SVS PSO Governance Policies

ARTICLE I. Name

The organization shall be known as the Society for Vascular Surgery Patient Safety Organization, a wholly owned subsidiary of the Society for Vascular Surgery, hereinafter referred to as the "SVS PSO."

ARTICLE II. Purpose

The purpose of the SVS PSO is to improve the quality, safety, effectiveness and cost of vascular healthcare by collecting and exchanging information at both national and regional levels.

The SVS PSO is a Patient Safety Organization, as defined by the Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41), implemented to protect the confidentiality of all data and resulting patient safety work product. The SVS PSO engages in patient safety activities focused on vascular and related therapies, including, but not limited to:

(i) efforts to improve patient safety and the quality of health care delivery;
(ii) the creation and analysis of patient safety work product ("PSWP");
(iii) the development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;
(iv) the utilization of PSWP for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;
(v) activities related to the operation of a patient safety evaluation system ("PSES") and to the provision of feedback to participants in a PSES;
(vi) compilation of information regarding patients undergoing certain vascular procedures, preparation of anonymous comparisons and other quality reports; and
(vii) facilitating and providing administrative services in connection with the formation of regional quality groups consisting of three or more PSO contracting entities for the purpose of regional quality improvement by aggregating submitted data on a regional level, and compiling/organizing the results.

ARTICLE III. Participation

Hospitals, physicians or other practice entities contract with the SVS PSO to participate in the quality improvement activities protected under the Patient Safety and Quality Improvement Act. The form of the contract between SVS PSO and the practice entities must be approved by the SVS PSO Governing Council, including the costs for participation. The contract must affirm the practice entities' adherence to the SVS PSO policies and procedures. **See exhibits A and B**.

Regional quality groups comprised of at least three practice entities that participate in the SVS PSO may be accredited by the SVS PSO and afforded status as an SVS PSO regional vascular quality group with representation on the Governing Council, Quality Council, and Research Advisory Council. Individual physicians or practice entities, located in an area where a regional study group has not yet been formed, may also participate. The bylaws of each accredited regional quality group must be approved by the SVS PSO Medical Director. These must contain a purpose consistent with the SVS PSO,

mechanisms for regional quality improvement including semi-annual meetings, and a review process for research using non-identifiable regional data derived from the SVS PSO, including a mechanism for each contracting entity within the regional group to approve the use of their non-identifiable data for each approved research project.

ARTICLE IV. Governing Council

The Governing Council conducts the business of the SVS PSO and makes all decisions on behalf of the SVS PSO, including oversight of budgets, contracts, policies and procedures, publications, relationships with outside parties, and the general direction of the organization. With the Medical Director and the Administrative Director, the Governing Council shall assure compliance with federal regulations governing PSOs.

The decisions of the Governing Council are subject to approval by the Board of Directors of the Society for Vascular Surgery (SVS) for the following: adoption of an annual budget, authorization of major changes in the purpose or operations of the SVS PSO or any other action of the Governing Council identified by the chair of the Governing Council as involving a significant legal issue. No action of the Governing Council with respect to any such matter shall be effective and binding until approval by the SVS Board of Directors has been obtained.

The Governing Council consists of thirty-three representatives, including the chair and vice-chair, appointed by the Society for Vascular Surgery, two representatives appointed by the American Venous Forum, two representatives appointed by the Society for Vascular Medicine, two representatives appointed by the Society for Vascular Ultrasound, two representatives from the Vascular Access Society of the Americas, the SVS Vice President, the SVS PSO Medical Director, the chairs of the SVS PSO Quality and Research Advisory Councils, and one representative appointed by each regional vascular quality group. One representative may be appointed by any endorsing national specialty society not represented by a regional vascular quality group, provided that the endorsing society includes members participating in the SVS Vascular Quality Initiative (SVS VQI).

The duration of the term for Governing Council members is at the discretion of the organization being represented by the individual. In the event of a vacancy in the Governing Council, the remaining members of the Council may exercise the powers of the full Council until the vacancy is filled.

The Governing Council may meet in person, by conference call or by email. Meetings may be called by the chair, or at the request of 25% of the members of the Governing Council. The date, time and place of a regular meeting of the Governing Council shall be fixed and notified in writing not less than twenty-one (21) business days in advance of the date when it shall occur. An emergency meeting may be called within five (5) days of advanced written notice. The Governing Council chair and vice chair, in consultation with the SVS PSO General Manager or delegate, will develop and issue the agenda for each Governing Council meeting. Remote access will be provided for all Governing Council meetings.

A quorum of the Governing Council will be constituted by those in attendance at a meeting where due written notice has been provided. Minutes of the Governing Council meetings shall be distributed electronically to all Governing Council members.

ARTICLE V. Officers

The officers of the SVS PSO Governing Council shall consist of chair and vice-chair. The chair and vice chair of the Governing Council shall be appointed by the SVS Executive Board. The SVS PSO Governing Council Officers shall serve a three (3) year term, which can be renewed for one additional three (3) year term. Former Governing Council officers can serve as ex-officio members for an additional three (3) years.

The chair shall preside at all meetings of the Governing Council and shall, in general, perform all duties customarily incident to the position of president or chair and such other duties as may be prescribed from time to time. The chair shall report regularly to the SVS Board of Directors. The vice-chair shall assume the duties of the chair when the latter is not available.

ARTICLE VI. Executive Committee

An Executive Committee of the Governing Council shall exercise the authority of the Governing Council between Governing Council meetings, except as otherwise provided by these governance policies.

Membership
The Executive Committee shall consist of the following twelve (12) voting members: chair, vice chair, chairs of the Arterial, Venous and Research Advisory Quality Councils, three at-large members elected annually by the Governing Council from among Governing Council members and Registry Committee Chairs, SVS PSO Medical Director, SVS Vice President, and one representatives each from the Community and Office-Based Practice settings.

The at-large members will serve a three (3) year non-renewable term, with staggered timeframes. The election for replacement members shall occur in June of each year. The individual with the highest number of votes will be elected.

The Community and Office-Based Practice members will serve three (3) year non-renewable terms. Nominations for these individuals will be solicited from the SVS Community Practice Committee and the SVS Governing Council. Nominees from the SVS Community Practice Council must be current SVS PSO participants. The individuals with the highest number of votes will be elected.

The SVS Executive Director, who serves as the President of the SVS PSO, shall be a non-voting member of the Executive Committee.

Quorum and Voting. The Executive Committee typically meets monthly, either in person, by conference call or by email. Meetings may be called by the chair, or at the request of 25% of Executive Committee members. The date, time and place of a regular meeting of the Executive Committee shall be fixed and notified in writing not less than fourteen (14) business days in advance of the date when it shall occur. An emergency meeting may be called with five (5) days of advanced written notice. The Executive Committee chair and vice chair, in consultation with the SVS PSO General Manager or delegate, will develop and issue the agenda for each Executive

Committee meeting. Remote access will be provided for all Executive Committee meetings.

A quorum of the Executive Committee will be constituted by those in attendance at a meeting where due written notice has been provided. Minutes of the Executive Committee meetings shall be distributed electronically to all Executive Committee and Governing Council members.

ARTICLE VII. Councils and Committees

The Governing Council may from time to time establish such councils and committees as it deems advisable. Such councils and committees shall consist of such number of persons, and shall have such powers, as designated by the Governing Council.

SVS PSO standing councils and committees include the SVS PSO Quality and Research Advisory Councils and SVS PSO Registry Committees.

Arterial Quality Council (AQC) and Venous Quality Council (VQC)

The role of the SVS PSO Quality Councils is to improve patient safety and the quality of vascular healthcare delivery as directed by the Governing Council. This includes the creation and analysis of patient safety work product ("PSWP"); the development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices; and the utilization of PSWP for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.

The Quality Councils will design and implement appropriate data collection instruments, analyze submitted data, develop risk-adjustment algorithms, and prepare benchmark reports (PSWP) for SVS PSO members. They will coordinate quality efforts of regional groups and facilitate quality research performed by regional groups.

There shall be two quality councils, one for arterial and one for venous disease. The quality councils will oversee the work of their relevant individual registry committees (see below).

- The AQC shall include members who are active SVS PSO participants with an interest in arterial disease. The officers of the AQC shall consist of a chair and vice chair, appointed by the Executive Committee and ratified by the Governing Council. The AQC officers shall serve a three (3) year term, which can be renewed for one additional three (3) year term. The former chair of the AQC can serve as ex-officio member for an additional three (3) years. The members of the AQC will include two representatives from the Society for Vascular Medicine, Society for Vascular Ultrasound and the Vascular Access Society of the Americas, plus representatives from each regional vascular quality group. One representative may be appointed by any endorsing national specialty society not represented by a regional vascular quality group, provided that the endorsing society includes members participating in the SVS VQI. The number of representatives shall be determined by the Governing Council. The SVS PSO medical director shall be an ex officio member.

- The VQC shall include members who are active SVS PSO participants with an interest in venous disease. The officers of the VQC shall consist of a chair and vice chair. The VQC chair will be nominated by the American Venous Forum, appointed by the Executive Committee and ratified by the Governing Council. The chair will serve a three (3) year term, which can be renewed for one additional three (3) year term. The former chair of the VQC can serve as ex-officio member for an additional three (3) years. The vice chair will be appointed by the Executive Committee and ratified by the Governing Council. The vice chair will serve a three (3) year term, which can be renewed for one additional three (3) year term. Members to the VQC will consist of two members appointed by the Society for Vascular Surgery, three members appointed by the American Venous Forum, two members appointed by the Society for Vascular Medicine and a representative from each regional vascular quality group. One representative may be appointed by any endorsing national specialty society not represented by a regional vascular quality group, provided that the endorsing society includes members participating in the VQI. The SVS PSO medical director shall be an ex officio member.

Research Advisory Council

The role of the Research Advisory Council is to review research proposals and approve SVS PSO data releases according to the data release policies established by the Governing Council. The Research Advisory Council also maintains a database of studies and publications derived from SVS PSO data. Research Advisory Councils may be established for arterial research and for venous research.

The officers of Research Advisory Council shall consist of a chair and vice chair. The officers will be appointed by the Executive Committee and ratified by the Governing Council. The Research Advisory Council officers shall serve a three (3) year term, which can be renewed for one additional three (3) year term. The former Research Advisory Council officers can serve as ex-officio members for an additional three (3) years.

Registry Committees

The Governing Council has established a Committee for each SVS VQI Registry. The role of each Registry Committee is to guide the development and maintenance of the registries. Under supervision and oversight of their respective Quality Council, these Committees will also establish the critical reporting measures for each registry and assist SVS PSO staff with providing guidance and education to SVS VQI members.

The officers of each Registry Committee shall consist of a chair and vice chair. The officers will be nominated by their respective Quality Council chair (AQC or VQC), appointed by the Executive Committee and ratified by the Governing Council. Registry officers shall serve a three (3) year term, which can be renewed for one additional three (3) year term. Former Registry chairs can serve as ex-officio members for an additional three (3) years.

Ad Hoc Committees

The Chair of the Executive Committee shall appoint on an as needed basis, all temporary, special, and advisory committees as may be deemed necessary and advisable by the Executive Committee. All temporary, special, and advisory committee duties shall be outlined at the time of organization and the committee(s) shall be considered dissolved when its duties have been completed. Establishment and guidelines for each ad hoc committee will be approved by the Governing Council at its next duly

noticed meeting.

ARTICLE VIII. Staff

The SVS PSO Governing Council through its Executive Committee shall engage a Medical Director to provide clinical and scientific expertise and to manage the work of the SVS PSO. The Medical Director appointment is subject to approval by the SVS Board of Directors. The term of the Medical Director will be determined by contract negotiated with the President of the SVS PSO (SVS Executive Director with advisory input from the SVS PSO Executive Committee and the SVS Board). The Medical Director shall engage such additional staff for the SVS PSO as are needed to fulfill the organizational and analytical needs of the SVS PSO, subject to budget approval by the SVS PSO Governing Council through its Executive Committee.

The Medical Director shall be a voting member of the Governing Council and the Executive Committee and an ex officio member of the SVS PSO Arterial and Venous Quality Councils.

The SVS PSO staff shall provide administrative support for the SVS PSO Governing Council and Governing Council Executive Committee.

ARTICLE IX. Indemnification

To the full extent permitted by, and in accordance with the procedure prescribed in the General Not for Profit Corporation Act of Illinois, the Society for Vascular Surgery shall indemnify any and all of the members of the Governing Council and any and all of the officers, staff, agents and representatives of the SVS PSO for certain expenses and other amounts paid in connection with legal proceedings in which any such persons become involved by reason of their serving in any such capacity for the SVS PSO.

ARTICLE X. Amendments

These governance policies may be amended by the Board of Directors of the Society for Vascular Surgery. Participating practice entities will be notified of changes in a timely manner.

Exhibit A – Policies for Participation

1. Shared Registry Data Ownership

Each practice entity (hospital, physician group, or physician) owns the data that it submits to the SVS PSO, and is entitled to specify and control the use of its data in the manner set forth in the contract. The SVS PSO may use such data for quality improvement activity and may release non-identifiable aggregated summaries (data combined from all sites) without the prior consent of the practice entity. However, any release of practice entity specific non-identifiable data on a per procedure level must be approved by the practice entity.

2. Requirements

The following principles guide the function of the SVS PSO and must be adhered to by all participants.

a. All activities of the SVS PSO must be consistent with the purpose of the PSO, as stated in its governing documents.

b. Each physician member must submit data for all consecutive procedures in the modules in which they participate that are recorded by the SVS PSO and must agree to submit office claims data on a periodic basis to allow an audit to ensure accurate and complete data entry.

c. Each member hospital agrees to submit ICD-9 based claims data on a periodic basis to allow an audit to ensure accurate and complete data entry.

d. Each member hospital and physician must submit complete data forms, including all elements of the SVS PSO registry for all eligible procedures, using a web-based system approved by the SVS PSO, including follow-up data at one year, or other time points established by the SVS PSO.

e. Each member hospital and physician agrees that Patient Safety Work Product including any comparative data can never be disclosed or used for competitive marketing. Hospitals and physicians own their own data, and can download and publish such data and indicate that it was derived from their participation in the SVS PSO. However, they may not publish Patient Safety Work Product provided in benchmarking reports that compares their hospital or practice with other groups in the SVS PSO.

f. Each SVS PSO hospital and physician member agrees to follow all regulations contained within the Hospital Insurance Portability and Accountability Act (HIPAA) and the Patient Safety Quality Improvement Act (PSQIA). This includes, but is not limited to not disclosing any patient, hospital or provider identifiable information.

g. Failure to adhere to these policies may result in loss of membership in SVS PSO for a hospital or physician, if so determined by a majority vote of the Governing Council.

Exhibit B – Data Release Policies

The SVS PSO may prepare non-identifiable datasets for research or quality improvement activities as set forth in the Patient Safety Quality Improvement Act. Recipients of non-identifiable data can include SVS PSO member researchers or non-SVS PSO members, including medical device or pharmaceutical manufacturers, regulatory agencies such as the Food and Drug Administration, and health insurers, provided that these research and quality improvement projects are approved by the SVS PSO.

1. **Non-identified data for regional quality groups**

Non-identifiable datasets may be used by regional quality groups to perform quality improvement projects, upon a request from the regional quality group via its medical director or chair of its research or quality committee. The use of data for quality improvement activities that do not include scientific presentation or publication beyond the specific regional quality group does not require the approval of each participating contracting entity, since quality improvement activities are central to the work of regional quality groups.

Non-identifiable datasets for research purposes may be prepared for members of regional quality groups after approval by the process specified in the bylaws of the regional quality group, using data from each contracting entity within the regional group that has approved the use of their data for the specific research project. It is anticipated that such research projects will lead to scientific presentation or publication beyond the regional quality group. Requests for non-identifiable datasets from regional groups shall indicate that the above requirements have been met, and identify the principal investigator, the purpose of the project, and contain an agreement that restricts the use of such data to the designated project. The SVS PSO shall maintain a log of such projects. Parties who receive non- identifiable data for research from the SVS PSO agree to indicate that such data was non-identifiable in any publication or presentation.

2. **Non-identified data set release for multi-region and/or national projects**

Non-identifiable datasets may be used by the SVS PSO Arterial or Venous Quality Committee to perform quality improvement projects, upon a request from the chair of these groups. Such datasets may also be used by PSO staff to perform quality improvement projects as directed by the SVS PSO Governing Council, Quality Committees, or the Medical Director. The use of data for quality improvement activities in this manner does not require the approval of each participating contracting entity, since quality improvement activities are central to the work of the SVS PSO. Such quality analyses may lead to findings and quality recommendations that merit presentation or publication outside the SVS PSO, which is permitted.

Non-identifiable datasets for research purposes may be prepared for SVS PSO members using data from more than one regional quality group or the entire SVS PSO dataset. Requests for such datasets shall be reviewed and coordinated by the SVS PSO Research Advisory Committee (RAC). Each regional group, via the regional research approval process outlined in their regional bylaws must approve the use of their regional data in order for it to be included in a multi-regional/national dataset.

Prior to releasing non-identifiable data, the SVS PSO shall obtain permission from each

contracting entity as specified in their contract with the SVS PSO.

To ensure that data shared by the VQI is used for projects consistent with the quality improvement mission of the SVS PSO, research projects must meet the following criteria:

- The project is a study that addresses knowledge gaps in the care of patients with vascular disease.
- The project is a study that is well designed and addresses a topic of interest to SVS VQI participants.
- The project is submitted by a study team that can execute and interpret analyses presented in the study proposal.

There are three requirements for collaboration:

- The abstract for all approved projects will be sent to each center to obtain their approval to include their non-identifiable data in the project.
- Each region that contributes data towards the project will be invited to select an investigator to be involved in the conduct of the project and any subsequent publication.
- All publications must have the byline "from the Society for Vascular Surgery Vascular Quality Initiative."

3. Non-identified dataset release to non-SVS PSO members

The SVS PSO may prepare non-identifiable datasets for research or quality improvement activities initiated by medical device or pharmaceutical manufacturers, regulatory agencies such as the Food and Drug Administration, and health insurers. Each project must be approved by the Arterial or Venous Quality Committee, and the Governing Council. The following rules will govern the use of such data:

- Data provided to industry may be used for internal quality improvement and R&D purposes, or to meet reporting requirements to regulatory agencies.
- Data may not be used for device or drug comparative marketing purposes.
- Data may not be published or used in marketing materials without prior written approval by the SVS PSO.
- Data must only be used for the approved project and cannot be distributed to another party without prior written approval by the SVS PSO.

The following comparison rules will apply:

- In cases where an analysis is requested that compares a specific device or drug to all other industry devices or drugs, the individual device or drug will be compared to "all others" only when at least three devices or drugs manufactured by different companies are available for comparison, in order to provide anonymity.

Figure 1 – Adapted from https://www.ncbi.nlm.nih.gov/books/NBK22878/ **A Framework for a Systems Approach to Health Care Delivery**