# Homoeopathic Pharmacopoeia Convention of the United States (HPCUS)

**Procedure Manual** 

**May 2019** 

**Revision 6.1** 

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#### Introduction

The purpose of this document is to describe the **Structure**, **Processes**, and **Governance** of the Homoeopathic Pharmacopoeia Convention of the United States (HPCUS). The HPCUS produces the *Homoeopathic Pharmacopoeia of the United States (HPUS)*, which is recognized in the Federal Food, Drug, and Cosmetic Act (FDCA) as an official compendium within the meaning of the statute.

Homeopathy is defined as:

"Homeopathy is the art and the science of healing the sick by using substances capable of causing the same symptoms, syndromes, and conditions when administered to healthy people.

Any substance may be considered a homeopathic medicine if it has known "homeopathic provings" and/or known effects which mimic the symptoms, syndromes, or conditions that it is administered to treat, and is manufactured according to the specifications of the *Homœopathic Pharmacopoeia of the United States (HPUS)*."

#### 1. Structure

#### 1.1 Members

The HPCUS is composed of members of two categories. Associate Members are individuals possessing education, training, and skills necessary to the function of HPCUS, who have undergone the HPCUS Membership Application Process and been duly proposed for election to the Convention by the Board with approval of the Active Members. Associate Members are asked to participate on HPCUS Committees and in HPCUS deliberations.

After a period of one year, Associate Members, at the request of the Board, may be advanced to Active Membership status by approval of the Active Members. HPCUS requires Committee Chairpersons and Board members to be Active Members in good standing.

#### 1.2 Executive Director

An Executive Director for HPCUS may be appointed by the Board of Directors and shall report to the President. The duties of the Executive Director will be assigned from time to time by the HPCUS Board, and may be changed at their discretion. A general description of the contracted activities is outlined in section 1.2.1. In the event that the Executive Director position is vacant, the duties of the Executive Director shall be undertaken by the President or the President's designee(s).

#### 1.2.1 HPCUS Executive Director Duties and Responsibilities

#### 1.2.1.1 Editorial Information

- 1. Maintain *HPUS* bibliographic materials on the website in an accessible condition within 15 days.
- 2. Provide direction to research monographs in support of various committee activities.
- 3. Coordinate the preparation of monographs for publication in *HPUS*.
- 4. Oversee the preparation of General Pharmacy and HPCUS editorial copy for publication in *HPUS*.
- 5. Support S&C committee activities.
- 6. Oversee the preparation of S&C committee monographs for publication in *HPUS*.
- 7. Act as primary liaison to sponsors and those inquiring about HPUS monographs...
- 8. Provide official copies of *HPUS* monographs.
- 9. Coordinate HPCUS board activities.
- 10. Support website maintenance in conjunction with web committee of HPCUS.

#### 1.2.1.2 Administrative Activities

- 1. Provide outreach to the broader pharmaceutical community including *USP*, Medical Associations and Societies and the Pharmaceutical communities (industry, academia, professional, community, consumer, etc.), and other non-governmental organizations (e.g. National Advertising Division of the Better Business Bureau.).
- 2. Provide the primary communication with U.S. governmental agencies.
- 3. Provide outreach to media and public relations firms, coordinating media materials to reach appropriate members of HPCUS.
- 4. Respond to correspondence with HPCUS members in coordination with the HPCUS President as well as inquiries to www.hpus.com.
- 5. Systematically review and automate HPCUS accounting systems, including cash management, sales management and financial reporting.
- 6. Maintain HPCUS database lists: membership, customer/subscriber, and vendor.
- 7. Communicate with HPCUS members in coordination with the President.

- 8. Arrange and attend board and Annual Meetings in coordination with the President.
- 9. Provide annual dues notices and collect dues from subscribers.
- 10. Oversee budgets in coordination with HPCUS President and Chairperson of the Sales and Finance committee.
- 11. Execute annual financial reports, including tax returns.
- 12. Prepare annual strategic plan in conjunction with the President.
- 13. Support the recruitment of new members into the HPCUS.
- 14. Maintenance of copyrights.
- 15. Maintenance of records of committee actions at the direction of the Secretary.
- 16. Maintenance of IRS reporting for 501(c)3 status.

#### 1.2.1.3 Sales Support

- 1. Maintain inventories of updated paper and electronic versions of *HPRS/HPUS*.
- 2. Follow-up on non-renewed subscriptions to identify reason for non-renewal or obtain renewal subscriptions.
- 3. Support the development and implementation of a profitable marketing program.
- 4. Process *HPRS/HPUS* subscriptions and fulfillment, in conjunction with the President.
- 5. Maintain records of all sales and financial transactions.

#### 1.3 Administrative Structure of HPCUS

The HPCUS is organized into a governing Board of Directors that supervises Administrative and Working Committees. All decisions for the HPCUS must be undertaken or approved by the Board of Directors.

Appointment of all Committees and of their Chairperson, except for the Executive Committee and the Nominating and Credentials Committee, which are designated by the Bylaws, is made by the HPCUS President from members of the HPCUS. Active and Associate Members may serve on Committees. In fact, participation by Associate Members on their assigned Committees is prerequisite for advancement to Active Member status. Chairpersons of Committees must be Active Members in good standing of the Convention. Only Active Members are permitted to vote on Committee matters.

Board Members may serve on Committees.

#### 1.3.1 Board of Directors

#### Composition

The number of Directors shall be not less than five (5), not more than eleven (11). (*Bylaws*, Art. VI, Section 2). To be elected to the Board, one must have been an Active Member of the HPCUS for not less than one year. (*Ibid*.).

#### **Officers**

The Officers of the Corporation, who also shall be members of the Board of Directors, shall be: Chairman, President, First Vice President, Second Vice President, Secretary, and Treasurer who shall be elected by the Board. (*Bylaws*, Art. VII, Section 1). Their duties are outlined in the *Bylaws*.

#### **Terms**

Each Director shall hold office for a term of three (3) years. (*Bylaws* Art. VI, Section 3). Each Officer shall hold office for one (1) year or until a successor shall have been duly elected or appointed. (Art. VII, Section 2).

#### Purpose(s)

The fundamental function of the Board of Directors is to be the executive and administrative mechanism of the Homoeopathic Pharmacopoeia Convention of the United States in all areas that advance and nurture the Homoeopathic Pharmacopoeia Convention of the United States. The Board of Directors seeks the following:

- 1. To select and appoint competent and suitable chairpersons and staff to perform the work of the convention,
- 2. To hear reports of work in progress, and to evaluate their quality and quantity,
- 3. To raise funds when necessary to support and to complete the purposes of the convention,
- 4. To maintain a diplomatic liaison with federal agencies for the advancement of homeopathy, and to be aware of any legal changes in drug regulation that pertain to the homeopathic method, and
- 5. To be the final authority on changes and additions to the *Pharmacopoeia*.

#### Records

The Secretary of the Convention shall be responsible for the keeping of written minutes of all meetings of the Board of Directors, whether the meeting is in person or by conference call. The Secretary shall maintain a file of all official correspondence whether of the Board or of a Committee.

#### Reporting

The Board of Directors reports to the Membership of the Convention at the Annual Membership Meeting. The report is made by the President of the Convention.

#### 1.3.2. Committees

#### 1.3.2.1 Executive Committee

#### Composition

The Executive Committee shall be composed of the President and such two other officers as the Board may designate, (Art. VIII, Section 1), a majority of which shall constitute a quorum.

#### Purpose(s)

The Executive Committee shall exercise the authority of the Board of Directors in the management of the business of the Corporation between meetings of the Board. (Art. VIII, Section 1).

#### Records

Written minutes of the meetings of the Executive Committee, whether in person or by conference call, shall be kept by the Secretary.

#### Reporting

Actions of this Committee shall be reported to the Board of Directors.

#### 1.3.2.2 Nominations and Credentials Committee

#### Composition

The Executive Committee shall serve as the Nominations and Credentials Committee. (Art. VIII, Section 2), a majority of which membership shall serve as a quorum. The President shall appoint the Chairperson.

#### Purpose(s)

The Nominations and Credentials Committee shall administer the election of Associate and Active Members, Directors, and Officers of HPCUS, as well as make recommendations for advancement of Associate to Active membership.

#### Records

The Secretary shall receive all inquiries for HPCUS membership, forwarding them to the Chair of the Nominations and Credentials Committee who shall provide membership applications to the applicants. These completed forms shall be returned to the chairperson of the Nominations and Credentials Committee who shall cause them to be distributed, with an accompanying action form, to the Nominating and Credentials Committee membership, for their recommendation, to be returned to the chairperson of the Nominations and Credentials Committee for preparation of a written report.

#### Reporting

The Nominations and Credentials Committee shall report to the Board of Directors. The chairperson of the Nominations and Credentials committee shall prepare the written report.

#### **Procedure**

Whenever possible, a member of the Board will arrange a meeting with the applicant and personally report to the rest of the Board before a vote is taken on that applicant's application.

#### 1.3.3.3 Finance & Audit Committee

#### Composition

The Chairperson and membership of this Committee shall be appointed by the HPCUS President. A Secretary may be elected at the will of the Committee.

#### Purpose(s)

The purposes of this Committee are to prepare a budget; to prepare a development plan; to review expenditures, other than legal and review the Financial Statements of the Convention after preparation by the outside accountants.

#### Records

The Chairperson of this Committee shall keep written records of all Committee meetings, transactions, and correspondence, as well as a record of Committee membership attendance, and participation. For specifics on Communications, see the appropriate section in this *Procedure Manual*.

#### Reporting

This Committee reports to the President of the Convention.

#### 1.4 Operational Structure and Committees

#### **1.4.1 Editor**

#### **Appointment**

The Editor is appointed by the Board of Directors.

#### **Duties**

The Editor is responsible for the preparation and the review of new and existing monographs for homeopathic drugs and for forwarding the recommendations for action on monographs to the Board of Directors.

The Editor is to provide, for a fee, copies of monographs to interested parties from whom he has received a written request accompanied by the requisite fee.

The Editor is to have published a list of the monographs that the Monograph Review Committee (MRC) or the Pharmacopoeia Revision Committee (PRC) has designated **approved** or **rejected**, and the reasons for the action taken, in appropriate publications. Monographs returned to the sponsor for clarification shall be on the agenda at the next meeting if that sponsor has returned the information to the HPCUS by the deadline established by the committee.

Specific details of the Editor's duties are found in the contract between HPCUS and the Editor.

Specific details of the Editor's procedures are found in the official Monograph Review Procedure for the *Homoeopathic Pharmacopoeia of the United States* (HPRS .1988-13).

#### Records

The Editor is charged with maintaining original sets and copies, to be stored with the Convention Secretary, of all monographs accepted or in process. He is to maintain records as to the progress of submitted monographs, including their status within each pertinent Committee.

#### Reporting

The Editor reports to the President of the Convention.

#### 1.4.2 Committees

The HPCUS President makes appointments of all Committees and their Chairpersons from members of the HPCUS. Active and Associate Members may serve on Committees. In fact, participation by Associate Members on their assigned Committees is prerequisite for advancement to Active Member status. Chairpersons of Committees must be Active Members in good standing in the Convention. Only Active Members are permitted to vote on Committee matters; Associate Members are encouraged to contribute to, and participate, in the deliberations of their respective committees.

#### 1.4.3 Monograph Review Committee (MRC)

#### Composition

The Chairperson and the members of the Monograph Review Committee are appointed for one year by the HPCUS President from the Active and Associate Members of the Convention. Members of these classes may apply for appointment to this Committee. A Secretary may be elected from its membership at the will of the Committee.

#### Purpose(s)

The MRC is to make recommendations to the Board of Directors on monographs after reviewing nomenclature, biological classification, chemical formulae, molecular weight, description; range and habitat for botanicals and zoologicals; other general properties of starting materials, preparation, stability, toxicology, classification and suggested attenuation levels for OTC, RX, External and Homeopathic Pharmaceutical Necessity (HPN) use for substances under consideration; and to perform an initial review of references. For monographs submitted to the HPCUS for potential inclusion in the pharmacopeia, the MRC is also to make a review of quality control standards for appropriateness to the substance being monographed. The committee should be guided by a consensus model of decision-making and is free to adopt a written S.O.P. if desired.

#### Records

The Chairperson shall be responsible for seeing that written records are kept of all meetings, including attendance roster and member participation verification. Signed conflict of interest and confidentiality statements shall be received annually from all participants and kept on file with the Convention. Written records of the meetings shall include all actions recommended by the Committee as well as the reason(s) or rationale for each recommendation, including both acceptance and rejection of proposed changes. If the recommendations are not unanimously supported by all members present at a meeting, the records shall indicate the breakdown of the voting. When necessary, the report should include the referenced materials, as well as minority viewpoints. The committee may use a standardized report format if the Chairperson so chooses.

Specific details for Communications are found in the appropriate section of this *Procedure Manual*.

#### Reporting

The MRC reports to the Pharmacopoeia Editor and to the HPCUS President, the latter to receive reports only, not copies of monographs under review.

#### 1.4.4 Pharmacopoeia Review Committee (PRC)

#### Composition

The Chairperson and the members of the Pharmacopoeia Review Committee are appointed for one year by the HPCUS President from the Active and Associate Members of the Convention. Members of these classes may apply for appointment to this Committee. A Secretary may be elected at the will of the Committee.

#### Purpose(s)

The PRC is to make recommendations to the Board of Directors on monographs after completing an in depth review of references, ensuring adequacy and utility of the symptom picture and/or proving according to Convention guidelines and full compliance with the *Criteria for Eligibility of the HPUS*. For monographs for which a proving is lacking, the PRC should review clinical information or case reports to confirm that the substance can be used in a manner that conforms to the Law of Similars. The committee should be guided by a consensus model of decision-making and is free to adopt a written S.O.P. if desired.

#### Records

The Chairperson shall be responsible for seeing that written records are kept of all meetings, including attendance roster and member participation verification. Signed conflict of interest and confidentiality statements shall be received annually from all participants and kept on file with the Convention. Written records of the meetings shall include all actions recommended by the Committee as well as the reason(s) or rationale for each recommendation, including both acceptance and rejection of proposed changes. If the recommendations are not unanimously supported by all members present at a meeting, the records shall indicate the breakdown of the voting. When necessary, the report should include the referenced materials, as well as minority viewpoints. The committee may use a standardized report format if the Chairperson so chooses.

Specific details for Communications are found in the appropriate section of this *Procedure Manual*.

#### Reporting

The PRC reports to the Pharmacopoeia Editor and to the HPCUS President, the latter to receive reports only, not copies of monographs under review.

#### 1.4.5 Council on Pharmacy (CoP)

#### Composition

The Chairperson and the members of the Council on Pharmacy are appointed for one year by the HPCUS President from the Active and Associate Members of the Convention. Members of these classes may apply for appointment to this Committee. A Secretary may be elected from its membership at the will of the Committee.

#### Purpose(s)

The purpose of this Committee is to deliberate upon and to make recommendations for changes to the technical sections of the *HPUS* (for example: the *Guidelines for Manufacturing Homeopathic Medicines*, the *Labeling Guidelines*, etc.) and other issues not related to individual monographs. The Council's recommendations will be forwarded to the Board of Directors for official action. Additional tasks will be assigned by the President of the HPCUS. The committee should be guided by a consensus model of decision-making and is free to adopt a written S.O.P. if desired.

#### Records

The Chairperson shall be responsible for seeing that written records are kept of all meetings, including attendance roster and member participation verification. Signed conflict of interest and confidentiality statements shall be received annually from all participants and kept on file with the Convention. Written records of the meetings shall include all actions recommended by the Committee as well as the reason(s) or rationale for each recommendation, including both acceptance and rejection of proposed changes. If the recommendations are not unanimously supported by all members present at a meeting, the records shall indicate the breakdown of the voting. When necessary, the report should include the referenced materials, as well as minority viewpoints. The committee may use a standardized report format if the Chairperson so chooses.

Specific details for Communications are found in the appropriate section of this *Procedure Manual*.

#### Reporting

The CoP reports to the Pharmacopoeia Editor and to the HPCUS President, the latter to receive reports only, not copies of monographs under review.

#### 1.4.6 Standards and Control Committee (S&C)

#### Composition

The Chairperson and the members of the Standards and Control Committee are appointed for one year by the HPCUS President from the Active and Associate Members of the Convention. Members of these classes may apply for appointment to this Committee. A Secretary may be elected from its membership at the will of the Committee

#### Purpose(s)

The purpose of this Committee is to establish quality standards and controls applicable to HPUS homeopathic drug monographs. The Committee is to review specific test language in monographs and recommend a specific wording in a consistent style and format to provide utility to HPIUS subscribers. The committee is to maintain a list of reagent definitions as well as information on special test procedures as a service to subscribers.

#### Records

The Chairperson shall be responsible for seeing that written records are kept of all meetings, including attendance roster and member participation verification. Signed conflict of interest and confidentiality statements shall be received annually from all participants and kept on file with the Convention. Written records of the meetings shall include all actions recommended by the Committee as well as the reason(s) or rationale for each recommendation, including both acceptance and rejection of proposed changes. If the recommendations are not unanimously supported by all members present at a meeting, the records shall indicate the breakdown of the voting. When necessary, the report should include the referenced materials, as well as minority viewpoints. The committee may use a standardized report format if the Chairperson so chooses.

Specific details for Communications are found in the appropriate section of this *Procedure Manual*.

#### Reporting

The S&C reports to the Pharmacopoeia Editor and to the HPCUS President, the latter to receive reports only, not copies of monographs under review.

#### 1.4.7 Toxicology and Safety Committee (T&S)

#### Composition

The Chairperson and the members of the Toxicity and Safety Committee are appointed for one year by the HPCUS President from the Active and Associate Members of the

Convention. Members of these classes may apply for appointment to this Committee. A Secretary may be elected from its membership at the will of the Committee

#### Purpose

The purpose of this committee is to review safety and toxicological information and make recommendations for appropriate safe dosage levels for OTC, Rx, External Use, and Homeopathic Pharmaceutical Necessity (HPN) attenuations based on with current information and in accordance with contemporary methods for calculating and assigning safe dosage levels for homeopathic drug products. The committee should be guided by a consensus model of decision-making and is free to adopt a written S.O.P. if desired.

Recommendation shall be made to the Board of Directors for consideration for publication in the monographs and potency tables

#### Records

The Chairperson shall be responsible for seeing that written records are kept of all meetings, including attendance roster and member participation verification. Signed conflict of interest and confidentiality statements shall be received annually from all participants and kept on file with the Convention. Written records of the meetings shall include all actions recommended by the Committee as well as the reason(s) or rationale for each recommendation, including both acceptance and rejection of proposed changes. If the recommendations are not unanimously supported by all members present at a meeting, the records shall indicate the breakdown of the voting. When necessary, the report should include the referenced materials, as well as minority viewpoints. The committee may use a standardized report format if the Chairperson so chooses.

Specific details for Communications are found in the appropriate section of this *Procedure Manual*.

#### Reporting

The T&S reports to the Pharmacopoeia Editor and to the HPCUS President, the latter to receive reports only, not copies of documents under review.

#### 2. Processess

#### 2.1 Monograph Review and Approval

Monographs may be submitted to HPCUS by private sponsors or by HPCUS itself. The monograph should be prepared in a format and with supporting documentation and safety data according to the guideline documents in the *HPUS*.

The monograph should be submitted to the Editor for preliminary review and comment. The Editor may suggest changes, where appropriate, and return the monograph to the submitting party. A completed monograph, including both a *Main Monograph* document and a *Quality Control Specifications* document along with all supporting documentation should be submitted to the Editor for distribution to the monograph review committee (MRC) and Pharmacopoeia Revision Committee (PRC). The complete supporting documentation should meet the content and format requirements of the *Guidelines For Technical Information Requirements For Monograph Review*, and the *HPCUS Proving Guidelines* document.

The MRC shall review the monograph for technical details as described in Section 1.4.2.1 (Purposes). The MRC shall recommend the monograph to the Board for approval, to be declined, or may return the monograph to the sponsor for more information.

Concurrently, the PRC shall review the monograph for technical details with a focus on clinical issues as described in Section 1.4.2.2 (Purposes). PRC shall recommend to the Board for approval, to be declined or may return the monograph to the sponsor for more information.

The MRC and PRC recommendations shall be referred to the Board for review and decision. The Board can decline, return the monograph to the sponsor for additional data, or approve the monograph for publications; the approval for publication can also be made, depending on the data in the supporting documentation, subject to clinical verification.

The Editor shall publish the decision of the Board for public comment 90 days after approval for publication by the Board. After the comment period, the relevant comments shall be referred to the Board. Upon review of the comments, the Board can publish the monograph, decline, return the monograph to the sponsor for additional data. If a monograph is to be published pending clinical verification, the sponsor shall be so informed. The sponsor should then contact the Editor for details of the clinical verification. Study requirements will vary according to potential toxicity of the substance and principal clinical indications.

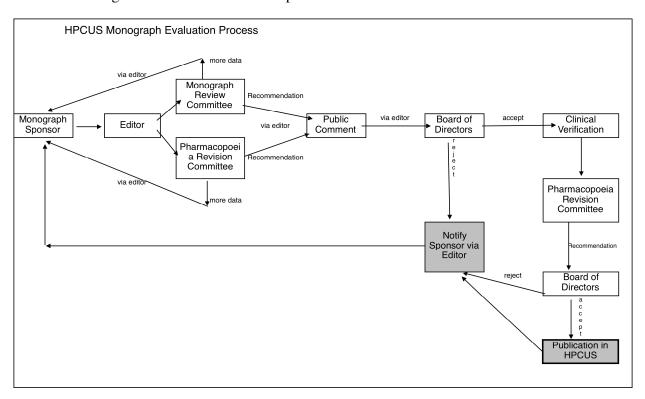
The Pharmacopoeia Revision Committee shall review clinical verification data, and make a recommendation to the Board. The Board will make a final determination after review of these data and the PRC recommendation.

Concurrent with the original approval for publication by the Board, the Standards and Controls Committee shall complete an in-depth review of the *Quality Control Specifications* document from the sponsor; and will take the necessary steps to ensure the information is presented in a format consistent with other official monographs. Where possible, the S&C will prioritize this review when setting the agenda for its meetings.

Upon completion of its work, it will forward to the Editor and the Board its recommended wording and format of the *Quality Control Specifications* for approval and publication as soon as possible after the completion of the comment period.

Monographs that have been previously approved may be re-reviewed at the request of an HPCUS member and upon approval of the Board.

The following flowchart documents the process:



#### 2.2.1 Editorial Changes to HPUS

All changes proposed to HPUS must be approved by the Board of Directors before the changes are official.

#### 2.2.2 Change Procedure

To insure the integrity of the HPUS, all proposed changes must follow the Change Control Procedure as outlined in Section 2.9.

#### 2.2.3 Editorial Changes to General Pharmacy

Any member of the Council on Pharmacy may suggest editorial changes to General Pharmacy. Suggested language should be forwarded to the chairperson for dissemination

to the COP. Language will be reviewed at a regular COP meeting and a recommendation made to the Board for action.

#### 2.3 Errors and Omissions

Errors and omissions in the HPUS data should be brought, in writing, to the attention of the Editor with an explanation of the error or omission, along with suggestions for remediation, if necessary.

#### 2.4 Web Posting

Materials approved by the Board shall be posted to the website within 30 days of decision.

#### 2.5 Consultants

Committees may employ appropriately qualified consultants with approval of the Board. The consultant's proposed job description, along with *curriculum vitae* and budget should be submitted to the Board for approval and budgetary review.

#### 2.6 Panel of Experts

#### 2.6.1 Purpose

The purpose of the Panel of Experts is to fulfill special needs of the Convention when current membership lacks the special education, training, or experience.

#### 2.6.2 Membership

The members of this Panel shall be individuals who possess special education, training, or experience and are available and willing to assist the Convention in its duties, but are unable or unwilling to assume the obligations of full membership in the HPCUS.

#### 2.7 Meetings

Operating committee meetings may be held in person or by electronic means. Proper notice should be given 30 days in advance of each meeting.

#### 2.7.1 Annual Board of Directors

The Annual Meeting shall be held at a time and a place to be determined by the Board of Directors. Failure to hold this meeting will not work a forfeiture or dissolution of the Corporation. Proper notice should be given 30 days in advance of each meeting. (*Bylaws* Art.VI Section 5)

#### 2.7.2 Special Board of Directors

Any three Directors may call special Meetings. Proper notice should be given 15 days in advance of each meeting. (*Bylaws* Art. VI Section 5.)

#### 2.7.3 Annual General Membership

The Annual Meeting may be called by any three Directors with thirty days notice by the Secretary. The time and place of the meeting is to be determined by the President. Although the Board of Directors is self-perpetuating, the active participation and support of the membership is essential for the success of the Convention.

#### 2.7.4 Administrative Committees

Frequency

The Committee Chairperson, depending upon the needs of the Convention, shall determine necessity or frequency of meetings.

#### **2.7.5** Operational Committees

Frequency

The Committee Chairperson, Executive Director, or Editor, depending upon the needs of the Convention, shall determine necessity or frequency of meetings.

#### 2.8 Correspondence and Communication

#### 2.8.1 Official Correspondence

The Chairperson/ Secretary or Secretary shall be responsible for forwarding committee correspondence to the editor, Executive Director, and the Board. Copies of the correspondence shall be appended to the interim or annual reports and submitted to the Convention Secretary. Official Correspondence will be sent to the Convention Secretary for review and/or official action and will be sent by the Convention Secretary to the Correspondent. If the document is altered in any way by the Board, the Committee Chairperson shall be notified of the changes.

All correspondence from interested parties to the HPCUS regarding monographs in progress and Council on Pharmacy issues in progress, should go through the Editor.

#### 2.8.2 Committee Reports

The Committee Chairperson and the Editor shall prepare and submit to the Board a specimen of the reporting format for approval. The format should provide sufficient information organized in such a way that the Board can deliberate and process the data in

an efficient manner. When necessary, the report should include the referenced materials, minority viewpoints, and reasons for acceptance or rejection. A glossary of terms may be required.

There will be five copies of Interim and Annual reports.

- 1. One copy will be maintained by the Committee Chairperson/ Secretary or Secretary.
- 2. One copy each will be sent to the Convention Secretary, President, and Executive Director.
- 3. One copy will be sent to the Editor.

In lieu of sending printed reports, the committee chairpersons may electronically transmit the reports, provided the Committee Chairperson/Secretary retains a printed copy in case of electronic file corruption.

Interim reports or "Minutes" will be prepared by the Chairperson/ Secretary or Secretary after every meeting, signed or circulated and forwarded to the Editor and the Secretary of the Convention.

An Annual Report shall be prepared, and be presented prior to the Annual Meeting. This report will be made a part of the Convention Proceedings

#### 2.8.3 Minority Reports

The Committee Chairperson shall be responsible for the production of a Minority Report should circumstances warrant it. The Chairperson/ Secretary or Secretary may write the report or may designate a Committee member who represents, or who has been selected by, the Minority to write the Minority Report. The Minority Report shall be signed by those whose views it represents. The original of the Minority Report shall be forwarded to the Secretary of the Convention, and a copy shall be sent to the Editor and a copy shall be maintained with the Committee records.

#### 2.8.4 Record of Attendance

A record of members attending a meeting will be kept and made a part of the report. A roster of committee members will be maintained which will indicate when each member attends committee meetings. Signed conflict of interest statements shall be received from all participants, appended to the minutes, and retained by the committee chairperson with the printed copy of the report.

#### 2.8.5 Requests for custom bibliographic research

The HPCUS entertains requests from subscribers that require significant research of HPCUS files and reports; for instance subscribers might request copies of provings cited in a series of monographs. The data are available, however they have been collected over many years from multiple sources and exist in various forms (photocopies of old books, microfiche/film prints from library journals, electronic documents). The files are located in various locations; thus it will take time to locate and collate the requested materials.

Accordingly, such requests will be administered in the following manner:

- 1. The Editor will determine if fulfilling the request is reasonable, e.g. that the information exists.
- 2. The Editor will estimate the amount of time, materials and outside services required to complete the task; this information will be communicated to the Executive Director or President for discussion with the requester.
- 3. Either the Executive Director or President will communicate to the requestor of the appropriate fee billed at \$100.00 per hour.
- 4. Once a check, made payable to the HPCUS, has been received at the Southeastern PA address, the Editor will produce the work for the requester.
- 5. The Editor will be compensated by the HPCUS at \$75.00 per hour for the amount of time that has been estimated.
- 6. The fee will be treated as "other income" on the HPCUS income statement, offset by "editor's fees" paid to the editor.

#### 2.8.6 Document Security and Retention

Committee members are encouraged to keep careful notes of committee proceedings for their own use. No personal notes, nor any interim documents, calculations, reports or analyses are to be circulated or distributed outside the membership of your respective committee. Only official committee reports prepared by the chair, or the chair's designee, and approved by the committee members and the HPCUS Board may be shared outside the HPCUS membership.

Members of the Convention and its committees have responsibility for safeguarding any confidential information with which we have been entrusted in furthering the purposes of the Convention. This includes confidential information submitted by monograph sponsors and documents delivered, or information conveyed orally, to various committees by interested parties.

Documents and files that outside parties, committees, and Convention members wish the Convention to treat as *Confidential* must be so marked on every page. Likewise, orally conveyed information that outside parties, committees, and Convention members wish the Convention to treat as *Confidential* should be so noted at the time of presentation. In the absence of such marking or noting, the Convention will assume the information is not required to be treated as confidential.

Committee members are expected to handle such *Confidential* documents and information with at least as much care as similarly confidential files and information of their own organizations. As a minimum:

- All hardcopy *Confidential* documents and notes about orally presented *Confidential* information maintained by each committee member should be stored in a secured area accessible to only that individual.
- All electronic *Confidential* documents maintained by each committee member should be password protected with password access only by that individual.
- When committee deliberations concerning any *Confidential* documents or
  information are complete, committee members must return any hard copies to the
  committee chair for destruction (or return to the sponsor), and committee
  members must permanently delete all electronic copies from all electronic data
  storage systems, including all data backup copies.

Prior to beginning deliberations on any matter involving *Confidential* documents or orally presented information, committee members will be required to sign a statement acknowledging the above points and their ability to comply with them. Distribution of *Confidential* documents will be predicated upon receipt of such a signed acknowledgement. The Committee Chair shall retain these acknowledgements on file for each committee and the Convention President shall do the same for the Convention membership as a whole.

#### 2.8.7 Handling of Confidential Documents Statement

HPCUS Handling of Confidential Documents Statement is included with this document as Appendix B.

#### 2.9. Change Control Process

The HPCUS is in a continual state of update and revision. Two types of changes to the online text may result. Those changes that are minor / technical and are non-substantive in nature, and those changes resulting from committee or Board deliberations that are substantive in nature.

#### 2.9.1 Non-substantive Technical Changes and Corrections

The requirement for minor technical corrections should be brought to the attention of the Editor or the Change Control Coordinator. The Editor and the Change Control Coordinator will together assess whether such edits are substantive in nature. If, in their opinion, the corrections are minor and non-substantive in nature, the editor may make such corrections. Upon completion and verification, the editor should inform the Change Control Coordinator in writing using the Abbreviated Change Control Form.

#### 2.9.2 All Other Changes, Additions and Deletions to HPUS

In order to maintain transparency and assure that all changes to the HPUS are properly approved, the following Change Control procedure will be followed for any changes not subject to section 2.9.1.

Step	What	Action	By Whom
1	Suggestion/ Correction	Starts Change process.	Anyone
2	Received by Coordinator / Editor	Initiates Change Control Form + Process	Change Control Coordinator or Editor
3	Decide if <b>Minor</b> Change	Yes – Go to Step 10	Change Control Coordinator or Editor
4	Decide if <b>Major</b> Change	Yes – Go to Step 5	Change Control Coordinator or Editor
5		Forward to Responsible Working Group [CoP, T&S, S&C, etc.]	Change Control Coordinator
6	Evaluate issue/ topic/ monograph/ detail	Make Recommendation for change / no change (with reason for no change when appropriate)	Responsible Working Group Chair
7	Fill out Change Control Form	Forward Change Control form to Change Control Coordinator	Responsible Working Group Chair

8		Collate Change Recommendations and Forward For Board Action	Change Control Coordinator
9	Evaluate Recommendations	Approve or Not Approve (with reason for no change when appropriate)	Board of Directors
10	Implement Change	Forward Change Control Forms to Editor / Webmaster	Change Control Coordinator
11	Update Website	Make Changes as per Change Control From	Editor / Webmaster
12	Acknowledge Website Updated	Return Change Control Form to Change Control Coordinator	Editor / Webmaster
13		Inform Originator (Step 1 or 6) that change has been made (or not with reason when appropriate)	Change Control Coordinator
14	File Completed Change Controls	Forward to Executive Director for Filing + Archive	Change Control Coordinator

#### 2.9.3 Archiving and Notification of Changes

#### 2.9.3.1 Change Control Log

The Change Control Coordinator will maintain a change control log that documents the complete process by which changes were made and approved. The Secretary will keep copies of the change control sheets in the books and records of the Convention.

#### 2.9.3.2 Public Notification

The Change Control Coordinator will post all changes made pursuant to Sections 2.9.1 and 2.9.2 on the public pages of the HPCUS website. Such postings will be made within 15 days of the changes being effected.

#### 3.0 Governance

#### 3.1 Board of Directors

HPCUS shall be governed by a Board of Directors as described in section 1.3.1 herein.

#### 3.2 Recusal

The Board will expect a member, in whole or in part, to recuse him/herself if (s)he is:

- 1. an employee of a company submitting the proposed monograph or suggested matter before the board and thus has worked on the documents being submitted,
- 2. a consultant who has written the documents that support the proposed action, or
- 3. a spokesperson for the action at the HPCUS presentation.

#### 3.3 Conflict of Interest

HPCUS members are required to complete a Conflict of Interest Statement each year declaring what, if any, conflicts s/he might have with matters to be decided. These signed documents will be maintained with the Convention's files. HPCUS members are required to inform his/her committee chair(s) prior to the next meeting of his/her committee(s) if the circumstances of any potential or actual conflicts of interest change since the most recent Conflict of Interest Statement has been signed.

#### 3.4 Open Meetings

Meetings are usually open for technical discussions. Meetings may be open or closed at the discretion of the Committee chairperson.

#### 3.5 Bylaws

HPCUS Bylaws are included with this document as Appendix A.

#### 3.6 Conflict of Interest Statement

HPCUS Conflict of Interest Statement is included with this document as Appendix B.

### Appendix A, BYLAWS OF THE HOMOEOPATHIC PHARMACOPOEIA CONVENTION OF THE UNITED STATES

#### **ARTICLE 1. DEFINITIONS**

As used in these *Bylaws*, the term (a) "Corporation" means Homoeopathic Pharmacopoeia Convention of the United States, (b) "Act" means the District of Columbia Nonstock Corporation Act, as amended from time to time, (c) 'Articles of Incorporation" or "Articles" mean the original articles of incorporation and all amendments thereto, (d) "Bylaws" means the code or codes of rules the Corporation adopted for the regulation or management of the affairs of the Corporation and all amendments thereto, (e) "Member" means one having membership rights with respect to one of the four classes of membership in the Corporation in accordance with the provisions of the Articles of Incorporation or Bylaws, (f) "Membership" means all classes of members, (g) "Board of Directors" means the group of persons vested with the management of the affairs of the Corporation. (h) "Recorder of Deeds" means the Recorder of Deeds, Corporation Division of the District of Columbia.

#### **ARTICLE 11. IDENTIFICATION**

Section 1. <u>Name</u>. The name of the Corporation is Homoeopathic Pharmacopoeia Convention of the United States.

Section 2. <u>Registered Office and Registered Agent.</u> The Corporation shall have and continuously maintain in the District of Columbia a registered office that may be, but need not be, the same as its place of business, and a registered agent, which agent shall be an individual and a resident of the District of Columbia.

The address of the initial registered office of the Corporation is 4974 Quebec Street, NW, Washington. DC 20016.

The name of the initial registered agent of the Corporation, an individual and a resident of the District of Columbia, is Wyrth Post Baker, M.D.

Section 3. Change of Registered Office or Registered Agent. The Corporation may change its registered office or its registered agent, or both, upon filing in the office of the Recorder of Deeds a statement setting forth the facts required by the Act. Any registered agent may resign upon filing the written notice required by the Act, executed in triplicate, with the Recorder of Deeds.

Section 4. <u>Keeping of Books and Records</u>. The Corporation shall keep correct and complete books and records of account and shall keep minutes of the proceedings of its Members and Board of Directors.

#### ARTICLE III. BASIC POLICIES AND PURPOSES

- A. This Corporation is not organized for profit, is nonstock, and is not organized for the private pecuniary gain of any individual. It is organized for exclusively charitable, educational and scientific activities as defined in Section 501(c)(3) of the Internal Revenue Code of 1954 (or the corresponding provision of any future United States Internal Revenue Law).
- B. This Corporation is not organized to engage in any activity ordinarily carried on for profit, and no part of the net earnings of the Corporation shall inure to the benefit of any private member or individual, or any group of private members or individuals.
- C. This Corporation may conduct any or all lawful affairs for which corporations may be incorporated under the District of Columbia Nonstock Corporation Act.
- D. The specific and exclusively charitable, educational and scientific purposes for which this Corporation are formed are:

To accumulate pertinent information and publish and to sell the *Homoeopathic Pharmacopoeia of the United States* and any additions or supplements thereto, to promote the art of healing according to the natural laws of cure from a strictly homoeopathic standpoint; to diffuse knowledge among the laity and professionals in the health care field concerning homoeopathic principles through means of publications; to research and obtain a thorough knowledge of the pathogenicity of each drug offered for inclusion in the *Homoeopathic Pharmacopoeia of the United* States as a homoeopathic drug; to develop criteria for eligibility of drugs for inclusion in the *Homoeopathic Pharmacopoeia of the United States* to serve as a repository for homoeopathic literature and drugs; and generally to do, perform, undertake, direct, encourage and investigate all aspects and functions of any nature directed to the furtherance of homoeopathic healing.

#### ARTICLE IV. MEMBERS

Section 1. <u>Classes of Members</u>. The Corporation shall have four classes of members Which shall be called Active, Associate, Honorary and Life, but that the specific qualifications for becoming a member and maintaining membership in any such class shall be defined by resolution of the Board of Directors or elsewhere in these Bylaws.

Section 2. <u>Election to Membership</u>. Candidates for membership shall apply to the Nominating and Credentials Committee, supplying the documentation for meeting the criteria of member ship. Upon the Committee's report, the Board of Directors shall vote on the candidate. Upon the unanimous approval of the application by the Board, the candidate will become an Associate Member. Associate Members then are eligible to become Active Members, Honorary Members or Life Members according to stipulations in Article IV, Section 3.

Section 3. Qualifications of Members Generally. Members shall generally possess the following qualities: appropriate training and experience in one of the healing arts, biology, botany, chemistry, pharmacy, philosophy, pharmaceutic manufacture and marketing, business management; and In addition knowledge and Interest In the principles of Homeopathy.

With respect to the specific classes of membership:

- (a) Active Members shall meet the general qualifications for membership, and must have participated actively as Associate Members in the functions of the Convention for one year or longer, and must be approved for advancement to active status by two-thirds (2/3) vote of the Active Members in attendance at an annual membership meeting.
- (b) Associate Members shall meet the general qualifications for membership in the Convention, and shall express a desire and willingness to participate in the activities of the Convention.
- (c) Candidates for the title of Honorary Member, having been proposed to the Board of Directors by three or more Directors or by five or more Active Members and approved by a two-thirds (2/3) majority of the Board, may have that honor conferred on them by two-thirds (2/3) vote of the Active Members in attendance at an annual membership meeting.
- (d) Life Members shall meet the general qualifications for membership. and shall have participated consistently in the activities of the Convention and contributed time and energy in support of the Convention to an exceptional degree. Candidates for this honor having been proposed to the Board of Directors by three or more Directors or five or more Active Members, and approved by a two-thirds (2/3) majority of the Board, shall be elected to this honor by two-thirds (2/3) vote of the Active Members in attendance at an annual membership meeting.

Section 4. <u>Rights of Members</u>. Members of the Active class of members may vote on the matter of dissolution, merger or consolidation of the Corporation and on the conferring of Active Member status on the appropriately qualified Associate Member, of Honorary Member status, and of Life Member status. Upon serving one year or longer as an Active Member, an Active Member shall be eligible to be called upon to serve as a Committee Chairman or as a Director. Members of any class of membership shall not be entitled to vote with respect to the election of Directors to the Corporation's Board of Directors, amendment of the Articles or amendment of these Bylaws. Members of all classes are entitled to attend annual and special meetings under Section 5 of these Bylaws.

<u>Section 5. Annual and Special Meetings.</u> The annual meeting of the membership shall be held at a time and place to be determined by the Board of Directors in each year

beginning with the year 1982 for the purpose of considering such business as necessary. Failure to hold the annual meeting at the designated time shall not work a forfeiture or dissolution of the Corporation.

Special meetings of the members may be called by or at the request of any four Directors. The persons authorized to call special meetings of the members may fix the place for holding any special meeting of the members called by them.

Section 6. Notice. Notice of any annual or special meeting shall be given at least thirty (30) days previously thereto by written notice delivered personally or mailed to each member at his business address, or by telegram. If mailed, such notice shall be deemed to be delivered when deposited in the United States mail so addressed, with postage thereon prepaid. If notice be given by telegram, such notice shall be deemed to be delivered when the telegram is delivered to the telegraph company. Any member may waive notice of any meeting. The attendance of a member at a meeting shall constitute a waiver of notice of such meeting, except where a member attends a meeting for the express purpose of objecting to the transaction of any business because the meeting is not lawfully called or convened.

Section 7. Scheduled Agenda Items Any matters or issues requiring a vote of the membership under Section 4 of Article IV of these Bylaws shall be scheduled on the agenda expressly for the purpose of said vote. Any four Directors may schedule any matter or issue by giving written notice, duly executed by four Directors to the Secretary of the Corporation, delivered personally, mailed or by telegram and actually received by the Secretary at least fifteen (15) days prior to the date of the next annual or special meeting of the membership.

Section 8. <u>Attendance</u> No member shall be represented or shall vote by proxy at a meeting of the membership.

Section 9. Quorum of the Members. A quorum at the annual meeting of members is fifty fifty-one percent 5 1%) of the Active class of membership, represented in person. If a quorum is found to exist at a meeting, it shall be deemed to exist until adjournment, notwithstanding the withdrawal of enough members to leave in attendance less than a quorum, provided that, subject to any provision of law, the Articles or these Bylaws requiring a greater number of votes, no action shall be taken by the members except by the affirmative vote of more than twenty percent (20%) of the votes entitled to be cast at the time of such meeting on such matters as may the members of the Active class of members vote.

If less than a quorum is found to exist at a meeting, the individual designated under Section 12 of Article IV of these Bylaws to conduct the meeting may adjourn the meeting from time to time without further notice.

Section 10. <u>Voting</u>. Subject to any provisions of law, or the Articles of Incorporation, or these Bylaws, the affirmative vote of two-thirds (2/3) of the votes actually cast by the members of the Active class of membership present in person at a meeting at which a quorum is present shall be necessary for the adoption of any matter voted upon by the members entitled to vote on such matters under Section 4 of Article IV of these Bylaws.

Section 11. Action by Members' Written Consent. Any action required or permitted to be taken by the membership of the Corporation at a meeting may be taken by mail ballot. To be effective, ballots of seventy percent (70%) of the members of the Active class of the Corporation must be returned within a 21-day period commencing with the date of mailing said ballots, and two-thirds (2/3) of the ballots received within the period shall constitute a decision. A Certificate of the Secretary or other officer of the Corporation with respect to the outcome of such decision shall be filed in the minute book of the proceedings of the membership of the Corporation and a copy of said filing shall be mailed within a reasonable time to each member of record.

Section 12. <u>Conduct of Meeting.</u> The President of the Board of Directors of the Corporation shall preside at meetings of the members. In the absence or the President, the Vice President shall preside. The Secretary of the Corporation or, in his absence, a member designated by the presiding officer of the meeting, shall act as Secretary of the Meeting.

Section 13. <u>Termination of Membership</u>. The right of a member to vote and all right, title or Interest in or to the Corporation shall cease upon the termination of membership. Termination shall be automatic upon submission of a written resignation to the President or Secretary of the Corporation, upon nonpayment of dues as described in Section 6, Article V, or upon cessation or withdrawal for any reason, of such member's designation described in Section I of Article IV.

#### ARTICLE V. DUES

Section 1. <u>Amount of Dues.</u> The amount of annual dues of all classes of membership shall be established from time to time by the Board of Directors. Dues are payable on the first day of January. each year, in advance.

Section 2. <u>Dues - Age Waiver.</u> The annual dues of members who have attained the age of 70 years, and who have paid their dues annually during the preceding ten years, upon application to and approval by the Board of Directors, may be remitted.

Section 3. <u>Dues - Hardship Waiver.</u> The annual dues of members of any age who have paid their dues annually during the preceding ten years, in case of hardship and application to, and approval by the Board of Directors, may be waived without publicity thereof.

Section 4. <u>Life Members An application of a member to become a Life Member shall</u> be accompanied by a payment computed as follows:

- (a) Age 65 69 \$ 100.00
- (b) Age 70 74 \$50.00
- (c) Age 75, or more \$25.00
- (d) Life Members shall NOT be required to pay dues.

Section 5. <u>Rate and Assessments</u>. The rate of the annual dues established by the Board of Directors may be increased or decreased at any regular annual meeting of the Board of Directors or at any special meeting of the Board of Directors called for such purpose, provided notice of the meeting includes notice of proposed change in dues, by a majority vote of the Directors in attendance. The Board of Directors may levy a special assessment against members, in an amount not to exceed the annual dues then in effect, which assessment shall be due and payable within thirty (30) days after billing therefor. This section may be changed only by a majority vote of the Directors In attendance and entitled to vote at a duty convened meeting of the Corporation.

Section 6. Nonpayment If the dues or assessments of any member shall not be paid within thirty (30) days of the due date, above, the privileges of membership shall be suspended, and the member shall be notified in writing. In the event of a failure to pay the delinquent dues or assessments within sixty (60) days of the due date, above, the Executive Committee shall cause the delinquent member to be dropped from membership, with notice thereof in writing to such member.

Section 7. Reinstatement. The suspension, above, shall be lifted upon the payment of delinquent dues or assessments within such sixty (60) day period. A member dropped, as above provided, may be reinstated by the Executive Committee upon application in writing therefor from such member, accompanied by the payment of all delinquent dues and assessments plus one (1) per cent per month or fraction of a month for each month beyond the aforesaid sixty (60) day period.

#### ARTICLE VI. BOARD OF DIRECTORS

Section 1. General Powers. The business and affairs of the Corporation shall be managed by its Board of Directors, The Board or Directors by resolution may establish one or more committees. The Board of Directors shall carry on the business of the Corporation within the provisions of the Act. The initial Bylaws of the Corporation shall be adopted by its Board of Directors. The power to alter, amend, or repeal the Bylaws or adopt new Bylaws shall be vested solely in the Board of Directors.

Section 2. <u>Election and Number of Directors</u> The number of directors of the Corporation shall not be less than five (5) nor more than eleven (11). The Directors shall be elected by the Board of Directors and, to be eligible, must have been an Active

Member in good standing for one year or longer, subject to the limitations otherwise set forth herein. Directors need not be residents of the District of Columbia.

Section 3. <u>Tenure</u> Each Director shall hold office for a term of three (3) years, such term expiring immediately upon the election of a successor Director. A duly elected Director who misses three consecutive Board Meetings may be removed by a majority vote of the total number of Directors.

Section 4. <u>Annual Meetings and Special Meetings of the Board of Directors</u> The Annual Meeting shall be held at a time and place to be determined by the Board of Directors each year beginning in 1982 for the purpose of organization and conduct of essential business affairs as determined by majority vote of the Board.

Special meetings of the Board of Directors may be called by or at the request of any three Directors. The person or persons authorized to call special meetings of the Directors may fix the place for holding any special meeting of the Directors called by them. Meetings of the Board of Directors, annual or special, may be held either within or without the District of Columbia.

Section 5. Notice of any annual meeting shall be given at least thirty (30) days, (fifteen 15) days for special meetings) previous thereto by written notice delivered personally or mailed to each Director at his business address, or by telegram. If mailed, such notice shall be deemed to be delivered when deposited in the United States mail so addressed, with postage thereon prepaid. If notice be given by telegram, such notice shall be deemed to be delivered when the telegram is delivered to the telegraph company. Any Director may waive notice of any meeting. The attendance of a Director at a meeting shall constitute a waiver of notice of such meeting, except where a Director attends a meeting for the express purpose of objecting to the transaction of any business because the meeting is not lawfully called or convened. The fifteen (15) day written notice may be waived by unanimous consent of the Directors in the case of special meetings.

Section 6. Scheduled Agenda Items Any matter or issue requiring a vote of the Board of Directors at any annual or special meeting shall be scheduled on the agenda expressly for the purpose of said vote. A majority of the number of Directors fixed by Section 2 of Article VI shall be required to schedule any such matter or issue on the Agenda by written notice, duty executed by such majority of Directors to the President of the Board or his designee and actually received by the President of the Board or his designee at least fifteen (15) days prior to the annual or special meeting to which such agenda related.

The time period of fifteen (15) days for receipt of said written notice required under this Section as hereinbefore set forth may be waived and a reduced time period of one (1) day may be substituted in its place upon the affirmative and unanimous vote of all the Directors.

The agenda as determined by a majority of the Directors fixed under Section 2 of Article VI shall accompany the notice of any special meeting as prescribed in Section 5 of Article VI and shall accompany any waiver of notice as prescribed in Article XIV.

Section 7. Quorum. A majority of the number of Directors fixed by Section 2 of Article VI shall constitute a quorum for the transaction of business at any meeting of the Board of Directors, but it less than such majority is present at a meeting, a majority of the Directors present may adjourn the meeting from time to time without further notice.

Section 8. <u>Manner of Acting</u> The act of the majority of the Directors present at a meeting at which a quorum is present shall be the act of the Board of Directors. The President of the Board of Directors, or in his absence, the Vice President shall preside ever meetings of the Board of Directors.

Section 9. <u>Action Without a Meeting</u>. Any action that may be taken by the Board of Directors, or any duly appointed committee, may be taken by mail or telephone without a meeting, providing consent in writing, setting forth the action so taken. shall be signed before or after such action by all of the Directors or committee members respectively.

Section 10. <u>Vacancies</u>. A vacancy occurring in the Board of Directors because of death, resignation, disqualification or removal shall be filled by the affirmative vote of a majority of the Board of Directors, and such election shall be for the purpose of filling the unexpired term of the predecessor.

Section 11. <u>Compensation</u> Directors shall not receive any stated salary for their services as such, but may receive reimbursement for ordinary and necessary expenses incurred by a Director incident to the attendance of a property called or convened meeting, or in the execution of the duties of his office.

Section 12. <u>Presumption of Assent</u> A Director of the Corporation who is present at a meeting of the Board of Directors at which action on any corporate matter is taken shall be presumed to have assented to the action taken unless his dissent shall be entered in the minutes of the meeting or unless he shall file his written dissent to such action with the person acting as the Secretary of the meeting before the adjournment thereof or shall forward such dissent by registered mail to the Secretary of the Corporation immediately after the adjournment of the meeting. Such right to dissent shall not apply to a Director who voted in favor of such action.

#### ARTICLE VII. OFFICERS

Section 1. <u>Number</u> The officers of the Corporation, who shall also be members of the Board of Directors, shall be a President, a First Vice President, a Second Vice President, a Secretary and a Treasurer, who shall be elected by the Board and shall serve at the pleasure of the Board. The Second Vice President may act as Secretary in the absence of

a duly elected Secretary. Such non-voting additional officers (e.g., Executive Director, Assistant Secretary, Editor, etc.) may be created by resolution of the Board of Directors from time to time as required.

Section 2. <u>Election and Term of Office</u> Each officer shall hold office for one (1) year or until the successor shall have been duly elected or appointed.

Section 3. <u>Removal</u> The President, First or Second Vice President, Secretary or Treasurer may be removed by a two-thirds (2/3) vote of the Board of Directors with or without cause. Election or appointment of any officer under Section I shall not of itself create contract rights.

Section 4. <u>Vacancies</u> A vacancy in any office, because of death, resignation, removal, disqualification or otherwise may be filled by the Board of Directors for the unexpired portion of the term.

Section 5. <u>President</u> The President shall be the Chief Executive Officer of the Corporation and, subject to the control of the Board of Directors, shall in general supervise and control all of the business and affairs of the Corporation. He may co-sign, with the Secretary or any other proper officer of the Corporation thereunto authorized by the Board of Directors, certificates for membership in the Corporation, any deeds, mortgages, bonds, contracts for services, equipment, furniture, books or supplies, or other instruments which the Board of Directors has authorized to be executed, except In cases where the signing and execution thereof shall be expressly delegated by the Board of Directors or by these Bylaws to some other officer or agent of the Corporation, or shall be required by law to be otherwise signed or executed; and in general shall perform all duties incident to the Office of President and such other duties as may be prescribed by the Board of Directors. The President must be a Director.

Section 6. <u>First Vice President In</u> the absence of the President or in event of his death, inability or refusal to act, the First Vice President shall perform the duties of the President, and when so acting shall have all the powers of and be subject to all the restrictions upon the President.

Second 7. Second Vice President In the absence of the President and First Vice President or in event of the latter's inability or refusal to act, the Second Vice President shall perform the duties of the President, and when so acting, shall have all the powers of and be subject to all the restrictions upon the President. The Second Vice President shall act as Secretary in the absence of a duly elected Secretary.

Section 8. <u>Secretary</u> The Secretary shall: (a) keep the minutes of the proceedings of the Board of Directors in one or more books provided for that purpose; (b) see that all notices are duly given In accordance with the provisions of these Bylaws or as required by law; (c) be custodian of the corporate records and of the seal of the Corporation and

see that the seal of the Corporation is affixed to all documents, the execution of which on behalf of the Corporation under its seal is duly authorized; (d) keep a register of the post office address of each member which shall be furnished to the Secretary by such member; (e) sign, with the President, certificates of membership in the Corporation; and (f) in general perform all duties incident to the office of Secretary and such other duties as may be assigned by the President or by the Board of Directors.

Section 9. Treasurer The Treasurer shall: (a) have charge and custody of and be responsible for all funds and monies due and payable to the Corporation from any source whatsoever, and deposit all such monies in the name of the Corporation in such banks, trust companies or other depositories as shall be selected in accordance with the provisions of these Bylaws, and (b) in general perform all the duties incident to the office of Treasurer and such other duties as may be assigned by the President or by the Board of Directors. If required by the Board of Directors, the Treasurer shall give a bond for the faithful discharge of his duties in such sum and with such surety as the Board of Directors shall determine.

Section 10. <u>Salaries</u> The Corporation, by resolution of its Board of Directors, may make payment for reimbursement of expenses which are reasonable and necessary to carry out the tax-exempt purpose of the Corporation. If the Board determines by resolution to appoint an Executive Director, Assistant Secretary. Editor or other non-voting officer, said resolution may contain a provision for compensation for services rendered.

#### ARTICLE VIII COMMITTEES

Section 1. <u>Executive Committee</u> The Executive Committee shall be composed of the President and such other two officers as the Board may designate, who shall exercise the authority of the Board of Directors in the management of the business of the Corporation between meetings of the Board of Directors.

Section 2. <u>Nominating and Credentials Committee and Other Committees</u> The Executive Committee shall serve as the Nominating and Credentials Committee for the election of Associate Members, Directors and Officers. The President shall appoint such other committees as are necessary to conduct the business of the Corporation.

Section 3. <u>Quorum</u> The majority of the Executive Committee and of all other committees shall be the quorum.

#### ARTICLE IX. CONTRACTS. LOANS, CHECKS AND DEPOSITS

Section 1. <u>Contracts</u> The Board of Directors may authorize any two officers, or agents, to enter into any contract or execute and deliver any instrument in the name of and on behalf of the Corporation. Such authority shall be confined to specific instances.

Section 2. <u>Loans</u> No loans shall be contracted on behalf of the Corporation and no evidence of indebtedness shall be issued in its name unless authorized by a resolution of the Board of Directors. Such authority shall be confined to specific instances.

Section 3. <u>Checks, Drafts, etc.</u> All checks, drafts or other orders for payment of money, notes or other evidence of indebtedness issued in the name of the Corporation, shall be countersigned by two officers of the Corporation in such manner as shall be determined by resolution of the Board of Directors.

Section 4. <u>Deposits</u> All funds of the Corporation shall be deposited promptly to the credit of the Corporation in such banks. trust companies, or other depositories as the Board of Directors may select by resolution.

#### ARTICLE X. CERTIFICATE FOR MEMBERSHIP

Section 1. Certificate for Membership Certificates representing each class of membership (to be so designated) in the Corporation, if the Board of Directors resolves to issue same, shall be in such form as may be determined by the Board of Directors. Such certificates shall be signed by the President and by the Secretary and sealed with the Corporate Seal. All certificates for membership shall be consecutively numbered or otherwise identified and shall state that the Corporation is a nonprofit corporation and that the certificate is nontransferable. The name and address of the person to whom the certificate is issued, with the date of issuance, shall I be entered on the membership books of the Corporation. All certificates surrendered to the Corporation shall be cancelled. In case of a lost, destroyed or mutilated certificate, a new one may be issued by the Board of Directors.

Section 2. <u>Transfer of Membership Certificate</u> Membership certificates of the Corporation shall not be transferable.

#### ARTICLE X1. FISCAL YEAR

The fiscal year of the Corporation shall be determined by the Board of Directors.

#### ARTICLE XII. DIVIDENDS, INCOME, PROFIT

The Corporation shall not pay dividends or distribute any part of its net income or profit to its members, directors, or officer.

#### ARTICLE XIII. CORPORATE SEAL

The Board of Directors shall provide a Corporate Seal which shall be circular in form and shall have inscribed thereon the name of the Corporation and the jurisdiction of incorporation and the word "nonprofit".

#### ARTICLE XIV. WAIVER OF NOTICE

Unless otherwise provided by law, whenever any notice is required to be given to any member or director of the Corporation under the provisions of these Bylaws or under the provisions of the Articles of Incorporation or under the provisions of the Act, a waiver thereof in writing, signed by the person or persons entitled to such notice, whether before or at the time stated therein, shall be deemed equivalent to the giving of such notice.

#### ARTICLE XV. AMENDMENTS

These Bylaws may be altered, amended or repeated and new or revised Bylaws may be adopted by a two-thirds (2/3) vote of the total number of Directors, by mail or at any Annual or Special meeting of the Board of Directors, provided the proposed amendments are placed on the official agenda or submitted in writing to all members of the Board of Directors at least fifteen (15) days in advance of the proposed action in accordance with Article VI. Section 6.

Amended May 2019

## Appendix B Conflict of Interest and handling of Confidential Documents Statement HOMOEOPATHIC PHARMACOPOEIA CONVENTION OF THE UNITED STATES

I,, as a Member of the Homœopathic Pharmacopæia
Convention of the United States (HPCUS), understand the HPCUS requirement that HPCUS
be made aware of potential or actual conflicts of interest of its Members with regard to any
HPCUS matter that will culminate in a Membership or Committee vote or decision. I
understand that a conflict of interest occurs whenever a Member has a direct, indirect, or
financial interest, or the appearance of a conflict of interest, in the outcome of any matter
involving HPCUS. Among other situations, a conflict of interest can arise as a result of
employment relationships, consulting arrangements, the receipt of gifts of material value,
honoraria or any other funding, or the promise of such future gifts, honoraria, or other
funding. A conflict of interest also occurs whenever a Member has a relationship with other
parties to a matter such that the relationship might reasonably be expected to affect the
judgment of the Member in the particular matter, whether in a manner adverse to HPCUS or
favorable to other parties to the transaction.

In addition, I understand that the deliberations of the Convention and of committees are solely for the purposes of making informed recommendations to the Board of the HPCUS and are not to be shared in any manner outside the committee or the Convention. I further understand and agree that members of the Convention and committees each have a responsibility for safeguarding any confidential information with which we have been entrusted in furthering the purposes of the Convention; this includes confidential information submitted by monograph sponsors and documents delivered to various committees by interested parties. Documents and files that outside parties, committees, and Convention members wish the Convention to treat as *Confidential* will be so marked on every page. Likewise, orally conveyed information that outside parties, committees, and Convention members wish the Convention to treat as *Confidential* should be so noted at the time of presentation. I will handle such *Confidential* documents and information with at least as much care as similarly confidential files of my own organization.

- No personal notes, nor any interim documents, calculations, reports or analyses are to be circulated or distributed outside the membership of my respective committee(s).
- Only official committee reports prepared by the chair, or the chair's designee, and approved by the committee members and the HPCUS Board may be shared outside the HPCUS membership.

- I will store all hardcopy Confidential documents and notes about orally presented *Confidential* information stored in a secured area accessible only to me.
- I will maintain all electronic Confidential documents in password protected formats with the password access only to me.
- When committee deliberations concerning any Confidential documents or information are
  complete, I must return any hard copies to the committee chair for destruction (or return to the
  sponsor), and I must permanently delete all electronic copies from all electronic data storage
  systems, including all data backup copies.

In keeping with this understanding, I acknowledge that I understand the above points regarding communication outside the committee membership, the handling of *Confidential* documents, and I will abide by requirements for the handling, storage and return/deletion of all documents marked *Confidential*.

Further, in keeping with this understanding, during any Membership or Committee meeting, I will openly disclose all such potential or actual conflicts of interest in a manner that will allow the conflict to be fully reflected in the meeting minutes, and for the purpose of this meeting I am disclosing the following matters:

Lastly, I will recertify my understanding and agreement with these points annually and will inform my committee chair(s) if the circumstances of any potential or actual conflicts of interest change prior to the next meeting of my committee(s).				
Signed:	-			
Print Name:	Date:			