive Committee for approval when required by the bylaws, Board policies, or in instances when the Health Policy and Regulatory Affairs Committee is unable to reach consensus on an issue.



• Train members to ensure the committee has access to the expertise it needs and identify emerging leaders to ensure a strong succession.

Related to Committee-Specific Functions

- Develop and implement an advocacy strategy to promote optimal policies and standards for the study, treatment, management, and appropriate physician reimbursement of treatments for cardiac rhythm disorders.
- Communicate the Society's positions to the relevant federal agencies including the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the U.S Congress, private research organizations, and other interested parties with guidance on important questions in coverage, reimbursement, patient safety and advocacy issues.
- Represent membership interests with industry, third-party payers and other entities with whom the membership has critical relationships.
- Communicate with public and government entities to improve their understanding of issues related to heart rhythm disorders.
- Collaborate with relevant stakeholder organizations, professional societies, and federal
 agencies to promote optimal patient care through research, training, education and
 advocacy.
- Monitor government actions and manage issues proactively, including communicating regularly to members.
- Assume other duties at the direction of the Board

Decision-Making Authority

- Set the Society's health policy and advocacy strategy.
- Establish the committee's procedures.
- Refer unresolved issues to the Board or Executive Committee for decision.

Meeting Frequency

Seven-to-ten conference calls per year. Additional meetings as needed.

Estimated Time Commitment

2 hours per month for members 6-8 hours per month for Chair

Scheduled

Monthly Committee Conference Calls

Busiest Times of the Year

The Health Policy and Regulatory Affairs Committee's activity level is dependent on the work related to the CPT and RUC calendars, and CMS annual physician payment policy regulatory policy update schedule.



Other

The Health Policy and Regulatory Affairs Committee requires rapid response to provide the Society's position on health policy and advocacy issues, especially for the Chair who initiates member notifications of industry safety alerts.

Conflicts of Interest (COI)

The Health Policy and Regulatory Affairs Committee receives confidential information about emerging technologies, and frequently advocates for coding and coverage policies that impact new or emerging EP services. This information has the potential to move markets and thus preference will be given to appointing members with limited relationships with industry (RWIs).

The Chair must have no financial relationships with industry, excluding institutional research and fellowship support. The policies regarding income and consulting relationships as applied to the President and President-Elect of the Society (described below), shall apply to the Chair of the Committee.

President and President-Elect

The Society's President and President-Elect shall be prohibited from receiving income from commercial entities which have the potential for conflict of interest, during the year(s) in which they hold the position.

Continued participation in industry sponsored clinical trials, steering committees and data safety monitoring boards without remuneration are allowed, as well as continued participation as an expert witness on behalf of device or pharmaceutical companies if these relationships were established prior to assuming the HRS role.

Consulting relationships, with or without remuneration from companies with financial interest in heart rhythm management, are not permitted. In addition, the individual must not own stock or stock options or have ownership, royalty income, partnership, licensing or principal interests in a heart rhythm related enterprise (including a start-up company), excluding mutual funds that may hold such stock in its portfolio.

Permitted Industry-Funded Travel: Industry funds to support travel, food and beverage are permitted only for meetings pertaining to multi-center clinical trials or other pre-existing research commitments where attendance is deemed critical by the Ethics Committee.