



REPORT OF THE CONSTITUTION AND BYLAWS COMMITTEE

February 22, 2010

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ADVANCING HEALTH THROUGH PUBLIC STANDARDS

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References

- **Draft Rules of the Council of the Convention**
- **Draft Rules of the Council of Experts**





PART I
MEMORANDUM FROM THE
CONSTITUTION & BYLAWS COMMITTEE

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

PART I. MEMORANDUM FROM THE USP CONSTITUTION AND BYLAWS COMMITTEE

The USP Constitution and Bylaws (C&B) are considered USP's primary governing documents, second only to the organization's Articles of Incorporation, which incorporated USP in 1900. The C&B essentially provide the framework within which USP governs itself and conducts its standards setting activities. It is critical, therefore, that the C&B contain sufficient safeguards for USP's structure and processes as a means of preserving the credibility of USP's standards setting authority. At the same time, the documents must be flexible enough to allow the organization to evolve and grow over time. Like any organization, USP periodically assesses the C&B to determine whether the documents continue to meet the organization's needs. This review usually occurs prior to the five-year Convention membership meeting, so that any needed changes can be discussed by the membership and voted upon in person in accordance with existing C&B provisions. Although not required by the C&B, the President typically forms a committee composed of members to perform this review and propose C&B amendments to the entire membership.

Accordingly, on October 14, 2008, USP President, René H. Bravo, M.D., appointed a C&B Committee and charged it to undertake a comprehensive review of the current USP Constitution and Bylaws and, working with USP staff, to propose any amendments or changes to the documents deemed necessary to update and/or improve their usefulness to the organization. Dr. Bravo chose the C&B Committee from among the members of the Council of the Convention (CoC) noting their deep understanding of USP's strategic direction, priorities and membership history and structure as requisite knowledge for the task.

At its first meeting on October 24, 2008, the C&B Committee received an initial assessment and proposal from USP staff to amend and restate the current C&B. During the October meeting and through two subsequent meetings in November and December 2008, the Committee conducted a thorough review of the C&B, including staff's recommendations, and in January 2009, sent its initial proposal to President Bravo and the CoC for discussion and feedback. The C&B Committee also sent the proposed changes to the Membership Committee (MC), as changes to the composition of the Convention membership were part of the proposal. The MC endorsed the changes made by the C&B Committee and recommended that a joint resolution sponsored by the MC and C&B Committee accompany the new Bylaws. The resolution grandfathers in all organizations currently named in the Constitution as a means of maintaining continuity with the membership, because the new Bylaws do not specifically name any organizations as permanent members of USP.

The C&B Committee also reached out directly to all member organizations and delegates to inform them of the substantive changes that were being proposed and actively sought their feedback. This early dissemination and request for input was a new approach from previous cycles. The C&B Committee posted the draft Amended and Restated Bylaws on the USP website and provided an email portal to collect comments. Three webinar briefings (January-March, 2009) were conducted in which C&B Committee members discussed the important changes and addressed member/delegate concerns and questions in real time.

All written comments, feedback from the CoC, and issues raised during the webinar discussions were considered by the C&B Committee and further modifications were made to their proposal.

The initial draft of the C&B Committee's proposed amendments was submitted to the Board of Trustees in March 2009 and the Board of Trustees provided feedback and endorsed the C&B Committee's approach. In September 2009, the Board of Trustees reviewed final amendments and voted to recommend their adoption.



The section following this memorandum, entitled Summary of Changes, highlights the major changes that are being proposed by the C&B Committee. In this section, the C&B Committee provides background information on the issues that were identified, describes how the issues were addressed in the amendments, and discusses the rationale for the approach chosen by the Committee. Because the C&B are being consolidated and streamlined, the C&B Committee is not providing a “redlined” version; rather, the proposed Amended and Restated Bylaws contain cross references to the existing C&B. Once the vote on the Bylaws is concluded, the cross references will be removed. The Summary of Changes addresses:

- Format and Structure
- Membership Classes and Categories
- Convention Committees
- Officers and Trustees
- Council of Experts
- Process for Amending the Bylaws

The remaining sections in this report include the Proposed Amended and Restated Bylaws, Frequently Asked Questions, a Glossary of Terms, the Proposed Joint Resolution from the C&B Committee and Membership Committee, and the existing C&B. In addition, draft versions of Rules and Procedures of the Council of the Convention and the Council of Experts are being made available separately.

We encourage you to review the C&B Committee’s report and proposal carefully. The decision whether to modify the C&B is a serious one and an important responsibility that rests with the membership.

Respectfully submitted,

Lowell J. Anderson, R.Ph., D.Sc.
Chairman, Constitution and Bylaws Committee



MEMBERS OF THE USP CONSTITUTION AND BYLAWS COMMITTEE

CHAIR

Lowell J. Anderson, R.Ph., D.Sc., *Member-at-Large*

MEMBERS

Thomas R. Clark, R.Ph., M.H.S., *American Society of Consultant Pharmacists*

Joseph W. Cranston, Ph.D., *Honorary Member*
(*At the time of appointment to the C&B Committee, Dr. Cranston represented the American Medical Association*)

Rita Munley Gallagher, Ph.D., R.N., *American Nurses Association*

Paul M. Schyve, M.D., *Member-at-Large, Former USP Trustee*

Rebecca P. Snead, R.Ph., *National Alliance of State Pharmacy Associations*





PART II

SUMMARY OF CHANGES

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

PART II. SUMMARY OF CHANGES

1. FORMAT AND STRUCTURE

a. *Background and Issues*

Because the C&B have been amended multiple times over decades, with new sections and language added as USP has grown and evolved, the documents have become highly detailed, complex, and difficult to understand. While the Constitution and Bylaws are separate documents, their provisions often overlap, increasing the difficulty of navigation and compliance. In addition, the level of operational detail contained in the documents has become constraining, in a time when organizations like USP must evolve and adapt quickly to maintain relevance. This problem is exacerbated by the fact that the C&B generally can only be amended every five years, at the membership meeting. Today, the C&B no longer represent best non-profit governance practices, which favor a simpler, higher level approach to these documents.

b. *Proposed Changes*

To address these issues, the Committee modernized the format of the C&B into a single, simple Bylaws document. The provisions formerly in the Constitution have been subsumed into the new Bylaws, obviating the need for a separate Constitution. The proposed new Bylaws transfer operational details and descriptions out of the C&B and into separate “Rules” documents, which are referenced in the Bylaws. These Rules documents, which are similar to the Rules and Procedures of the Council of Experts and the Rules of Business Practice of the Board of Trustees already in place today, remain subject to review by the Board of Trustees and a new membership Governance Committee (described further below) but can be more easily updated to reflect evolutions in governance and standards-setting practices.

c. *Rationale*

Through consolidation of the C&B and elimination of their complex, overlapping provisions, the Committee has created a more straightforward, readable Bylaws document that provides a stable framework and structure for the governance of the organization and facilitates compliance. The Committee’s objective in simplifying the Bylaws and moving more detailed provisions to the Rules documents was to introduce greater flexibility for organizational growth while maintaining sound governance practices, including appropriate oversight by the Board and membership. The result is a streamlined Bylaws document that is organized in a clear, logical sequence and positions USP for the future while preserving its heritage as a practitioner-based, volunteer-driven standards setting organization.

2. MEMBERSHIP CLASSES AND CATEGORIES

a. *Background and Issues*

Prior to 1995, all of USP’s members were specifically named in the Constitution. If a new member was added, the Constitution had to be amended to reflect this. To provide greater flexibility to include a broader range of stakeholders in USP’s membership, in 1995, the C&B membership provisions were significantly amended to: define categories within the membership, limit the size of each category, and allow the Board to “invite” organizations to membership in addition to those named in the Constitution. Since these amendments were adopted, USP has not added any new Constitutionally-named members but instead has relied exclusively on the “invited” component to evolve its membership. As USP

continues to expand in scope (e.g. to food ingredients) and becomes an increasingly global organization, the existing membership provisions create a number of issues and challenges for USP, as follows:

- Having two types of members – those that are Constitutionally-named and those that are invited – creates the perception that Constitutionally-named members hold greater status or privilege than invited members.
- Reinviting organizations each cycle is administratively cumbersome and jeopardizes continuity in USP membership.
- Mandating specific limits on the number of organizations in each category; e.g., international, trade, etc., limits USP’s ability to engage organizations that are desirable and that wish to participate.
- Relegating “international” organizations to a separate, limited category rather than allowing organizations in each category to come from the United States or abroad is inconsistent with USP’s increasingly global nature and the Board’s Strategic Plan, which directs USP to work both nationally and internationally in furtherance of its mission.
- The Constitution makes the individual “delegate” appointed by the organization, rather than the organization itself, the “member.” This creates additional problems for continuity and limits USP’s ability to form strong, ongoing relationships with its member organizations by discouraging the engagement of multiple representatives from an organization in various capacities.

b. Proposed Changes

To address the areas identified above, the Committee has proposed the following changes:

- The concept of Constitutionally-named members has been eliminated; the new Bylaws do not specifically name any organizations as permanent members of USP. However, the Committee proposes that all existing Constitutionally-named organizations be automatically invited to USP membership, which will allow these organizations to continue to remain members of USP. Members should note the accompanying resolution, which has been proposed jointly by the C&B Committee and the Membership Committee, that grandfathers currently named organizations.
- Once an organization is invited to membership, that membership continues unless and until an organization resigns or is removed for cause. The new Bylaws vest the ultimate authority for rescinding the membership of an organization in the Board of Trustees upon recommendation by the Council of the Convention. However, the C&B Committee felt it was important to articulate the criteria for such removal; thus, what constitutes “cause” is clearly defined in the Bylaws. Also, the procedures for removal will include prior notification to the delegate, as well as the executive officer, of the intent to remove and grounds for removal.
- The new Bylaws create more *general* categories within the membership (e.g., academic institutions rather than individual schools) to allow for member engagement that matches USP’s evolution both domestically and internationally.
- The existing caps of the number of members in each membership category have been eliminated and replaced with an overall cap on the total number of USP members and a requirement that 60% of the members remain practitioner-based organizations.
- The organization rather than the named delegate is recognized as the member. The new provisions differentiate between a delegate authorized to vote for the member organization and other representatives from the member organization that might work with USP in other ways. In this way, the “one organization, one vote” concept is retained, but USP has the ability to work with other representatives from the organization in other capacities such as service on a Convention committees.

- The official observer status that was implemented in this cycle is codified in the new Bylaws as another way of engaging a broad range of organizations while retaining USP's historical balance of membership.

c. *Rationale*

The proposed changes would resolve the membership issues and challenges that exist today by providing for a single class of invited organizational members and allowing those organizations to remain members in perpetuity as long as they fulfill their membership responsibilities. The accompanying resolution will ensure that existing Constitutionally-named members are not disenfranchised by these changes and will automatically have the opportunity to continue their membership. By allowing representatives other than the named delegate to engage with USP, they increase the volunteer base available to USP and allow USP to strengthen and deepen its relationships with its organizational members by establishing multiple avenues of interaction. In relaxing the specific constraints on each category of membership, the new provisions provide greater flexibility for USP to grow its membership in light of new activities (such as food ingredient standards) and USP's increasingly global orientation. The overall goal is to ensure that USP will remain predominantly a practitioner-based pharmacopeia with broad-based representation from practitioner societies and academic institutions, while allowing USP to develop and maintain a more highly committed and engaged membership body that is reflective of its evolving scope and mission.

3. CONVENTION COMMITTEES

a. *Background and Issues*

The existing C&B calls for seven Convention committees: Council of the Convention, Membership Committee, Resolutions Committee, Committee of Tellers, Nominating Committee for Officers and Trustees, and Nominating Committee for the Council of Experts. As mentioned above, the C&B Committee actually is not provided for in the C&B, but traditionally is appointed by the President to fulfill the requirement that amendments must be proposed by at least five members of the Convention. The Council of the Convention, which was created via a Constitutional amendment in 2005, is an important group that reflects and represents the membership as a whole, yet it has no C&B-defined responsibilities. This situation presents the following issues:

- The current roles and responsibilities of the committees in some cases overlap (e.g. Membership Committee and Council of the Convention, which both focus on composition of membership) and in other cases are extremely narrow (e.g. Committee of Tellers). In addition, as noted above, the roles of the C&B Committee and Council of the Convention are defined only by custom or resolution, rather than being specified under the C&B.
- The management and support of so many committees is very time-consuming and resource-intensive for staff; at the same time, volunteers may not always feel fully engaged or that their time and expertise are being well-utilized.
- Most importantly, because of the limited role and duration of many of these committees, the members who serve on them do not always have the opportunity to learn about and be involved with USP in a substantive way, and USP is hindered in its efforts to grow and develop a knowledgeable and committed volunteer leadership base.

b. *Proposed Changes*

The new Bylaws simplify the Convention committee structure by providing for only four committees of the Convention, each with important and clearly-defined roles.

- The Council of the Convention. This committee will take on the current responsibilities of the Membership Committee and the Resolutions Committee. As a committee that is representative



of USP's various member constituencies and includes individuals with long-standing experience and engagement with USP, the Council of the Convention is well-situated to assume and execute these responsibilities. Rules and Procedures of the Council of the Convention will be created to specify in greater detail how the Council will carry out these functions.

- A new Governance Committee. This committee will assume the duties of the C&B Committee and the Committee of Tellers, and will be responsible for reviewing, on behalf of the Convention membership at large, the Rules and Procedures of the Council of Experts and Council of the Convention. While today, the Rules and Procedures of the Council of Experts are provided to the entire membership for comment, comments are very rarely if ever received. Under the new structure, the Governance Committee will be entrusted with and be responsible for actively performing this function on behalf of the Convention.
- Nominating Committee for Officers and Trustees. The responsibilities of this committee are unchanged with an increase in the size of the committee. The increase in the number of members is intended to broaden USP's ability to identify and recruit potential Board candidates.
- Nominating Committee for Council of Experts. The responsibilities of this committee are unchanged with a decrease in the size of the committee and a greater balance among Council of Experts, Convention, and at-large members on the committee.

c. *Rationale*

The objective of the Committee's changes in this portion of the C&B was to streamline and consolidate committees, broaden and strengthen their roles, and eliminate overlapping functions. The result is a smaller number of committees that each have a substantive and clearly specified set of responsibilities and, in the case of the Council of the Convention and Governance Committee, function more continuously throughout the five-year cycle. In this way, members will have the opportunity to participate in a more meaningful, ongoing way in USP governance, and USP's ability to cultivate highly knowledgeable and dedicated volunteers will be enhanced.

4. OFFICERS AND TRUSTEES

a. *Background and Issues*

The current C&B sections that cover the President, Executive Vice President-CEO, Secretary, Treasurer, and Board of Trustees contain unnecessarily detailed descriptions of functions and operational activity that, according to contemporary governance practices, are better placed in a "Rules" or other subsidiary document. In addition, some details are repeated in multiple sections and this redundancy contributes to the length of the existing C&B and makes these documents more difficult to comprehend and comply with. In addition, the Committee identified three other issues with the existing C&B provisions concerning officers and trustees. First, the C&B currently requires that nominees for officer and trustee positions be members of USP. This requirement has not been meaningful; rather it has just created an extra step in the nominations process to appoint prospective nominees as Members-At-Large. Second, the existing C&B provisions allow nominations for officers and trustees to come from the floor at the regular membership meeting, which potentially circumvents the careful vetting process provided for through the Nominating Committee for Officers and Trustees. Third, the fixed size and composition of the Board under the existing C&B may make it difficult to bring to the Board specific expertise that is needed as the organization's needs and governance practices evolve.

b. *Proposed Changes*

To address these issues, the C&B Committee has consolidated and streamlined the relevant and required provisions about the role of officers and trustees and proposes that ancillary provisions, to the extent they need to be retained, be moved to the Rules of Business Practice of the Board of Trustees. These Rules of Business Practice, which exist today and govern Board committees and other Board

operations, can be expanded if necessary to accommodate these provisions. The Committee also removed the requirement that the nominees for officer or trustee positions must be USP members at the time of their nomination and eliminated the provision allowing nominations for elected officer and trustees positions to come from the floor at the membership meeting. Finally, the new Bylaws create some flexibility in the size of the Board, allowing the number of trustees to range between twelve and fifteen each cycle. The Convention membership will continue to elect two trustees representing the medical sciences, two trustees representing the pharmaceutical sciences, one public member, and three at-large members, who will serve on the Board along with the elected President and Treasurer, the Past President, and the EVP-CEO. Up to three additional at-large members may be appointed by the Board at any time during the cycle to provide expertise that the Board believes is needed or desirable to meet evolving Convention needs.

c. Rationale

The more general provisions regarding officers and the Board of Trustees in the new Bylaws eliminate unnecessary and burdensome operational detail while retaining fundamental roles and responsibilities for officers and trustees in accordance with recognized non-profit law and practice. The nominations process has been made more rational, and the provision for expanding the size of the Board will allow the organization to expand expertise in the Board based on new areas in which USP may become involved and consistent with evolving governance practices, including those which may increase the need for trustees with financial and other expertise. At the same time, traditional representation from the medical and pharmaceutical sciences and the public will be maintained.

5. COUNCIL OF EXPERTS

a. Background and Issues

The Council of Experts (CoE) section in the existing C&B includes detailed provisions for the structure and operation of the CoE, including its Executive Committee. In addition, many of the other sections of the C&B also contain references to the operation and activities of the CoE. Again, these provisions have become extremely complex and difficult to follow, and limit USP's ability to evolve the CoE to most effectively and efficiently carry out its standards-setting activities. Another issue that has arisen repeatedly under the existing C&B is the lengthy and cumbersome election process required to add new CoE members or fill vacancies when they occur. This election process can take from four to six months, which can delay the important work of Expert Committees, and participation by Convention members in these elections is generally low.

b. Proposed Changes

The C&B Committee has taken the same approach here as in other areas of the Bylaws; i.e., consolidating relevant and needed provisions in clear, concise language and moving operational details to the Rules and Procedures of the CoE. Also of note in the proposed revisions is that between regular, five-year meetings of the membership, vacancies and additional positions in the CoE will be filled by the CoE itself rather than requiring a new election by the membership. A change has also been made with respect to the position of Chair of the CoE. Currently, the EVP-CEO serves as Chair of the CoE. In the proposed revisions, the EVP-CEO may delegate these responsibilities to another staff member.

c. Rationale

The shift of detailed provisions regarding the CoE from the C&B to the Rules and Procedures of the Council of Experts is consistent with the C&B Committee's overall goals of creating more flexibility for the organization while preserving USP's fundamental policies and principles such as strict conflict of interest provisions. The Rules and Procedures of the Council of Experts is already the primary day-to-day governing document for USP's standards-setting activity, so this change simply expands the use of

that document as the vehicle for establishing objective, credible, and transparent standards-setting processes. As noted above, the CoE Rules will be reviewed by the Governance Committee to assure appropriate membership oversight.

The change allowing vacancies and additional positions to be filled by the CoE itself alleviates the need for a time-consuming, burdensome election process mid-cycle. It also aligns the process for filling vacancies in the CoE with that used for officers and trustees, which under both the existing C&B and new Bylaws is an appointment process.

The change allowing the EVP-CEO to delegate the Chair duties reflects the fact that as USP has grown in scope and complexity, so have the responsibilities of the EVP-CEO. The Chair of the CoE is a critical position that requires a significant amount of time and attention. Allowing delegation of these responsibilities will provide flexibility to the EVP-CEO if he/she believes that given other commitments to the organization, USP would be best served by having another senior manager at USP assume these duties.

6. PROCESS FOR AMENDING THE BYLAWS

a. Background and Issues

Under the existing C&B, proposed amendments to the C&B presented to the membership at the regular five-year meeting must be approved by a three-quarters vote. For amendments proposed mid-cycle for approval by written ballot, the threshold is even higher; these must be approved by a seven-eighths vote. These provisions make it extremely difficult to amend the C&B between regular meetings. At the same time, existing provisions contain a very low threshold for the number of members required to propose an amendment (five or ten, depending on whether the proposal is made prior to or at the Convention meeting).

b. Proposed Changes

Under the new Bylaws, a three-quarters vote of the membership is required to approve amendments either at a meeting or by written ballot. In addition, the new Bylaws allow the Board to amend the Bylaws to correct errors or comply with changes in law without the need for membership approval. However, the membership must be given notice of any amendments adopted by the Board under this provision. The new Bylaws also require that ten percent of the membership petition for any amendment, ensuring that some reasonable proportion of the membership support any proposed amendment.

c. Rationale

The new provisions make it less onerous to amend the Bylaws between meetings and provide greater flexibility for the organization in this regard. At the same time, they retain a super-majority voting requirement for amendments, recognizing the importance of these actions. They also allow the Bylaws to be easily changed in the event of error or changes in legal requirements, while making sure that the membership is informed of such changes. By requiring that a larger number of members support a proposed amendment, they avoid the possibility of “special interest” amendments that do not serve the Convention as a whole.



PART III

PROPOSED AMENDED AND RESTATED BYLAWS

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

PART III. PROPOSED AMENDED AND RESTATED BYLAWS

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1 **BYLAWS**

2
3 **ARTICLE I. NAME AND PRINCIPAL OFFICE**

4
5 ***Section 1. Name.***

6 The name of the corporation is The United State Pharmacopoeial Convention (hereinafter the "Convention").
7 The alternative spelling, "Pharmacopoeial," also may be used.

8

Constitution Article I

9
10
11 ***Section 2. Principal Office.***

12 The principal office of the Convention shall be in such suitable place as the Board of Trustees may from time
13 to time determine as necessary or desirable for the conduct of the affairs of the Convention.

14

Constitution Article I; Bylaws Chapter VI, Section 15

15
16
17
18 **ARTICLE II. PURPOSES**

19 The purposes for which the Convention is formed are as set forth in the Articles of Incorporation and
20 include developing and disseminating public standards for medicines and other articles, and engaging in
21 related public health programs. The Convention may also set forth by resolution or in separate documents a
22 more detailed mission statement.

23
24

Constitution Article I, Section 2

25
26
27
28 **ARTICLE III. MEMBERSHIP**

29
30 ***Section 1. Categories and Qualifications.***

31 The members of the Convention ("Members") shall consist of the following, and shall be hereinafter
32 collectively referred to as the "Membership":

33

Constitution Article II, Sections 1 and 7; Bylaws Chapter XII, Sections 2 and 3

34
35
36 a. ***Voting Members.***

37 The Convention shall have two categories of voting Members ("Voting Members"), as set forth
38 below, which shall have voting rights set forth in Section 3 below.

39
40 (i) ***Voting Organizational Members.*** Voting organizational members ("Voting Organizational
41 Members") shall be organizations or governmental bodies representing the following categories;
42 providing, however, that not less than sixty percent (60%) of the Organizational Voting
43 Members shall fall within subcategories (a) or (b) below, and provided further, that the total
44 number of Voting Organizational Members shall not exceed six hundred (600).

45
46 (a) Academic institutions including accredited colleges and schools of medicine, pharmacy and
47 nursing and other recognized academic institutions in health and science-related fields, and
48 associations thereof;

49
50 (b) Health practitioner professional and scientific associations and organizations including
51 those that represent medicine, pharmacy, and nursing;



- (c) Consumer and other organizations representing the public interest;
- (d) Manufacturer, trade, and affiliated associations;
- (e) Governmental bodies or divisions or associations thereof; and
- (f) Non-governmental standards-setting and conformity assessment bodies.

(ii) Voting At Large Members. In addition to the Voting Organizational Members, there shall be not more than twenty-five individual Members-at-large (“Voting At Large Members”) appointed by the Board of Trustees for a specified term for their special competence in relation to the administrative or scientific needs of the Convention.

b. Honorary Members.

The Board of Trustees may in its discretion select honorary, non-voting members of the Convention (“Honorary Members”) in recognition of their distinguished contributions to the Convention.

Section 2. Selection of Voting Organizational Members.

Voting Organizational Members shall be selected by the Board of Trustees based on recommendations made by the Council of the Convention. The Council of the Convention shall develop internal rules and procedures for considering and inviting organizations to become Voting Organizational Members, and such rules and procedures shall be subject to approval by the Board of Trustees in accordance with Article IX, Section 3. In developing such rules and procedures, the Council of the Convention shall consider any applicable resolutions adopted by the Convention Membership.

Constitution Article II, Sections 2 through 6; Bylaws Chapter VI, Sections 18 and 19, Chapter XII

Section 3. Voting Rights.

Voting Members shall have the right to vote at a meeting of the Membership (“Membership Meeting”) or by written ballot, as specified in Section 6 below. Honorary Members may attend Membership Meetings and, at the discretion of the Chair, participate in the discussion, but may not vote. Upon acceptance of an invitation to become a Voting Organizational Member, the organization shall designate one representative of the organization who is authorized to vote for the Voting Organizational Member at any Membership Meeting or on any written ballot sent to the Voting Members (“Delegate”). Such Delegate may be changed from time to time upon written notice to the Convention.

Section 4. Regular Membership Meetings.

Every five years, there shall be a regular Membership Meeting upon such date, time, and place as the Board shall determine (“Regular Membership Meeting”). At the Regular Membership Meeting, those Voting Members present in person shall vote on the following matters to advance the purposes of the Convention as set forth in Article II: election of Officers and Trustees; election of the Council of Experts; adoption of resolutions that shall guide the Convention until the next Regular Membership Meeting; and approval of amendments to the Bylaws in accordance with Article XV, Section 3.

Not later than thirty (30) days prior to the Regular Membership Meeting, the following shall be made available to the Membership by electronic mail or by a link to the USP website: report of the Nominating Committee for Officers and Trustees; report of the Nominating Committee for the Council of Experts; report of the Council of the Convention on proposed resolutions; and report of the Governance Committee on proposed amendments to the Bylaws.

Constitution Article VII; Bylaws Chapter XIV



1 ***Section 5. Special Membership Meetings.***

2 Special Membership Meetings (“Special Membership Meetings”) may be called by the President, the Board of
3 Trustees, or upon the request of twenty-five percent (25%) of the Voting Members. Notice shall be given to
4 the Membership not less than ten (10) nor more than ninety (90) days prior to the Special Membership
5 Meeting in the manner specified in Section 2 of Article XIII of these Bylaws, and the notice shall state the
6 purposes of the Special Membership Meeting. No business other than that stated in the notice may be
7 considered at a Special Membership Meeting. Any Member may participate in a Special Membership Meeting
8 by means of a conference telephone or similar telecommunications device that allows all persons participating
9 in the Special Membership Meeting to hear each other, and for purposes of the quorum requirement
10 described in Section 6a below such participation shall be deemed presence in person at such Special
11 Membership Meeting.

12

Constitution Article VII; Bylaws, Chapter XIV

13
14
15 ***Section 6. Quorum and Voting.***

16
17 a. Voting at a Membership Meeting.

18 Each Voting Member in good standing shall have one vote at any Membership Meeting where votes
19 are cast. Each Voting Organizational Member shall cast its vote through its Delegate. A quorum
20 shall consist of Delegates present in person representing twenty-five percent (25%) of the total
21 Voting Members. Proxy voting shall not be allowed. Unless otherwise required by these Bylaws, a
22 majority of the votes cast at a meeting at which a quorum is present shall constitute the action of the
23 Membership.

24
25 b. Voting by Written Ballot.

26 Any action that may be taken at a Special Membership Meeting may be taken without a Special
27 Membership Meeting if the Convention delivers by electronic mail or otherwise makes available on
28 the Internet to all Voting Members a written ballot. Voting by written ballot shall be conducted as
29 follows:

- 30
31 (i) The ballot shall set forth each proposed action and shall provide an opportunity to vote either
32 for or against each proposed action.
33
34 (ii) The number of ballots received by the Convention must equal or exceed the quorum that would
35 have been required had there been a Membership Meeting (i.e., ballots must be received from
36 twenty-five percent (25%) or more of the Voting Members).
37
38 (iii) Unless otherwise indicated in these Bylaws, a majority of the affirmative votes cast by ballot shall
39 constitute the action of the Membership with respect to each matter on the ballot.
40
41 (iv) All solicitations for votes by written ballot shall indicate the number of responses needed to meet
42 the quorum requirement, state the percentage of approvals necessary to approve each matter,
43 and specify the time by which a ballot must be received by the Convention in order to be
44 counted, which shall not be less than thirty (30) days after the ballot is made available.

45

Constitution Article VIII

46
47
48 ***Section 7. Removal.***

49 Any Voting Organizational Member may be removed for cause from Membership by a two-thirds vote of the
50 Board of Trustees upon the recommendation of the Council of the Convention, pursuant to rules and
51 procedures developed by the Council of the Convention and approved by the Board of Trustees in



1 accordance with Article IX, Section 3. Such procedures shall include prior notification to the Voting
2 Organizational Member of the grounds for removal and intent to remove. As used herein, “cause” shall
3 mean (i) failure by a Voting Organizational Member to name a Delegate within twelve (12) months after
4 issuance of an invitation to become a Voting Organizational Member, or (ii) failure of a named Delegate to
5 attend two (2) consecutive Regular Membership Meetings.

6 Bylaws Chapter XII, Section 6
7
8

9 ***Section 8. Observers.***

10 Based on criteria established under Article IX, Section 1c below, the Council of the Convention may invite an
11 organization to become an observer (“Observer”) to the Convention. Observers may send a representative
12 to attend Regular Membership Meetings, but Observers are not Members, shall not have voting rights, and
13 shall comply with all rules and procedures for their participation established by the Council of the
14 Convention pursuant to Article IX, Section 1c.

15 Bylaws Chapter VI, Section 20
16
17

18
19 **ARTICLE IV. OFFICERS**
20

21 ***Section 1. Officers.***

22 The officers of the Convention (“Officers”) shall consist of a President, a Past President, a Secretary, a
23 Treasurer, and an Executive Vice President–Chief Executive Officer (“EVP–CEO”).

24 Constitution Article III, Section 1
25
26

27 ***Section 2. Election of Officers.***

28 The President and Treasurer of the Convention shall be elected by the Voting Members of the Convention at
29 the Regular Membership Meeting. The EVP–CEO shall be an employee hired by the Board, and may serve
30 in such capacity for as long as the Board deems appropriate. The Secretary of the Convention shall be an
31 employee of the Convention appointed by the EVP–CEO.

32 Constitution Article III, Sections 2 and 3
33
34

35 ***Section 3. Term of Office.***

36 Except for the EVP–CEO and Secretary (who shall be employees of the Convention), the Officers of the
37 Convention shall be installed on the July 1st following the Regular Membership Meeting at which they are
38 elected and shall hold office for five years, or until their respective successors shall have been duly elected and
39 installed. Officers shall be subject to the term limitations set forth in Article V, Section 3.

40 Bylaws Chapter I, Section 9 and Chapter V, Section 6
41
42

43 ***Section 4. Resignation.***

44 Any Officer may resign at any time by giving written notice to the President or the Secretary of the
45 Convention. Such resignation shall take effect at the time specified therein, or, if no time is specified, at the
46 time of acceptance thereof as determined by the President.

47 Bylaws Chapter VI, Section 33
48



1 ***Section 5. Removal.***

2 Any Officer may be removed by a two-thirds vote of the Board of Trustees at any regular or special meeting
3 of the Board at which a quorum is present, whenever in its judgment the best interests of the Convention
4 would be served thereby, but such removal will be without prejudice to the contract rights, if any, of the
5 Officer so removed.

6

Bylaws Chapter VI, Section 25

7
8
9 ***Section 6. Vacancies.***

10 A vacancy in any office because of death, resignation, removal, disqualification, or otherwise, shall be filled
11 for the unexpired term as follows: a vacancy in the position of Past President shall be left vacant; a vacancy
12 in the position of President, Treasurer or EVP-CEO shall be filled by the Board of Trustees; and a vacancy
13 in the position of Secretary shall be filled by appointment by the EVP-CEO.

14

Constitution Article III, Section 4; Bylaws Chapter I, Section 10; Chapter V, Section 7; and Chapter VI, Section 24

15
16
17 ***Section 7. President.***

18 The President shall chair Membership Meetings and meetings of the Council of the Convention and make
19 appointments to the Council of the Convention, the Governance Committee, the Nominating Committee for
20 Officers and Trustees, and the Nominating Committee for the Council of Experts as set forth in Articles IX,
21 X, XI and XII. In addition, the President may call Special Membership Meetings as provided in Article III,
22 Section 5 of these Bylaws.

23

Bylaws Chapter I

24
25
26 ***Section 8. Past President.***

27 The position of Past President shall be held by the immediate Past President of the Convention.

28

Bylaws Chapter II

29
30
31 ***Section 9. Secretary.***

32 The Secretary shall keep the minutes of the meetings of the Board and Membership Meetings; serve as
33 Secretary of the Council of the Convention, the Nominating Committee for Officers and Trustees, the
34 Nominating Committee for the Council of Experts, and the Governance Committee; see that all notices are
35 duly given in accordance with the provisions of these Bylaws or as required by law; and in general perform all
36 duties incident to the office of Secretary and such other duties as may be assigned by the President or by the
37 Board of Trustees.

38

Bylaws Chapter IV

39
40
41 ***Section 10. Treasurer.***

42 The Treasurer reviews the work of the Convention's auditors and, along with the auditors, as appropriate,
43 shall present the audited financial statement to the Board of Trustees. In addition, the Treasurer shall
44 perform all the duties incident to the office of Treasurer and such other duties as from time to time may be
45 assigned by the President or by the Board of Trustees.

46

Bylaws Chapter V



1 ***Section 11. Executive Vice President–Chief Executive Officer.***

2 The Executive Vice President–Chief Executive Officer (“EVP–CEO”) shall be a member of the Board of
3 Trustees, *ex officio*, without vote. The EVP–CEO, or the EVP–CEO’s designee, shall serve as Chair of the
4 Council of Experts and of the Executive Committee of the Council of Experts, and in such capacity shall
5 have charge of the work of the Council of Experts, organize the Council of Experts in accordance with these
6 Bylaws, and have such other duties and authority as set forth in the rules and procedures for the Council of
7 Experts. The EVP–CEO may appoint advisory bodies to advance the work of Council of Experts and the
8 Convention and provide advice to staff on policy matters. The EVP–CEO shall appoint the Secretary and
9 other staff officers as deemed appropriate.

10
11 Constitution Article III, Section 3; Chapter IV, Section 16; and Chapter VII, Sections 1, 2, 8, 9, and 12 through 15
12 Bylaws Chapter III and Chapter VI, Section 16
13

14
15 **ARTICLE V. BOARD OF TRUSTEES**

16
17 ***Section 1. Duties.***

18 There shall be a Board of Trustees of the Convention (hereinafter the “Board” or “Board of Trustees”),
19 which shall oversee the management, property, and affairs of the Convention, except as otherwise expressly
20 provided by law, the Articles of Incorporation of the Convention, or these Bylaws.

21
22 Bylaws Chapter VI, Sections 7 through 24 and 26 through 32
23

- 24 a. The specific duties of the Board of Trustees include, but are not limited to: hiring and supervising the
25 Executive Vice President–Chief Executive Officer; establishing policy for the Convention, including
26 the development of a strategic plan for the Convention; approving the budget of the Convention;
27 additional duties as set forth in these Bylaws; and performing such other duties as it deems necessary
28 and proper.
- 29
- 30 b. The Board of Trustees shall develop rules and procedures to supplement the provisions of this Article
31 and Article VI below and govern the conduct of its affairs.
32

33 ***Section 2. Number and Qualifications.***

34 The Board of Trustees shall be composed of not less than twelve (12) or more than fifteen (15) individuals.
35 The Board of Trustees shall include the following officers as *ex officio* members: President (with vote); Past
36 President (with vote); Treasurer (with vote) and Executive Vice President–Chief Executive Officer (without
37 vote). The Board of Trustees shall also include eight (8) Trustees elected by the Convention at its Regular
38 Membership Meeting as follows: two shall be representative of the pharmaceutical sciences, two shall be
39 representative of the medical sciences, one shall be a public member, and three shall serve without restriction
40 concerning their affiliation. The Board of Trustees by majority vote may appoint at any time up to three (3)
41 additional Trustees to provide expertise that the Board determines is necessary or desirable to meet the needs
42 of the Convention. Such appointed Trustees shall serve until the next Regular Membership Meeting of the
43 Convention.

44
45 Bylaws Chapter VI, Section 1
46
47

1 ***Section 3. Election and Term of Office.***

2 Except as otherwise provided in the Officers section of these Bylaws (Article IV) and Section 2 above, the
3 members of the Board of Trustees shall be elected by a majority vote of a quorum of the Voting Members of
4 the Convention at the Regular Membership Meeting. Elected Trustees shall serve for a term of five years.
5 Other than the EVP–CEO, no person may serve on the Board of Trustees more than two consecutive terms,
6 including any partial term resulting from appointment.

7

Constitution Article IV

8
9
10 ***Section 4. Chair.***

11 Each year, the Board of Trustees shall elect from among the Trustees a Chair, who shall chair each meeting
12 of the Board that year and shall perform such other duties as the Board may assign. In the absence of the
13 Chair, a member of the Executive Committee of the Board selected by the Chair shall chair meetings of the
14 Board.

15

Bylaws Chapter VI, Section 2

16
17
18 ***Section 5. Resignation.***

19 Any Trustee may resign at any time by giving written notice to the President of the Convention. Such
20 resignation shall take effect at the time specified therein, or, if no time is specified, at the time of acceptance
21 thereof as determined by the President of the Convention.

22

Bylaws Chapter VI, Section 33

23
24
25 ***Section 6. Removal.***

26 Any Trustee may be removed from such office, with or without cause, by a two-thirds vote of the Trustees at
27 any regular, or special meeting of the Board of Trustees called expressly for that purpose.

28

Bylaws Chapter VI, Section 25

29
30
31 ***Section 7. Vacancies.***

32 Vacancies shall be filled by appointment by majority vote of the remaining members of the Board of Trustees
33 for the unexpired term of the vacant position.

34

Bylaws Chapter VI, Section 24

35
36
37 ***Section 8. Regular Meetings.***

38 Regular meetings of the Board of Trustees shall be held not less than annually at such time, day, and place as
39 shall be designated by the Chair or a majority of the voting Trustees then in office, for the purpose of
40 transacting such business as may come before the meeting.

41

Bylaws Chapter VI, Section 4

42
43
44 ***Section 9. Special Meetings.***

45 Special meetings of the Board of Trustees may be called at the direction of the Chair or by a majority of the
46 voting trustees then in office, to be held at such time, day, and place as shall be designated in the notice of the
47 meeting.

48

Bylaws Chapter VI, Section 4



1 ***Section 10. Notice.***

2 Notice of the time, day, and place of any meeting of the Board of Trustees shall be given at least ten days
3 previous thereto in the manner set forth in Section 2 of Article XIII hereof. The purpose or purposes for
4 which a special meeting is called shall be stated in the notice thereof. Any Trustee may waive notice of any
5 meeting by a written statement executed either before or after the meeting.
6

7 ***Section 11. Quorum.***

8 A majority of the voting Trustees then in office shall constitute a quorum for the transaction of business at
9 any meeting of the Board of Trustees.

10

Bylaws Chapter VI, Section 4

11
12
13 ***Section 12. Manner of Acting.***

14 Except as otherwise expressly required by law, the Articles of Incorporation of the Convention, or these
15 Bylaws, the affirmative vote of a majority of the Trustees present at any meeting of the Board at which a
16 quorum is present shall be the act of the Board of Trustees. Each Trustee shall have one vote. Voting by
17 proxy shall not be permitted. Any action that may be taken at a meeting of the Trustees may also be taken
18 without a meeting if a written consent setting forth the action is signed by all of the Trustees entitled to vote.
19 Electronic signatures shall be permitted, and an electronic mail response may also be deemed to constitute
20 such signature. Such consent shall have the same force and effect as a unanimous vote.

21

Bylaws Chapter VI, Section 3

22
23
24 ***Section 13. Meeting via Telephone or Other Telecommunications Device.***

25 Any one or more Trustees may participate in a meeting of the Board of Trustees by means of a conference
26 telephone or similar telecommunications device that allows all persons participating in the meeting to hear
27 each other, and such participation in a meeting shall be deemed presence in person at such meeting.

28

Bylaws Chapter VI, Section 5

29
30
31 ***Section 14. Informal Board Action.***

32 The Board may discuss matters informally by an exchange of electronic mail, but electronic mail discussions
33 do not constitute a meeting, and no binding formal vote on an action may be taken without complying with
34 the provisions of Section 12 above. However, any action informally agreed to via electronic mail may be
35 formally ratified by the Board and thereby become effective either at a subsequent meeting of the Board
36 (which can include a meeting via telephone or other telecommunications device) or via unanimous written
37 consent in lieu of a meeting in accordance with Section 12 above.

38

Bylaws Chapter VI, Section 3

39
40
41
42 **ARTICLE VI. COMMITTEES OF THE BOARD**

43
44 ***Section 1. Committees of Trustees.***

45 The Board of Trustees may designate and appoint one or more committees, each consisting of two or more
46 Trustees, which committees shall have and exercise that authority as may be delegated by the Board; provided,
47 however, that no such committee shall have the authority of the Board in reference to amending, altering, or
48 repealing these Bylaws; electing, appointing or removing any Officer or Trustee; amending the Articles of
49 Incorporation; adopting a plan of merger or adopting a plan of consolidation with another corporation;
50 authorizing the sale, lease, exchange, or mortgage of all or substantially all of the property and assets of the



1 Convention; authorizing the voluntary dissolution of the Convention; adopting a plan for the distribution of
2 the assets of the Convention; or amending, altering, or repealing any resolution of the Board of Trustees.
3

4 **Section 2. Standing Committees.**
5

- 6 a. Executive Committee. Between meetings of the Board of Trustees, the day-to-day affairs of the
7 Convention shall be conducted by an Executive Committee, the membership of which shall be as
8 follows: the Chair, the President, the Treasurer, and the public member Trustee. The EVP–CEO also
9 shall serve as an *ex officio* nonvoting member. The Executive Committee shall have and exercise all
10 the powers and perform all of the duties commonly incident to and vested in the Board of Trustees,
11 subject to the limitations set forth in Section 1 above. All actions taken by the Executive Committee
12 shall require ratification by the Board at its next meeting following the date such actions were taken in
13 order for such actions to remain effective.
14
- 15 b. Other Standing Committees. The Board may designate other standing committees, and shall set
16 forth the duties, membership, terms of office, provisions for vacancies, quorum, and other provisions
17 of each committee in the Board’s rules and procedures.
18
19

20 **ARTICLE VII. COUNCIL OF EXPERTS**
21

22 **Section 1. Duties.**

23 There shall be a Council of Experts which together with its Expert Committees shall be responsible for
24 determining and approving content of the official compendia and other authorized publications of the
25 Convention (including, but not limited to, translations and line extensions of the *United States Pharmacopeia* and
26 *National Formulary* and other information that may be published by or on behalf of the Council of Experts and
27 the Expert Committees).
28

29

Bylaws Chapter VII

30

31 **Section 2. Election, Term and Removal**

32 The Council of Experts shall be composed of the chairs of the Expert Committees, together with the Chair
33 of the Council of Experts, who shall be an *ex officio* voting member. The members of the Council of Experts
34 other than the Chair and those members appointed by the Council of Experts under Section 4 and Section 7
35 below shall be elected by the Voting Members at the Regular Membership Meeting and shall serve a term of
36 five (5) years or until their successors are installed. Members of the Council of Experts other than the Chair
37 may serve no more than two consecutive terms, including any partial term resulting from appointment. Upon
38 the recommendation of the Chair or the Executive Committee of the Council of Experts, the Board of
39 Trustees may remove any member of the Council of Experts for cause.
40

41

Constitution Article VI; Bylaws Chapter VI, Section 11 and Chapter VII, Sections 1, 2, 4 and 18

42

43 **Section 3. Number and Types.**

44 Not less than twelve (12) months prior to each Regular Membership Meeting, the Chair of the Council of
45 Experts, in consultation with the Executive Committee of the Council of Experts, shall recommend to the
46 Board the number and types of Expert Committees for the next cycle. Upon approval of the Board, the
47 Nominating Committee of the Council of Experts shall develop a list of appropriately qualified candidates for
48 the chairs of such Expert Committees in accordance with Article XII.
49

50

Bylaws Chapter VII, Sections 1, 2, and 17



1 ***Section 4. Additional Expert Committee Chairs.***

2 At any time during the cycle, the Chair of the Council of Experts, in consultation with the Executive
3 Committee of the Council of Experts, may recommend to the Board that additional Expert Committees be
4 established to carry out the work of the Convention. If approved by the Board, the chairs of such additional
5 Expert Committees shall be appointed by majority vote of the Council of Experts.

6

Bylaws Chapter VII, Section 8

7
8
9 ***Section 5. Rules.***

10 The Council of Experts shall make such rules and adopt such procedures, not in conflict with these Bylaws,
11 as are sufficient to ensure the accuracy and adequacy of the content of the *United States Pharmacopeia*, the
12 *National Formulary*, and other authorized publications, and to provide for adequate notice and opportunity for
13 public comment and full and impartial consideration of all proposed changes in, and additions to, the content
14 of such publications. Such rules and procedures shall include provisions for the governance of the Council of
15 Experts (including, but not limited to, filling of vacancies, appointment of additional chairs, conflict of
16 interest rules, duties of the Council of Experts Executive Committee, the election and operation of Expert
17 Committees, the creation and operation of advisory bodies within the Council of Experts, etc.) and rules to
18 carry out its areas of responsibility. Prior to adoption, the proposed rules and procedures shall be submitted
19 to the Governance Committee of the Convention and the Board for review and approval as set forth in
20 Article X, Section 1c.

21

Bylaws Chapter VI, Section 9 and Chapter VII, Sections 5, 6, 8, and 11
--

22
23
24 ***Section 6. Executive Committee of the Council of Experts.***

25 The Executive Committee of the Council of Experts shall be appointed by the Chair of the Council of
26 Experts. The Executive Committee shall provide advice to the Chair on matters of general policy concerning
27 the planning and executing of publications and of supplements thereto. The Executive Committee also shall
28 receive and rule upon all appeals for reconsideration, revision, or abrogation of standards adopted and
29 decisions made by an Expert Committee. Each decision of the Executive Committee to deny such appeals
30 shall be referred to the Board of Trustees, which may uphold the denial or grant the appeal and remand for
31 reconsideration by the Council of Experts.

32

Bylaws Chapter VI, Section 10 and Chapter VII, Sections 15 and 16

33
34
35 ***Section 7. Vacancies.***

36 Vacancies shall be filled by appointment by majority vote of the remaining members of the Council of
37 Experts for the unexpired term of the vacant position.

38

Bylaws Chapter VII, Section 14

39
40
41
42 **ARTICLE VIII. CONFLICTS OF INTEREST AND COMPENSATION**

43

Bylaws Chapter VI, Section 6 and Chapter VII, Section 7

44
45
46 ***Section 1. Conflicts of Interest.***

47 All members of the Council of Experts and its Expert Committees ("Experts") and all Officers and Trustees
48 shall be required to adhere to the conflicts of interest provisions set forth in these Bylaws, in policies adopted
49 by the Convention, and in their respective rules and procedures. "Conflict of Interest," as referred to herein,
50 shall include, but shall not be limited to, any matter in which an Officer, Trustee, or Expert has a direct or
51

1 indirect financial interest or any other personal interest of any kind which would preclude or appear to
2 preclude such individual from exercising impartial judgment or otherwise acting in the best interests of the
3 Convention.
4

5 ***Section 2. Recusal.***

6 No Officer, Trustee, or Expert shall cast a vote, nor take part in the final deliberation in any matter in which
7 he or she has a Conflict of Interest. Any Officer, Trustee, or Expert who believes he or she may have such a
8 Conflict of Interest shall notify the Board or Expert Committee, as applicable, prior to deliberation on the
9 matter in question, and such body shall make the final determination as to whether the individual has a
10 Conflict of Interest in any matter. The minutes of the applicable meeting shall reflect disclosure and
11 resolution of any Conflict of Interest, including any recusal of an Officer, Trustee or Expert due to Conflict
12 of Interest.
13

14 ***Section 3. Compensation.***

15 No Expert, or Officer or Trustee (other than the EVP–CEO and Secretary, who are employees of the
16 Convention) shall receive compensation for his or her services as an Officer, Trustee, or Expert. Experts,
17 and Officers and Trustees shall be reimbursed for travel and other necessary expenses that may be incurred
18 by them in the performance of their duties.
19
20

21 **ARTICLE IX. COUNCIL OF THE CONVENTION**
22

23 ***Section 1. Duties.***

24 There shall be a Council of the Convention which shall have the following general duties:

25

Bylaws Chapters VIII and XI

26
27

- 28 a. Developing rules and procedures for inviting Voting Organizational Members, including criteria for
29 membership and procedures for removing Voting Organizational Members for cause as defined in
30 Article III, Section 7;
31
- 32 b. Recommending the invitation of additional Voting Organizational Members or the removal of Voting
33 Organizational Members to the Board of Trustees in accordance with the established rules and
34 procedures;
35
- 36 c. Establishing criteria for organizations to be invited as Observers to the Convention, inviting
37 organizations to become Observers pursuant to such criteria, and developing rules and procedures for
38 Observer participation;
39
- 40 d. Developing resolutions that advance the purposes of the Convention set forth in Article II for the
41 Voting Members to approve based on input from the Membership, the Board and, where appropriate,
42 the Council of Experts. The proposed resolutions shall be submitted to the Board and Council of
43 Experts for a resource assessment and provided to the Membership along with the findings of the
44 Board and Council of Experts by electronic mail or by a link to the USP website not later than thirty
45 (30) days prior to the Regular Membership Meeting; and
46
- 47 e. Developing approaches and mechanisms for engaging and communicating with the Membership in
48 the periods between Regular Membership Meetings.



1 ***Section 2. Number, Term and Qualifications.***

2 The Council of the Convention shall be composed of not more than twenty-five (25) persons who are (i)
3 Delegates or other representatives of Voting Organizational Members, or (ii) Voting At Large Members. The
4 Council shall include at least one Voting Organizational Member representative from each category of Voting
5 Organizational Member specified in Article III, Section 1a(i) above. The Council of the Convention
6 members shall be appointed by the President in consultation with the EVP-CEO and subject to the approval
7 of the Board of Trustees. The President of the Convention shall be the Chair of the Council of the
8 Convention. The Council of the Convention shall be organized not later than six months after the Regular
9 Membership Meeting and its members shall continue in office until adjournment of the next Regular
10 Membership Meeting or until their successors are appointed.

11

Constitution Article V

13
14 ***Section 3. Rules.***

15 The Council of the Convention shall adopt rules and procedures for its own governance and to carry out its
16 duties as described above. Prior to adoption, the proposed rules and procedures shall be submitted to the
17 Governance Committee of the Convention for review and to the Board for approval as set forth in Article X,
18 Section 1c.

19
20
21 **ARTICLE X. GOVERNANCE COMMITTEE**

22
23 ***Section 1. Duties.***

24 There shall be a Governance Committee, which shall have the following general duties:

25

Constitution Article IX; Bylaws Chapter VII, Section 11 and Chapter XIII
--

- 26
27
28 a. Ensuring the integrity, accuracy, and security of the voting process used by the Voting Members;
29
30 b. Developing and reviewing proposed amendments to these Bylaws, which proposed amendments shall
31 be submitted to the Board of Trustees for its comments and provided as a report to the Membership
32 by electronic mail or by a link to the USP website not later than thirty (30) days prior to the Regular
33 Membership Meeting or any Special Membership Meeting at which it is to be considered or, if the
34 amendment is to be voted on by written ballot, provided to the Voting Members along with such
35 written ballot; and
36
37 c. Reviewing the proposed rules and procedures of the Council of Experts and the Council of the
38 Convention to ensure consistency with these Bylaws, and forwarding such rules and procedures with
39 any comments to the Board of Trustees for its approval.
40

41 ***Section 2. Number, Term and Qualifications.***

42 The Governance Committee shall be composed of twelve (12) persons: eight persons who are (i) Delegates
43 or other representatives from Voting Organizational Members or (ii) Voting At Large Members; and four
44 persons who are members of the Council of Experts. The Governance Committee members shall be
45 appointed by the President in consultation with the EVP-CEO and subject to the approval of the Board of
46 Trustees. The President of the Convention shall appoint the Chair of the Governance Committee from
47 among the members of the Governance Committee. The Governance Committee shall be organized not
48 later than six months after the Regular Membership Meeting and its members shall continue in office until
49 adjournment of the next Regular Membership Meeting or until their successors are appointed.

1 **ARTICLE XI. NOMINATING COMMITTEE FOR OFFICERS AND TRUSTEES**

2
3 ***Section 1. Duties.***

4 There shall be a Nominating Committee for Officers and Trustees, which shall have the following general
5 duties:

6 Bylaws Chapter IX, Sections 2 through 5

- 7
8 a. Soliciting and reviewing officer and Trustee nominations;
9
10 b. Developing a list of final officer and Trustee nominees, with there being two nominees for each
11 officer and Trustee position on the ballot; and
12
13 c. Providing to the Membership, by electronic mail or by a link to the USP website not less than thirty
14 (30) days prior to the regular meeting, a report containing the list of nominees and information
15 regarding each nominee.
16

17 ***Section 2. Number, Term and Qualifications.***

18 The Nominating Committee for Officers and Trustees shall be composed of the following persons, who shall
19 be appointed by the President in consultation with the EVP-CEO and subject to approval by the Board of
20 Trustees: four persons who are (i) Delegates or other representatives of Voting Organizational Members or
21 (ii) Voting At Large Members; two Trustees, and two other persons. Members of the Nominating
22 Committee shall serve from the time of their appointment until their duties have been completed and an
23 election has been held. The chair of the Nominating Committee shall be appointed by the President from
24 among those Nominating Committee members representing the Voting Members or the Board of Trustees.
25 Members of the Nominating Committee shall serve from the time of their appointment until their duties have
26 been completed and an election has been held.
27

28 Bylaws Chapter I, Section 4 and Chapter IV, Section 1

29
30
31 **ARTICLE XII. NOMINATING COMMITTEE FOR THE COUNCIL OF EXPERTS**

32
33 ***Section 1. Duties.***

34 There shall be a Nominating Committee for the Council of Experts, which shall have the following general
35 duties:

36 Bylaws Chapter X, Sections 2 through 5

- 37
38
39 a. Soliciting and reviewing Council of Expert nominations based on the number and types of Expert
40 Committees approved in accordance with Article VII, Section 3;
41
42 b. Developing a list of final Council of Expert nominees, with there being two nominees for each
43 Council of Experts position on the ballot; and
44
45 c. Providing to the Membership, by electronic mail or by a link to the USP website not less than thirty
46 (30) days prior to the regular meeting, a report containing the list of nominees and information
47 regarding each nominee.
48
49

1 ***Section 2. Number, Term and Qualifications.***

2 The Nominating Committee for the Council of Experts shall be composed of the following persons: five
3 persons appointed by the President in consultation with the EVP-CEO who are (i) Delegates or other
4 representatives from Organizational Voting Members or (ii) Voting At Large Members; five persons
5 appointed by the EVP-CEO in consultation with the Executive Committee of the Council of Experts who
6 are members of the Council of Experts; and five other persons appointed by the EVP-CEO with the
7 approval of the Board of Trustees. The EVP-CEO shall be a member, *ex officio*, of the Nominating
8 Committee. The President of the Convention shall appoint the Chair of the Nominating Committee from
9 among those Nominating Committee members representing the Voting Members or the Council of Experts.
10 Members of the Nominating Committee shall serve from the time of their appointment until their duties have
11 been completed and an election has been held.

12

Bylaws Chapter I, Section 5 and Chapter X, Section 1
--

13
14
15 **ARTICLE XIII. MISCELLANEOUS PROVISIONS**

16
17 ***Section 1. Fiscal Year.***

18 The fiscal year of the Convention shall be July 1st through June 30th, unless modified by the Board of Trustees.
19
20

21 ***Section 2. Notice.***

22 Whenever under the provisions of these Bylaws, the Articles of Incorporation of the Convention, or statute,
23 notice of a Membership Meeting is required to be given to the Membership, such notice shall be given in
24 writing, by first-class mail or express delivery service with postage or express delivery charges thereon prepaid,
25 to each Member at the address which appears on the records of the Convention. A copy of any notice
26 provided to a Voting Organizational Member shall be provided to the Delegate of such Voting
27 Organizational Member. Such notice shall be deemed to have been given when deposited in the United
28 States mail or delivered to the express delivery service. For all forms of notice to Trustees, committee
29 members, and others required under these Bylaws, notice may also be given by hand delivery, facsimile,
30 electronic mail, or telephone, and will be deemed given when received.

31

Constitution Article VII; Bylaws Chapter I, Section 7 and Chapter XIV, Sections 1 and 2

32
33 ***Section 3. Use of Electronic Mail.***

34 To the fullest extent allowed by law, and unless otherwise limited by these Bylaws, all references in these
35 Bylaws to “mail” shall include electronic mail or other electronic means of communication, and any
36 requirement in these Bylaws that notices or other communications be in writing shall be satisfied by
37 electronic communications or transmissions to the extent permitted by law.
38
39

40 ***Section 4. Meeting Procedure.***

41 To the extent it does not conflict with any provision of state law, the Articles of Incorporation, or these
42 Bylaws, the latest edition of Robert’s Rules of Order will be used as a guide for the conduct of Membership
43 Meetings and meetings of the Board of Trustees, subject always to the discretion of the Chair of the meeting.
44

45

Bylaws Chapter XIV, Section 3

46
47 ***Section 5. Legal Order of Precedent.***

48 The Bylaws are subordinate to, in order of precedence, federal law, District of Columbia law, and the USP
49 Articles of Incorporation. Subordinate to these Bylaws, in order of precedence, are the Board of Trustees’
50 rules and procedures, any committee rules and procedures, and any policy statements of the Convention.
51



1 **ARTICLE XIV. INDEMNIFICATION AND INSURANCE**

2
3 Unless otherwise prohibited by law, the Convention shall indemnify any Trustee or Officer, any former
4 Trustee or Officer, any person who may have served at its request as a director or officer of another
5 corporation, whether for profit or not for profit, and may, by resolution of the Board of Trustees, indemnify
6 any employee, Expert, Convention Committee member, or any other volunteer against any and all reasonable
7 expenses and liabilities actually and necessarily incurred by him or her or imposed on him or her in
8 connection with any claim, action, suit, or proceeding (whether actual or threatened, civil, criminal,
9 administrative, or investigative, including appeals) to which he or she may be or is made a party by reason of
10 being or having held such position, subject to the limitation, however, that there shall be no indemnification
11 in relation to matters as to which he or she shall be adjudged in such claim, action, suit, or proceeding to be
12 guilty of a criminal offense or liable to the Convention for damages arising out of his or her own negligence
13 or misconduct in the performance of a duty to the Convention, unless such adjudication is a sole result of the
14 Convention's being adjudged guilty of a criminal offense or liable for negligence or misconduct in its affairs.

15
16 Amounts paid in indemnification of expenses and liabilities may include, but shall not be limited to, counsel
17 fees and other fees; costs and disbursements; and judgments, fines, and penalties against, and amounts paid in
18 settlement by, such person. The Convention may advance expenses to, or where appropriate may itself, at its
19 expense, undertake the defense of, any such person; provided, however, that such person shall undertake to
20 repay or to reimburse such expense if it should be ultimately determined that he is not entitled to
21 indemnification under this Article. The indemnification provided by this Article shall not be deemed
22 exclusive of any other rights to which such director, officer, employee, or volunteer may be entitled under any
23 statute, agreement, or vote of the Board of Trustees.

24
25 The Board of Trustees may also authorize the purchase of insurance on behalf of any director, officer,
26 employee, volunteer, or agent against any liability asserted against or incurred by him or her which arises out
27 of such person's status as a director, officer, employee, volunteer, or agent, or out of acts taken in such
28 capacity, whether or not the Convention would have the power to indemnify the person against that liability
29 under law.

30
31 If any part of this Article shall be found in any action, suit, or proceeding to be invalid or ineffective, the
32 validity and the effectiveness of the remaining parts shall not be affected.

33

Bylaws Chapter VI, Section 14

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36
37 **ARTICLE XV. AMENDMENTS TO BYLAWS**

38

Constitution Article IX; Bylaws Chapter VI, Section 23 and Chapter XVI
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40
41 ***Section 1. Amendment Process.***

42 Amendments to the Bylaws may be proposed by the President, the Board of Trustees, the Governance
43 Committee, or the written petition of ten percent (10%) of the Voting Members. A Bylaws amendment
44 proposed by Voting Members shall be reviewed by the Governance Committee and then forwarded to the
45 Board of Trustees for its comments with the Governance Committee's recommendation. Any proposed
46 amendment may be further modified by the Convention's legal counsel if counsel determines that such
47 modification is required to be consistent with any law, these Bylaws, or any other governance documents of
48 the Convention.



1 ***Section 2. Amendments Approved by the Board.***

2 Typographical and other non-substantive errors or omissions in the Bylaws, and any change in the Bylaws
3 required by a change in federal or state law, may be approved by a majority vote of the Board of Trustees.
4 All other changes to these Bylaws may be made in accordance with Sections 3 or 4 below. The Membership
5 shall be provided notice of any amendment to these Bylaws approved by the Board under this Section.
6

7 ***Section 3. Amendments Approved by Voting Members at a Meeting.***

8 Amendments to the Bylaws can occur with a three-quarters (3/4) vote of a quorum of Voting Members
9 present at any Membership Meeting, provided that such amendment has first been reviewed and approved by
10 the Governance Committee and made available to the Membership prior to such Membership Meeting as
11 provided in Article X, Section 1b.
12

13 ***Section 4. Amendments by Voting Members via Written Ballot.***

14 Amendments to the Bylaws also may be made by written ballot upon recommendation of the Board of
15 Trustees in accordance with Article III, Section 6b of these Bylaws, provided that such amendment has first
16 been reviewed and approved by the Governance Committee and made available to the Voting Members
17 along with such written ballot as provided in Article X, Section 1. The amendment shall be deemed
18 approved if the number of ballots required under Article III, Section 6b(ii) is received and three-quarters
19 (3/4) of Voting Members voting cast votes in the affirmative.
20

21 **ARTICLE XVI. DISSOLUTION**

22
23
24 In the event of dissolution of the Convention, the Board of Trustees shall, after paying or making provision
25 for the payment of all of the liabilities of the Convention, dispose of all of the assets exclusively for the
26 purposes of the Convention, in such manner as the Board of Trustees shall determine, to such organization
27 or organizations, organized and operated exclusively for charitable, educational, or scientific purposes as at
28 the time shall qualify as an exempt organization or organizations under Section 501(c)(3) of the Internal
29 Revenue Code of 1986 (or the corresponding provision of any future United States Internal Revenue Law).
30

Bylaws Chapter XVII



CONVENTION

2010

PART IV

FREQUENTLY ASKED QUESTIONS ABOUT THE NEW BYLAWS

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

PART IV. FREQUENTLY ASKED QUESTIONS ABOUT THE NEW BYLAWS

1. MEMBERSHIP

Question: My organization is currently named in the USP Constitution; however, this recognition will disappear if the Amended and Restated Bylaws are adopted. What are the implications for my organization?

Answer: The Constitution and Bylaws Committee and the Membership Committee have submitted a joint resolution that grandfathers all organizations that were named in the USP Constitution prior to the adoption of the Amended and Restated Bylaws. So, if the resolution is adopted, your organization will continue as a Voting Organizational Member (Member). The only way your organization would lose its membership is if the organization resigns its membership or is removed for cause.

Question: Can an organization petition USP for Convention membership?

Answer: Currently, the Membership Committee considers the request of any organization seeking an invitation to USP Convention membership. As reflected in the draft Rules and Procedures of the Council of the Convention, there is every expectation that this process will continue as membership responsibilities are shifted to the Council of the Convention in the new cycle.

Question: How will new organizations be invited to USP Membership?

Answer: The Board of Trustees retains the authority to invite organizations to USP Membership. The Council of the Convention (CoC) will have the responsibility for developing criteria and procedures for selecting and recommending to the Board of Trustees new Members. The Rules and Procedures of the Council of the Convention will contain the criteria and related procedures and will be publicly available once they are adopted. Draft Rules and Procedures are available now on the Member Page of the USP website.

2. DELEGATES AND REPRESENTATIVES

Question: Who is the central point of contact for a member organization?

Answer: Before a voting representative is appointed, the executive officer of a Voting Organizational Member (Member) is the point of contact. After the voting representative (Delegate) is appointed, communications go to both the executive and the Delegate, and the Delegate becomes the main point of contact. It should be noted that Convention Committee appointments are organizational appointments and can be filled by the executive officer of a Voting Organizational Member with any duly designated representative of that organization. Thus, Convention Committees may comprise Delegates and other representatives from member appointments.

Question: Can an appointed delegate who is unable to attend a Convention meeting allow someone else from the Member Organization to attend and vote in his/her stead? Should we have a provision for an alternate as we did in the current Bylaws

Answer: Because the organization is the member, the person designated to vote on behalf of the organization can be changed at any time by the executive officer. This should avoid the need to have



an alternate appointed. Voting responsibility can be shifted based on the Voting Organization Member's need.

Question: If a delegate retires or moves to another job, what process does USP go through to obtain a new delegate?

Answer: The process used for obtaining a new delegate will be developed by the Council of the Convention as part of their Rules and Procedures. At this time, the draft Rules and Procedures provide that once USP becomes aware that the voting representative (Delegate) for a member has left the organization, USP will contact the executive officer to request the name of the organization's new delegate.

3. REMOVAL OF AN ORGANIZATION

Question: What safeguards will be put in place to ensure that any member organization in danger of being removed has sufficient prior notice of USP's intended action?

Answer: The Council of the Convention (CoC) is responsible for developing procedures for removing a Voting Organizational Member, including proper notification being sent to the organization prior to USP action. Those Rules and Procedures, once finalized, will be reviewed by the Governance Committee and finally approved by the Board of Trustees to ensure that the process is fair. Currently, the draft Rules and Procedures for the CoC provide that before recommending removal of any organization, the CoC will notify the executive officer of the organization and any delegate or other representatives of record. The letter of notification will include the grounds for removal and give the member organization 30 days in which to respond. Further details are contained in the CoC Rules.

Question: Is there an appeals process for organizations that are removed from Convention membership by the USP Board?

Answer: There is no official appeals process for organizations that are removed from Convention membership by the Board; however, as reflected in the draft Rules and Procedures of the Council of the Convention, it is anticipated that a member will have ample notice and opportunity to request reconsideration prior to removal. In addition, there is nothing in the Bylaws or the draft Rules and Procedures of the Council of the Convention to prevent an organization from reapplying by requesting an invitation to the USP Convention membership.

4. NOMINATIONS

Question: If nominations from the floor of the Convention are eliminated, how can member organizations and delegates nominate qualified candidates for the Board of Trustees and Council of Experts?

Answer: One of the duties of the Nominating Committees for Council of Experts and Board of Trustees is to solicit nominations. It is expected that such solicitation would include a public call for candidates, which would allow member organizations and delegates to nominate qualified candidates for consideration while ensuring a thoughtful vetting process for all nominees.



5. RULES

Question: Many provisions of the current Constitution and Bylaws are being moved to “Rules” documents. Will Convention delegates get an opportunity to see what these proposed new rules include before voting on the Amended and Restated Bylaws?

Answer: Rules and Procedures documents for the Council of Experts and the Council of the Convention are in draft on the USP Website now. Although not yet formally adopted by the respective body, the documents reflect a comprehensive accounting of the expected provisions of the final documents. Each body is responsible for finalizing and adopting its Rules and Procedures. On behalf of the Convention membership the final Rules and Procedures documents will be reviewed by the Governance Committee for consistency with the Bylaws. Ultimately, the adopted Rules and Procedures will be submitted to the Board of Trustees for approval. The intent is to make these documents easily accessible to the public to ensure transparency and compliance.

Question: Is there a schedule by which the “Rules” documents are regularly reviewed and updated?

Answer: The draft Rules currently call for an annual review to be conducted. Any substantive revision to the Rules and Procedures would be reviewed by the Governance Committee and submitted for approval by the Board of Trustees



PART V

GLOSSARY OF TERMS FOR THE NEW BYLAWS

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

PART V. GLOSSARY OF TERMS

Board of Trustees — a governing body of the USP responsible for the management, property and affairs of the USP Convention that is elected by the Convention Membership.

Convention — the corporation headquartered in Rockville, Maryland.

Council of Experts — the scientific body elected by the Convention Membership. Each elected member of the Council of Experts chairs an Expert Committee and oversees the work of related Expert Panels.

Council of the Convention — a standing committee of the Convention, appointed by the President in consultation with the CEO, responsible for: recommending new members; removal of non-participating members; identifying and inviting observers; proposing resolutions; and advising on effective communications to members.

Delegate — an individual appointed by a Voting Organizational Member to represent the member's interests and perspective. The Delegate is authorized to vote on behalf of the Voting Organizational Member.

Executive Committee of the Council of Experts — a standing committee appointed by the Chair of the Council of Experts responsible for advising the Chair on policy matters related to the work of the Council of Experts and ruling on appeals for reconsideration of standards adopted by the Council of Experts.

Expert Committee — a committee of individual experts related to a particular scientific area. An Expert Committee makes scientific decisions on standards published in the *United States Pharmacopeia*, *National Formulary*, *Dietary Supplements Compendium*, *Food Chemicals Codex* and other authorized publications of the USP Convention.

Governance Committee — a standing committee of the Convention, appointed by the President in consultation with the CEO, responsible for: oversight of the membership's voting process; developing amendments to bylaws; and reviewing on behalf of the Convention Membership the rules and procedures of the Council of Experts and Council of the Convention.

Honorary Member — individual selected by the Board of Trustees, because of his/her contribution to the organization, to receive non-voting membership in the USP Convention.

Member—See Voting Organizational Member and/or Voting At Large Member

Membership — the governing body of the USP comprising invited voting organizational and at-large members responsible for advancing the purposes of the USP Convention. The Membership elects the corporation's Officers, Trustees, and Council of Experts, adopts resolutions, and amends the Bylaws. Honorary members also are part of this governing body, but are non-voting.

Nominating Committee for Officers and Trustees — a committee of the Convention formed prior to the Regular Membership Meeting. Committee members are appointed by the President in consultation with the CEO and are responsible for identifying, vetting, and selecting officer and trustee nominees for election by the Convention.



Nominating Committee for the Council of Experts — a committee of the Convention formed prior to the Regular Membership Meeting. Committee members are appointed by the President and CEO and are responsible for identifying, vetting, and selecting qualified nominees for election by the Convention.

Observers — non-voting organizations invited by the Council of the Convention to participate in activities of the Convention Membership

Officers — President and Treasurer elected by the Convention Membership at its five-year meeting, CEO and Secretary selected by the Board, and a Past President.

Regular Membership Meetings — five-year meeting of the USP Convention Membership at which Officers, Trustees, and Council of Experts are elected, resolutions are adopted and Bylaws are amended to advance the mission and vision of the corporation.

Representative, Other — an individual other than the Delegate designated by a Voting Organizational Member to represent the member's interests in various capacities; e.g., committee member, stakeholder forum, etc.

Special Membership Meetings — a meeting of the Convention membership that is called by the President, Board, or 25% of the voting membership to discuss a substantive topic.

Standing Committee—a committee of the Board of Trustees established under a provision of the Bylaws (e.g., Executive Committee) or designated by the Board of Trustees under its Rules and Procedures to assist the Board in its duties.

Voting At Large Member — an individual appointed by the USP Board of Trustees to the Convention Membership based on his/her expertise or specific competence needed by the Convention. Voting At Large Members are authorized to vote in elections of Convention Officers and Trustees, the Council of Experts, adopt resolutions, and amend the Bylaws of the USP

Voting Organizational Member — an organization or governmental body invited by the USP Board of Trustees to Convention Membership. Voting Organizational Members are authorized to vote in elections of Convention Officers and Trustees, the Council of Experts, adopt resolutions, and amend the Bylaws of the USP.

United States Pharmacopeial Convention (USP) — the corporation headquartered in Rockville, Maryland.





PART VI

APPENDICES

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

**APPENDIX A. EXCERPTS PERTAINING TO AMENDMENTS FROM THE
2005 – 2010 USP CONSTITUTION & BYLAWS**

CONSTITUTION — Article IX—Amendments

Section 1

Every proposition to amend this Constitution, except as hereinafter provided, shall be submitted to the Board of Trustees in writing, subscribed to by at least five members of the Pharmacopeial Convention, not later than one hundred and twenty days prior to a stated or a special meeting and, after review by the Board, shall be submitted, together with the Board's recommendation, not later than sixty days prior to a stated or a special meeting of the Pharmacopeial Convention, to the medical, pharmaceutical, and scientific press, to those authorized to send delegates to the Pharmacopeial Convention, and to those persons who are authorized to attend the stated or a special meeting. Except as provided in Section 3, at the next ensuing meeting of the Pharmacopeial Convention, after the expiration of the said sixty days, upon receiving the affirmative votes of not less than three-fourths of the members present and voting, the proposition shall become a part of this Constitution.

Section 2

An amendment also may be proposed in writing by ten or more members at any session of a stated meeting except the final session. Such amendment shall be referred to the Board of Trustees, which shall report upon it at the next succeeding session when, upon receiving the affirmative votes of not less than seven-eighths of the members present and voting, it shall become a part of this Constitution.

Section 3

The Board of Trustees may at its discretion mail to the members of the Convention a proposition to amend or alter this Constitution. A period of sixty days shall be allowed for the submission of comments on the proposition. A summary of the comments shall accompany the mail ballot by which the vote of the member may be recorded and returned within ninety days of the date appearing on the ballot. Upon receiving the affirmative vote of seven-eighths of the members voting, with a total of not less than one hundred and thirty members voting, the proposition shall become a part of this Constitution.

BYLAWS — Chapter XVI—Amendments

Section 1

Every proposition to amend these Bylaws, except as hereinafter provided, shall be submitted in accordance with the procedures to amend the Constitution as set forth in Article VIII, Sections 1 and 2, of the Constitution, and shall, under either procedure, upon receiving the affirmative votes of not less than three-fourths of the members present and voting, become a part of these Bylaws.

Section 2

The Board of Trustees may at its discretion mail to the members of the Pharmacopeial Convention a proposition to amend or alter these Bylaws. A period of sixty days shall be allowed for the submission of comments on the proposition. A summary of the comments shall accompany the mail ballot by which the vote of the member may be recorded and returned within ninety days of the date printed on the ballot. Upon receiving the affirmative vote of seven-eighths of the members voting, with a total of not less than one hundred and thirty members voting, it shall become a part of these Bylaws.

APPENDIX C. 2005–2010 CONSTITUTION AND BYLAWS

CONSTITUTION

ARTICLE I—NAME AND OBJECTS

Section 1

The corporate name of this corporation shall be “The United States Pharmacopoeial Convention,” hereinafter referred to in this Constitution as the Pharmacopoeial Convention.

The alternative spelling, “Pharmacopeial,” also shall be considered as official.

Section 2

Its objects shall be those declared in its Certificate of Incorporation, and include (a) the revision and publication of the information contained in the Pharmacopeia of the United States of America and the National Formulary, also referred to as the United States Pharmacopeia and as the USP and as the NF, respectively, and of the Supplements thereto; (b) the establishment and dissemination of authoritative information for the use of medicines and articles used in health care or for the improvement or maintenance of health by health care professionals, patients, and consumers; and (c) the publication regularly or at suitable times of other information of related scientific purpose. The term authorized shall be applied to such information when it has been prepared in accordance with the rules and procedures adopted by the Council of Experts, or otherwise by direction of the Board of Trustees.

Section 3

The Pharmacopeia of the United States of America and the National Formulary, together with their Supplements, are compilations prepared under the authority of the Pharmacopoeial Convention; they are prepared and regularly revised entirely or in part by a committee or committees of experts in medicine, pharmacy and other health care professional and scientific disciplines and other appropriately qualified individuals, chaired by elected members of the Council of Experts; their primary purpose is to provide authoritative standards and specifications for materials and substances and their preparations that are used in health care or for the improvement or maintenance of health; they establish titles, definitions, descriptions, and standards for identity, quality, strength, purity, packaging, and labeling, and also, where practicable, bioavailability, stability, procedures for proper handling, storage, and shipment, methods for their examination, and formulas for their manufacture or preparation.

ARTICLE II—MEMBERSHIP

Section 1

The members of the Pharmacopoeial Convention shall consist of: accredited delegates representing the following educational institutions, professional and scientific organizations, and designated divisions of the federal government, hereafter designated as eligible organizations, and others as herein provided.

In this Constitution and Bylaws “state” or “United States” includes each of the several states, the District of Columbia, the Commonwealth of Puerto Rico, and all territorial possessions of the United States of America.

- (a) Colleges and schools of medicine in the United States with programs accredited by the Liaison Committee on Medical Education sponsored by the Association of American Medical Colleges and by the Council on Medical Education of the American Medical Association; colleges and schools of



pharmacy in the United States with programs accredited by the Accreditation Council on Pharmacy Education; state medical associations or state medical societies, which are constituents of the American Medical Association; and state pharmaceutical associations or state pharmaceutical societies, which are entitled to voting delegates in the House of Delegates of the American Pharmacists Association.

- (b) Not more than seventy-five national and state professional and scientific organizations or sections thereof, designated by the Board of Trustees as eligible to appoint a delegate. The following national and state professional and scientific organizations shall be so designated: The American Association of Pharmaceutical Scientists; the American Chemical Society; the American Dental Association; the American Medical Association; the American Nurses Association; the American Pharmacists Association; the American Society for Clinical Pharmacology and Therapeutics; the American Society for Pharmacology and Experimental Therapeutics; the American Society for Quality; the American Society of Consultant Pharmacists; the American Society of Health-System Pharmacists; the American Veterinary Medical Association; the AOAC International; the Association of Food and Drug Officials; the Drug Information Association; the National Association of Boards of Pharmacy; the National Community Pharmacists Association; the Parenteral Drug Association; or the successors thereto.
- (c) Not more than twenty governmental bodies or divisions thereof, designated by the Board of Trustees as eligible to appoint a delegate. The following governmental bodies shall be so designated: The Centers for Medicare & Medicaid Services; the Department of Veterans Affairs Veterans Health Administration; the Food and Drug Administration; the National Institute of Standards and Technology; the Office of the Surgeon General, the Bureau of Medicine and Surgery, United States Navy; the Office of the Surgeon General, United States Air Force; the Office of the Surgeon General, United States Army; the Office of the Surgeon General, United States Public Health Service; and, the Office of the Secretary of the Department of Health and Human Services; or the successors thereto.
- (d) Not more than five governmental bodies designated by the Board of Trustees as eligible to appoint a delegate to represent nations, other than the United States, that give official recognition to the standards of the USP or the NF.
- (e) Not more than twenty-five organizations designated by the Board of Trustees as eligible to appoint a delegate to represent organizations representing the health sciences in other nations, international health, scientific, or professional organizations or other pharmacopeial bodies.
- (f) Not more than twenty-five domestic or international consumer organizations designated as eligible to appoint a delegate or individuals representing the public interest designated by the Board of Trustees to serve as public members also shall be members of the Pharmacopeial Convention.
- (g) The President, the Past President, the Treasurer, the Board of Trustees, the Executive Vice President-CEO, and the Chairpersons of Committees directed to report at a stated meeting, serving by authority of the preceding stated Pharmacopeial Convention or the Constitution and Bylaws, also shall be members, ex officio, of the Pharmacopeial Convention.
- (h) Not more than twenty-five members-at-large, selected by the Board of Trustees for their special competence in relation to the administrative or scientific needs of the Pharmacopeial Convention.
- (i) Not more than twenty-five organizations or divisions thereof, either domestic, international, or from other nations, designated by the Board of Trustees as eligible to appoint a delegate to represent manufacturers, trade, and affiliated associations. The following organizations shall be so designated: the Advanced Medical Technology Association, the American Hospital Association; American Chemistry Council; the



Animal Health Institute; Consumer Healthcare Products Association; Cosmetic, Toiletry and Fragrance Association; Council for Responsible Nutrition; Generic Pharmaceutical Association; Healthcare Distribution Management Association; National Association of Chain Drug Stores; the Pharmaceutical Research and Manufacturers of America.

- (j) Nominees for elective offices, selected in accordance with Chapter IX, Sections 2 and 3, of the Bylaws, shall be members of the Pharmacopeial Convention for the stated meeting when their names are presented as nominees in accordance with Chapter IV, Section 1(g), of the Bylaws, whether present or not.

Section 2

In designating those organizations or governmental bodies or divisions or sections thereof as eligible to appoint a delegate to the USP Convention, the Board of Trustees shall consider the membership guidelines provided by the Convention at the previous stated meeting, as well as recommendations made by the Membership Committee. The Board shall at least annually review the composition of the Convention and designate any additional organizations, governmental bodies, or divisions or sections thereof as deemed necessary.

Section 3

Each eligible organization entitled to representation in the Pharmacopeial Convention, as provided for in Article II, Section 1, of this Constitution shall elect or appoint in such manner as it may determine, one delegate who shall be approved as a member of the Pharmacopeial Convention, as provided in the Bylaws.

Section 4

Once approved by the Membership Committee, members appointed by organizations named in the Constitution shall continue to serve as members of the Convention until replaced by their appointing organizations, unless disqualified under the provisions of Article II, Section 6. The term of members appointed by organizations designated by the Board of Trustees shall end six months following the stated meeting.

Section 5

Six months prior to a stated meeting, each eligible organization shall be requested to elect or appoint in such manner as it may determine, one alternate delegate, who shall be approved as an alternate member of the Convention as provided in the Bylaws. The alternate delegate shall represent the appointing organization only if the member is unable to attend the stated meeting. The alternate delegate's term ends at the adjournment of the stated meeting.

Section 6

Each delegate and alternate delegate, at the time of his or her election or appointment, and each member of the Convention, during his or her membership, except those individuals named by the Board under Article II, Sections 1 (f), (g), and (h), shall be an officer or a member of the academic staff of the educational institution; an officer, active member, or employee of the organization; or an employee of the division of the federal government that he or she represents.

Section 7

By unanimous vote the Board of Trustees may elect honorary members to the Convention in recognition of their distinguished contribution to drug standardization, drug information, the sciences of medicine and pharmacy, the public health, or other special contribution to the USP. Each honorary member shall have the rights, privileges, and duties prescribed by the Constitution and Bylaws and defined by the Board of Trustees except the right to vote, to hold office, or to otherwise determine the policy and administration of the Convention.



ARTICLE III—OFFICERS

Section 1

The officers of the Pharmacopeial Convention shall be a President, a Past President, a Treasurer, and an Executive Vice President and Chief Executive Officer (CEO). Officers may also include one or more Senior Vice Presidents or Vice Presidents as the Executive Vice President-CEO may deem necessary and may appoint from time to time. The Executive Vice President-CEO shall also have the authority, but shall not be required, to designate officers as the Chief Operating Officer, the Chief Financial Officer or similar such titles.

Section 2

The President and the Treasurer, each shall be a member of the Pharmacopeial Convention at the time of their election and shall be elected by majority vote by ballot at each stated meeting. The President and the Treasurer shall be elected by ballot at each stated meeting. The Committee of Tellers shall report to the President the number of votes cast for each nominee, and the President shall announce to the Convention the winner(s) in each office or position without disclosing the number of votes cast or the number received by each nominee. However, any nominee may publicly or privately obtain this information with regard to his or her own election and the election of others seeking election to the same position or classification, and, in such event, to the degree it is necessary to do so in order that the Convention may rule upon the propriety of the election, the votes cast may be disclosed publicly.

Section 3

The Executive Vice President-CEO shall be an employee of the Convention, selected and hired by the Board of Trustees.

Section 4

Vacancies in these offices shall be filled as provided in the Bylaws.

ARTICLE IV—BOARD OF TRUSTEES

The members of the Pharmacopeial Convention shall elect a Board of Trustees from the members of the Convention at each stated meeting, as provided in the Bylaws. The Committee of Tellers shall report to the President the number of votes cast for each nominee, and the President shall announce to the Convention the winner(s) in each office or position without disclosing the number of votes cast or the number received by each nominee. However, any nominee may publicly or privately obtain this information with regard to his or her own election and the election of others seeking election to the same position or classification, and, in such event, to the degree it is necessary to do so in order that the Convention may rule upon the propriety of the election, the votes cast may be disclosed publicly.

ARTICLE V—THE COUNCIL OF THE CONVENTION

There is hereby created a Council of the Convention. The President of the Pharmacopeial Convention shall be the Chairperson of the Council. The Council of the Convention shall be appointed by the President and Executive Vice President-CEO with the advice and consent of the Board of Trustees.

The Council shall be composed of not more than 25 members of the Pharmacopeial Convention, with at least one member representing the institutions named in Article II, Sections 1(a), (b), (c), (d), (e), (f) and (i).



ARTICLE VI—THE COUNCIL OF EXPERTS

The members of the Pharmacopeial Convention shall elect the members of the Council of Experts at each stated meeting, as provided in the Bylaws. A member of the Council shall act until his or her successor shall have been elected and shall have assumed his or her duties.

ARTICLE VII—MEETINGS

Section 1

The stated meetings of the Pharmacopeial Convention shall be held in the United States at five-year intervals. The Board of Trustees is authorized to determine the day within the year and the place of the meeting.

Section 2

The President shall call a special meeting upon the written request of not fewer than sixty-five members of the Pharmacopeial Convention.

ARTICLE VIII—QUORUM

At any session of a meeting of the Pharmacopeial Convention, one hundred and thirty members who are eligible to vote shall constitute a quorum.

ARTICLE IX—AMENDMENTS

Section 1

Every proposition to amend this Constitution, except as hereinafter provided, shall be submitted to the Board of Trustees in writing, subscribed to by at least five members of the Pharmacopeial Convention, not later than one hundred and twenty days prior to a stated or a special meeting and, after review by the Board, shall be submitted, together with the Board's recommendation, not later than sixty days prior to a stated or a special meeting of the Pharmacopeial Convention, to the medical, pharmaceutical, and scientific press, to those authorized to send delegates to the Pharmacopeial Convention, and to those persons who are authorized to attend the stated or a special meeting. Except as provided in Section 3, at the next ensuing meeting of the Pharmacopeial Convention, after the expiration of the said sixty days, upon receiving the affirmative votes of not less than three-fourths of the members present and voting, the proposition shall become a part of this Constitution.

Section 2

An amendment also may be proposed in writing by ten or more members at any session of a stated meeting except the final session. Such amendment shall be referred to the Board of Trustees, which shall report upon it at the next succeeding session when, upon receiving the affirmative votes of not less than seven-eighths of the members present and voting, it shall become a part of this Constitution.

Section 3

The Board of Trustees may at its discretion mail to the members of the Convention a proposition to amend or alter this Constitution. A period of sixty days shall be allowed for the submission of comments on the proposition. A summary of the comments shall accompany the mail ballot by which the vote of the member may be recorded and returned within ninety days of the date appearing on the ballot. Upon receiving the affirmative vote of seven-eighths of the members voting, with a total of not less than one hundred and thirty members voting, the proposition shall become a part of this Constitution.



BYLAWS

CHAPTER I—THE PRESIDENT

Section 1

The President shall preside at all meetings of The United States Pharmacopeial Convention, hereinafter referred to in these Bylaws as the Pharmacopeial Convention. In the absence of the President or in the event of his or her inability to preside, a President pro tempore, to be appointed by the Board of Trustees, shall conduct the meeting.

Section 2

The presiding officer shall present an address at the stated meeting.

Section 3

The presiding officer shall have the right to call a member to the chair in order that he or she may take the floor in debate.

Section 4

Not later than six months before the stated meeting of the Pharmacopeial Convention, the President shall appoint, subject to the advice and consent of the Board of Trustees, five members of the Convention as a Nominating Committee for Officers and Trustees, two of whom shall be members of the Board of Trustees. Of the members appointed from the Board of Trustees, one shall be representative of the pharmaceutical sciences and one shall be representative of the medical sciences.

Section 5

The President shall appoint, with the advice and consent of the Board of Trustees, five members of the Convention to serve on the Nominating Committee for the Council of Experts, none of whom shall be members of the Council of Experts, Expert Committees, the Board of Trustees, salaried employees, nor officers of the Pharmacopeial Convention.

Section 6

The President shall appoint all committees of the Convention not otherwise provided for in these Bylaws.

Section 7

Not later than one year prior to the stated meeting of the Pharmacopeial Convention, the President, through the Secretary, shall mail a notice of the meeting to all members and a request to prepare for the authorization of a delegate where none has been appointed to each of those organizations eligible for representation under the Constitution. He or she shall mail a second notice of the meeting to all members and the request for the authorization of a delegate where none has been appointed and an alternate delegate not later than six months prior to the stated meeting. He or she shall also request medical, pharmaceutical, and other appropriate journals to publish the announcement of the said meeting.

Section 8

The President shall be a member, ex officio, of the Board of Trustees and of all committees except the Council of Experts and its Expert Committees.

Section 9

The President shall serve for one elected term of five years and act as President until his or her successor shall have been elected and installed.



Section 10

In the event of a vacancy in the office of President, the Board of Trustees shall, from the membership of the Pharmacopeial Convention, select a President.

Section 11

In the event of a temporary disability or absence of the President, or inability to perform his or her duties, an acting President may be appointed from the membership of the Pharmacopeial Convention by the Board of Trustees to act in the place of the President.

CHAPTER II—THE PAST PRESIDENT

Section 1

The Past President shall be the immediate past president.

Section 2

The Past President shall be a member, ex officio, of the Board of Trustees.

Section 3

In the event the immediate past president is unable to serve as Past President, the office shall remain vacant.

CHAPTER III—THE EXECUTIVE VICE PRESIDENT AND CHIEF EXECUTIVE OFFICER (CEO)

Section 1

The Executive Vice President shall serve as the chief executive officer (CEO) of the Convention. The Executive Vice President-CEO shall be an ex officio, non-voting member of the Board of Trustees. The Executive Vice President-CEO shall function within the framework of the policies and programs as determined by the Executive Vice President-CEO after consultation with the Board of Trustees.

Section 2

The Executive Vice President-CEO shall be a member, ex officio, and Chairperson of the Council of Experts and of the Executive Committee of the Council of Experts.

Section 3

The Executive Vice President-CEO shall organize the Council of Experts in accordance with Chapter VII of these Bylaws. The Executive Vice President-CEO shall appoint any ad hoc advisory bodies required for the work of the Council.

Section 4

The Executive Vice President-CEO shall have charge of the work and shall cause to be prepared the final text of the United States Pharmacopeia, the National Formulary, and other authorized publications, and any supplements thereto.

Section 5

The Executive Vice President-CEO shall consult with the Executive Committee of the Council of Experts, and the Division Executive Committees (if appointed) on matters of general policy concerning the planning and executing of the United States Pharmacopeia, the National Formulary, other authorized publications, and of supplements thereto.



Section 6

The Executive Vice President-CEO shall annually or more frequently, upon request of the Board of Trustees, certify in writing to the Board of Trustees that a new United States Pharmacopeia and new National Formulary, or a new Supplement or any change thereto, has been prepared in accordance with the rules and procedures of the Council of Experts. The Executive Vice President-CEO shall also certify in writing to the Board of Trustees that an authorized publication or its supplement has been completed in accordance with existing rules and procedures.

Section 7

The Executive Vice President-CEO shall annually, after consultation with the Council of Experts, present a report to the Board of Trustees of the activities of the Council of Experts. The Executive Vice President-CEO also shall present a report of the Council of Experts at the stated meeting of the Pharmacopeial Convention.

Section 8

In the event of a vacancy in the Chair of an Expert Committee, the vice chair shall serve in his or her absence. In the event the vice chair is unable to serve, the Executive Vice President-CEO shall appoint an acting Chairperson until a new Chairperson is elected.

Section 9

The Executive Vice President-CEO, after consultation with and upon notice to the Board of Trustees, may appoint advisory bodies to provide advice on policy matters. The Executive Vice President-CEO may also appoint such Stakeholder Forums and Project Teams as deemed necessary for the work of the Convention. Such Stakeholder Forums and Project Teams shall operate pursuant to rules promulgated by the Executive Vice President-CEO and approved by the Board of Trustees.

Section 10

The Executive Vice President-CEO shall serve at the will of the Board of Trustees.

Section 11

Officers shall have the authority and shall perform the duties set forth in these Bylaws or, to the extent consistent with the Bylaws, the duties prescribed by the Board of Trustees, by the Executive Vice President-Chief Executive Officer, or by an officer authorized by the Board to prescribe the duties of such officer. Any designation of duties by the Executive Vice President-CEO or other officer shall be subject to review by the Board of Trustees but shall be in full force and effect in the absence of such review.

CHAPTER IV—THE SECRETARY

Section 1

The Secretary shall serve as Secretary of the Board of Trustees and the Convention. The Secretary shall be appointed by, and act under the direction of the Executive Vice President-CEO and shall:

- (a) Keep the minutes of each meeting of the Pharmacopeial Convention and receive all reports and other documents presented to the said meeting;
- (b) Compile the proceedings of the stated and special meetings and submit them to the Board of Trustees and, upon its order, arrange for their publication;



- (c) At each stated meeting of the Pharmacopeial Convention, present a summary of the minutes of the preceding stated meeting;
- (d) Present to the Pharmacopeial Convention papers handed in for such purpose by the President;
- (e) Record the ayes and nays when required;
- (f) Notify the chairperson and other members of each committee of their appointment, giving each member the name of the chairperson of that committee and the names of the members and stating the business upon which the committee is to act;
- (g) Before the opening of the stated meeting of the Pharmacopeial Convention, provide to the membership the names of the Officers of the Pharmacopeial Convention, the members of the Board of Trustees, the members of the Council of Experts, and all members of the Expert Committees, the Chairpersons of Committees directed to report at the stated meeting, the persons selected by the Board of Trustees as members-at-large, the organizations designated as eligible organizations by the Board of Trustees, the persons selected by the Nominating Committee for Officers and Trustees as nominees for elected office, the members of the Convention approved by the Membership Committee, and the order of business;
- (h) During the stated meeting of the Pharmacopeial Convention, provide for each member two official ballots. One ballot shall contain the names of those nominated for President, and for Treasurer of the Pharmacopeial Convention, and for the eight elective memberships on the Board of Trustees. A second ballot shall contain the names of those nominated for the Council of Experts, classified according to the outline of the number and types of committees as provided in Chapter VII, Section 17, of these Bylaws. Balloting may be conducted electronically under the guidance of the Committee of Tellers.
- (i) Deliver all reports, papers, and other documents of the Pharmacopeial Convention to the Board of Trustees;
- (j) Issue such notices, announcements, and requests as provided for in Chapter I, Section 7, of these Bylaws, together with credential forms, and also mail the notices of special meetings as provided in Chapter XIV, Section 1, of these Bylaws;
- (k) Submit to the Nominating Committee for the Council of Experts, not later than ninety days prior to the stated meeting of the Pharmacopeial Convention, all recommendations that have been submitted for membership on the Council of Experts;
- (l) Acknowledge in writing the receipt of all resignations of organizations eligible to appoint members to the Convention and report them to the Board of Trustees;
- (m) Serve as Secretary of all committees of the Convention appointed by the President.

Section 2

In the absence of the Secretary or in the event of his or her inability to serve as Secretary, the Executive Vice President-CEO shall appoint an acting Secretary.



CHAPTER V—THE TREASURER

Section 1

The Treasurer shall oversee the receipt of all moneys coming from any source to the Pharmacopeial Convention and shall ensure that the payment of moneys is made only on the authorization of and in accordance with the procedures adopted by the Board of Trustees.

Section 2

The Treasurer shall present annually to the Board of Trustees an audited financial statement. The Treasurer shall present at the stated meeting of the Pharmacopeial Convention a complete financial statement for the period since the preceding stated meeting.

Section 3

The Treasurer shall be a member, ex officio, of the Board of Trustees.

Section 4

During any temporary disability or absence of the Treasurer, an Acting Treasurer may be appointed by the Board of Trustees to serve in place of the Treasurer.

Section 5

The Treasurer shall act as Treasurer until his or her successor shall have been elected and installed.

Section 6

No person shall be eligible for election as Treasurer if, at the adjournment of the stated meeting, he or she shall have served two successive elected terms as Treasurer.

Section 7

A vacancy in the office of Treasurer shall be filled by the Board of Trustees from the membership of the Convention.

CHAPTER VI—THE BOARD OF TRUSTEES

Section 1

The Board of Trustees shall consist of eight members of the Pharmacopeial Convention elected by plurality vote at the stated meeting; and the President, the Past President, and the Treasurer, ex officio, and the Executive Vice President-CEO, who shall serve as a non-voting, ex officio member of the Board of Trustees.

Of the eight members of the Board of Trustees elected by the Convention, two shall be representative of the pharmaceutical sciences, two shall be representative of the medical sciences, one shall be a public member, and three shall serve without restriction concerning their affiliation.

Except for the Executive Vice President-CEO, the members of the Board of Trustees shall not be members of the Council of Experts or its Expert Committees.

No person shall be eligible to be an elected member of the Board of Trustees who, at the adjournment of the stated meeting, shall have served two successive terms either as an elected member of the Board of Trustees or as an elected officer, or a combination thereof.

Section 2

The officers of the Board of Trustees shall consist of a Chairperson, who shall be elected by a majority vote of the Board, and a Secretary. The Chairperson of the Board of Trustees shall serve as a member, ex officio, of the Membership Committee. The Secretary of the Board of Trustees need not be a member of the Board of Trustees or a member of the Pharmacopeial Convention. The Secretary of the Board of Trustees shall serve as Secretary of the Convention.

Section 3

The Board of Trustees shall have the right to transact business by correspondence, including electronic or other means, as provided in the rules adopted by them. A motion by such means shall require no second.

Section 4

The Board of Trustees shall meet annually at such time and place as it shall determine. Special meetings of the Board of Trustees shall be called upon the written request of at least four members. The Chairperson shall have the right to call a special meeting whenever he or she shall deem it necessary. Six voting members of the Board of Trustees shall constitute a quorum.

Section 5

Members of the Board of Trustees may participate in a special meeting of such Board by means of a telephone conference or similar communications equipment by means of which all persons participating in the meeting can hear each other or perceive each other's comments at the same time, and participation by such means shall constitute presence in person at a meeting. Such meetings shall be conducted in accordance with rules adopted by the Board of Trustees.

Section 6

- (a) No member of the Board of Trustees elected by the Convention members shall receive compensation for his or her services. Members of the Board of Trustees elected by the Convention members shall be reimbursed from the funds of the Pharmacopeial Convention for travel and other necessary expenses that may be incurred by them in the performance of their duties.
- (b) No person, who during his or her service on the Board, has a financial interest that may conflict or may appear to conflict, with his or her duties and responsibilities, shall vote on matters, in which he or she has such financial interest. An employee's interest shall be presumed to coincide with that of his or her employer.
- (c) Where it appears that a conflict of interest may exist, or may be perceived to exist, any officer or member of the Board of Trustees may excuse him or herself from a deliberation of the Board of Trustees; any officer or member may be excused from a deliberation of the Board of Trustees by an affirmative vote of not less than two-thirds of the members of the Board, other than himself or herself, provided, the minutes of such meeting shall note that the officer or member was excused from such deliberation.

Section 7

The Board of Trustees shall manage and control the affairs, funds, and property of the Pharmacopeial Convention, except as is herein otherwise provided.

The Board of Trustees may invest the funds of the Pharmacopeial Convention, authorize the payment of all moneys due for services performed, transact business involving financial or other matters that may be for the best interests of the Pharmacopeial Convention, and perform such other duties as the Pharmacopeial Convention may direct. Any and all contracts or agreements authorized by the Pharmacopeial Convention or



by the Board of Trustees shall be executed on behalf of the Pharmacopeial Convention by the Chairperson and Executive Vice President-CEO, or by such other person or persons as the Board may designate.

Section 8

The Board of Trustees shall authorize the revision and release of text to the United States Pharmacopeia and the National Formulary. Upon approval of the content by the Council of Experts, in accordance with the rules and procedures adopted under Section 9, the Board of Trustees shall then act upon releasing the text and upon designating the date when it is to become official, said date to be reasonably distant from the date of its release. The Executive Vice President-CEO shall, annually or more frequently, upon specific request of the Board of Trustees, certify that the information contained in the United States Pharmacopeia, National Formulary, or other authorized publications has been prepared in accordance with the rules and procedures under Section 9.

Section 9

The Board of Trustees shall review all rules and procedures made or adopted by the Council of Experts and the Executive Committee of the Council and shall determine whether the rules and procedures conflict with the Constitution and Bylaws and whether they are sufficient to ensure the accuracy and adequacy of the content of the United States Pharmacopeia, the National Formulary, and other authorized publications. The Board shall determine whether such rules and procedures shall be sufficient to provide adequate notice and opportunity for comment and full and impartial consideration of all proposed changes in, and additions to, the text. Where such conflict or insufficiency is found, the Board shall propose such amendments as may be indicated and, after having given the Council of Experts and the Executive Committee of the Council an opportunity to be heard, shall revise or modify the rules and procedures to bring about conformity with the Constitution and Bylaws and to ensure their sufficiency. The Board of Trustees shall arrange for suitable publication of the rules and procedures of the Council of Experts.

Section 10

The Board of Trustees shall be informed of the decisions of the Executive Committee of the Council on appeals for reconsideration, revision, or abrogation of standards adopted and decisions made by a committee of the Council of Experts, Division Executive Committee, or other body. Upon consideration of the facts, where an appeal is determined by the Board to be on a matter of procedure, the Board may uphold the decision or remand the matter to the proper body for reconsideration under proper procedures; where the appeal is determined by the Board to be on a scientific matter, the Board may uphold the decision or may request the entire Council of Experts to review the decision.

Section 11

Upon recommendation of the Executive Vice President-Chief Executive Officer or of the Executive Committee of the Council of Experts, the Board of Trustees may remove any member of the Council of Experts for cause.

Section 12

The Board of Trustees shall issue an annual financial report of the Pharmacopeial Convention audited by a certified public accountant.

Section 13

The Board of Trustees shall arrange for the bonding of Officers and employees to the extent necessary to protect the interests of the Pharmacopeial Convention.



Section 14

The Pharmacopeial Convention may indemnify a current or former Trustee, Officer, Council of Experts or Expert Committee Member, Panelist, or employee against expenses, judgments, fines, penalties and settlements in connection with or arising out of any proceeding in which that person may be involved as a party or otherwise by reason of his/her having been such Officer, Trustee, Council of Experts or Expert Committee Member, Panelist, or employee. Such indemnification may be made only in accordance with the procedures adopted by the Board of Trustees.

Section 15

The Board of Trustees shall maintain a headquarters for conducting the business of the Pharmacopeial Convention.

Section 16

The Executive Vice President-CEO shall serve at the will of the Board of Trustees. In case of a vacancy in the position of Executive Vice President-CEO, the Chairperson of the Board of Trustees shall appoint an acting Executive Vice President-CEO, who shall serve until the Board of Trustees shall have selected an Executive Vice President-CEO. The Board of Trustees may request the advice of the Division Executive Committees and the Executive Committee of the Council of Experts before selecting an Executive Vice President-CEO.

Section 17

The Board of Trustees shall provide for such assistants to the Executive Vice President-CEO as may be deemed necessary.

Section 18

The Board of Trustees may select not more than twenty-five persons for their special competence in relation to the administrative or scientific needs of the Pharmacopeia to be members-at-large of the current or ensuing Pharmacopeial Convention.

Section 19

The Board of Trustees shall designate those organizations, governmental bodies or divisions, or sections thereof as eligible to appoint a delegate. In making such designations, the Board of Trustees shall consider membership guidelines provided by the Convention at the previous stated meeting, or recommendations made by the Membership Committee. Thereafter, the Board of Trustees shall at least annually review the composition of the Convention and designate any additional organizations, governmental bodies, or divisions or sections thereof as deemed necessary.

Section 20

The Board of Trustees may invite the national medical, pharmaceutical and other health care professional and scientific associations of other nations to send representatives as observers to a stated meeting of the Pharmacopeial Convention.

Section 21

The Chairperson of the Board of Trustees shall present a report for the Board at each stated meeting of the Pharmacopeial Convention.

Section 22

The Board of Trustees shall receive from the Secretary proceedings of the stated and special meetings of the Pharmacopeial Convention and shall arrange for their publication.



Section 23

The Board of Trustees shall receive and review any proposition to amend the Constitution and Bylaws and shall recommend such action as it deems advisable as provided in the Constitution and Bylaws.

Section 24

The Board of Trustees shall fill vacancies for unexpired terms of office of the eight elected members of the Board of Trustees; the President, and the Treasurer; from the membership of the Pharmacopeial Convention; and the Executive Vice President-CEO as herein provided.

Section 25

Any officer or member of the Board of Trustees may be removed for cause by an affirmative vote of not less than two-thirds of the members of the Board, other than himself or herself.

Section 26

The Board of Trustees shall approve the number and types of expert committees deemed necessary for the work of the Council of Experts.

Section 27

The Board of Trustees shall provide advice to the Nominating Committee on factors to be considered during the selection of candidates, so as to achieve appropriate balance and diversity.

Section 28

In the event it is determined that expertise is needed, which is not encompassed by existing divisions, the Chairperson of the Council of Experts, in consultation with, and with the approval of the Executive Committee and the Board of Trustees, shall determine the additional number and types of Expert Committees needed.

Section 29

The Board of Trustees shall approve the number of persons to be elected to each Expert Committee.

Section 30

Between stated meetings of the Pharmacopeial Convention, the Board of Trustees may, at its discretion, send the members of the Convention a proposal to be voted on. On any such vote, not less than one hundred and thirty members shall cast a ballot to constitute a valid action and a majority of those voting shall determine the action. The Board of Trustees shall promulgate rules to ensure adequate opportunity for comment, fairness, and confidentiality.

Section 31

The Board of Trustees may designate representatives to other organizations to represent the USP Convention; it may allow the USP Convention, as an organization, to participate in other organizations.

Section 32

The Board of Trustees shall adopt rules and procedures to govern its management of the affairs, funds, and property of the Pharmacopeial Convention and any conflict of interest of its members. Such rules and procedures shall be made available to members of the Convention and the public.

Section 33

Any officer of the Convention may resign at any time by giving notice to the Secretary, who shall promptly transmit such notice to the Board of Trustees. Any such resignation is effective when the notice is given, unless the notice specifies a later date.



CHAPTER VII—THE COUNCIL OF EXPERTS AND THE EXECUTIVE COMMITTEE OF THE COUNCIL

Section 1

The Council of Experts shall be composed of appropriately qualified individuals, elected by the Convention primarily from those nations that utilize the USP-NF as their official compendia, together with the Executive Vice President-CEO, ex officio. The members of the Council of Experts shall be elected at the stated meeting or by mail or electronic ballot between meetings by a plurality of the votes cast by the members of the Pharmacopeial Convention as provided in these Bylaws.

Section 2

- (a) The Executive Vice President-CEO shall be Chairperson of the Council of Experts and of the Executive Committee of the Council. In this Chapter, the terms “Executive Vice President-CEO” and “Chairperson of the Council of Experts” may be used interchangeably.
- (b) After a stated meeting, the Council of Experts may be organized by the Executive Vice President-CEO with the approval of the Board of Trustees into appropriate divisions, taking into consideration, among other things, the distinctiveness of the scope of work, the number of committees that would comprise a division, and efficiencies in the work. The Executive Vice President-CEO shall, after consultation with the Executive Committee of the Council of Experts, establish the parameters within which a division shall operate.
- (c) All references to divisions or Division Executive Committees throughout the Bylaws presume that the Executive Vice President-CEO shall have divided the Council of Experts according to the provisions of this section. Such references shall not have application to the extent the Council of Experts is not so divided.

Section 3

Two or more Expert Committees from different divisions may be organized by the Chairperson of the Council of Experts, after consultation with the Executive Committee, into multidisciplinary coordinating groups based on similarities of technology or other scientific reason.

The Chairperson of the Council of Experts, shall coordinate the work of the Expert Committees within the multidisciplinary coordinating group.

Where a multidisciplinary coordinating group is formed, the chairpersons of the Expert Committees of the multidisciplinary coordinating group, shall act in lieu of a division executive committee to approve the decisions emanating from the multidisciplinary coordinating group.

Section 4

- (a) Each elected member of the Council of Experts shall chair an Expert Committee. Each Expert Committee shall function until its successor committee is elected or until such date specified by the Chairperson of the Council of Experts.
- (b) To become effective at the stated meeting in 2010, a chair of an Expert Committee shall be ineligible to hold the same office for more than two consecutive terms. A member of the Council of Experts who has served as a chair of an Expert Committee for two consecutive terms may be nominated for re-election to the Council of Experts only if he or she stands for election as Chair to a different



expert committee of the Council of Experts (it shall not be permissible to stand for election as Chair of an Expert Committee if that Committee has been re-named).

Section 5

- (a) Each Expert Committee shall be composed of individuals elected by the chairs of the Expert Committees within the division or divisions in which the committee is placed. Individuals eligible for election to an Expert Committee shall be nominated by a committee composed of the President, the Vice Chairperson of the Nominating Committee for the Council of Experts, the Chairperson of the Council of Experts and the Chair of the Expert Committee. This Nominating Committee for Expert Committees shall, to the extent practical and necessary, select two nominees for each Expert Committee position from the names of qualified experts submitted to it by the Nominating Committee for the Council of Experts.
- (b) The immediate past chair of an Expert Committee shall be a member of the said Expert Committee without the requirement of nomination and election unless he or she shall stand for re-election to the Council of Experts.

Section 6

Upon request of the Chairperson of an Expert Committee, or upon his or her own initiative, the Chairperson of the Council of Experts may appoint an ad hoc Advisory Panel. Such ad hoc Advisory Panel shall be chaired by a member of the Expert Committee to which it reports. The scope of work of the ad hoc Advisory Panel shall be clearly defined and the panel terminated upon completion of its task.

Section 7

No person who, during his or her service on an Expert Committee, has a financial interest that may conflict or may appear to conflict, with his or her duties and responsibilities, shall vote on a matter in which he or she has such financial interest. An employee's interest shall be presumed to coincide with that of his or her employer. Except for the Executive Vice President-CEO, no member of the Committee shall receive compensation for his or her services, unless authorized by the Board of Trustees. Members of the Committee shall be reimbursed from the funds of the Pharmacopeial Convention for travel and other necessary expenses that may be incurred by them in the performance of their duties.

Section 8

During the period between stated meetings additional members may be added to the Council of Experts if the Board of Trustees, with the advice of the Executive Vice President-CEO, Council of Experts or Executive Committee, determines that such a need exists. The Nominating Committee for the Council of Experts shall nominate twice the number of qualified persons, from among whom the Convention members shall elect the additional Council members. Such election may be by mail and/or electronic ballot.

Section 9

The Chairperson of the Council of Experts shall appoint a division executive committee chairperson, after consultation with the chairs of the Expert Committees in such division, if the Council of Experts is divided into divisions as provided for in Section 2 of this Chapter. A Division Executive Committee shall be appointed by the Chairperson of that division from among the chairpersons of the Expert Committees within that division with the advice and consent of the Chairpersons in that division. A vacancy in a Division Executive Committee shall be filled by the Chairperson of the Division Executive Committee with the advice and consent of the Division Executive Committee.

Section 10

The Executive Committee of the Council of Experts shall be composed of not more than fifteen persons appointed by the Chairperson of the Council of Experts from among the members of the Council.

Section 11

The Council of Experts and the Executive Committee of the Council shall make such rules and adopt such procedures, not in conflict with the Constitution and Bylaws, as are sufficient to ensure the accuracy and adequacy of the content of the United States Pharmacopeia, the National Formulary, and other authorized publications, and to provide for adequate notice and opportunity for public comment and full and impartial consideration of all proposed changes in, and additions to, the content, as may be necessary to the proper discharge of their respective functions. Each Division and Expert Committee may make rules and adopt procedures for its operation, provided such rules and procedures are consistent with those of the Council of Experts. Prior to adoption, the proposed rules and procedures of the Council of Experts shall be made available to the members of the Pharmacopeial Convention for comment. The Committees shall submit the proposed rules and procedures so made for review by the Board and shall comment upon any proposals made by the latter pursuant to such review.

Section 12

The Chairperson of the Council of Experts shall, after consultation with the Division Executive Committees, determine the boundaries for the content of decisions made within the division, based on parameters established by the Executive Committee of the Council of Experts. Each Expert Committee shall function as a scientific decision-making body regarding the content of United States Pharmacopeia, National Formulary, and other authorized publications, having regard for the principles laid down by the Pharmacopeial Convention at its last meeting.

Section 13

The Council of Experts, through the Executive Vice President-CEO, shall present a report at the stated meeting of the Pharmacopeial Convention.

Section 14

Each Expert Committee shall elect a vice chairperson. In the event of a vacancy in the chair the vice chairperson shall become the acting chair until a new member of the Council of Experts is elected. In the event the vice chairperson cannot serve, the Executive Vice President-CEO shall appoint an acting chairperson until a new chairperson is elected.

Section 15

The Executive Committee of the Council of Experts, and the Division Executive Committees shall consult with the Executive Vice President-CEO on matters of general policy concerning the planning and executing of the United States Pharmacopeia, the National Formulary, and other authorized publications and of supplements thereto. The Executive Committee shall determine the proper placement of text within the publications of the Convention. The respective Division Executive Committees shall determine in their published rules and procedures the process by which decision making shall take place and be reviewed within that division. The respective Division Executive Committee shall authorize that appropriate notice and opportunity for public comment be given to all such proposals prior to their final approval and shall consider suggestions for changes contained in the comments received.

Section 16

The Executive Committee of the Council of Experts shall receive and rule upon all appeals for reconsideration, revision, or abrogation of standards adopted and decisions made by a Division Executive Committee or other Council body. Each decision of the Executive Committee on such appeals shall be referred to the Board of Trustees. If the Board of Trustees determines the appeal is one of a matter of

procedure, the Board may uphold the decision or remand it to the responsible body for reconsideration under proper procedures. If the matter on appeal is determined to be a scientific matter, the Board of Trustees may uphold the decision or remand it for review and vote by the full membership of the Council of Experts. After such review, which shall be given as promptly as practicable, the Council of Experts may uphold or reverse the Executive Committee's decision by a majority vote of the members voting.

Section 17

At least one year before the stated meeting of the Pharmacopeial Convention, the Executive Committee of the Council of Experts or the Division Executive Committees of the Council of Experts (if any) shall, at the request of the Chairperson of the Council of Experts, determine, prepare, and publish an outline of the number and types of Expert Committees deemed necessary for the efficient prosecution of the work of the next United States Pharmacopeia, the National Formulary, and other authorized publications. For scientific areas not currently encompassed by the present expert committees, the Chairperson of the Council of Experts shall consult with the Executive Committee of the Council and the Board of Trustees to determine the number and types of Expert Committees needed. Upon approval of the Board of Trustees, these determinations shall be followed in submitting to the Nominating Committee for the Council of Experts the names of persons to be considered for membership on the Council of Experts that is to be elected at the forthcoming stated meeting of the Pharmacopeial Convention.

Section 18

The Executive Committee of the Council of Experts may recommend to the Board of Trustees the removal, for cause, of any member of the Council of Experts or an Expert Committee.

CHAPTER VIII—THE COMMITTEE ON RESOLUTIONS

Section 1

The Committee on Resolutions, hereinafter referred to in this chapter as the Committee, shall consist of at least five members of the Pharmacopeial Convention.

At least sixty days prior to the stated meeting of the Pharmacopeial Convention, the President shall appoint at least five members of the Pharmacopeial Convention to serve as members of the Committee, one of whom shall be designated as Chairperson, and such additional associates, who need not be members of the Convention, as may be required to aid the Committee.

Section 2

The Committee shall be responsible for reviewing the recommendations made in the addresses and reports of the Officers, Committees, and Board of Trustees; reviewing resolutions that have been submitted to it in written form at least thirty days prior to a stated meeting by eligible organizations and by individual members of the Pharmacopeial Convention, conferring with the parties concerned whenever necessary about the intent or any other aspect of the resolution; for drafting statements in resolution form that shall reflect the official policy of the Pharmacopeial Convention; and for presenting all resolutions to the Convention for consideration, unless later introduction of a resolution by a member is permitted by two-thirds vote of the members present and voting.

Section 3

Prior to the stated meeting, the Committee shall present all resolutions for a needs assessment to the Board of Trustees and the appropriate Division Executive Committees. If the resolution calls for activity in a new area, then the Executive Committee of the Council of Experts and the Board of Trustees shall determine the need for a new Expert Committee or Committees.



Section 4

The Committee shall make an initial report in at least one session prior to the Final Session of the meeting; the final report of the Committee and the vote on the resolutions submitted by the Committee shall be conducted in the Final Session. If it has been determined that additional Council of Experts members are necessary to implement an adopted resolution or resolutions, the election may occur, if possible, after the vote on the resolutions.

CHAPTER IX—THE NOMINATING COMMITTEE FOR OFFICERS AND TRUSTEES

Section 1

The Nominating Committee for Officers and Trustees, hereinafter referred to in this chapter as the Committee, shall consist of five members of the Pharmacopeial Convention, one of whom shall be designated as Chairperson, appointed by the President with the advice and consent of the Board of Trustees, not later than six months before the stated meeting. Two of the members appointed shall be members of the Board of Trustees.

Section 2

The Committee shall nominate from the membership of the Pharmacopeial Convention or the Council of Experts, two members for the office of President, and two members for the office of Treasurer.

Section 3

The Committee shall nominate from the membership of the Pharmacopeial Convention or the Council of Experts sixteen members for the elected office of Trustee, divided into four classes: four shall represent pharmaceutical sciences, four shall represent medical sciences, six shall be without restriction concerning their affiliations, and two shall represent the public. Taking into account the nominees' backgrounds, the Committee may subdivide the ballot within each class, so as to present two nominees for each elected position within the sub-classification.

Section 4

The report of the Committee shall be submitted to the Secretary of the Pharmacopeial Convention not later than sixty days before the stated meeting; not later than forty-five days before the stated meeting, the Secretary shall notify the nominees of their selection by the Committee and the date of the stated meeting.

Section 5

The Committee shall present its report to the Convention, at which time additional nominations of Convention or Council of Experts members may be made from the floor for Officers and the Board of Trustees, which shall be seconded by at least ten members of the Pharmacopeial Convention and submitted in writing at once to the Secretary. A nomination for Trustee shall indicate in which of the four classes the nomination is being made or, if the ballot has been subdivided, which sub-classification.

CHAPTER X—THE NOMINATING COMMITTEE FOR THE COUNCIL OF EXPERTS

Section 1

The Nominating Committee for the Council of Experts, hereinafter referred to in this chapter as the Committee, shall consist of twenty persons, five of whom shall be members of the Pharmacopeial Convention, appointed by the President with the advice and consent of the Board of Trustees, together with ten members of the Council of Experts, appointed by the Executive Vice President-CEO taking into consideration the advice of the Executive Committee of the Council, and five other persons appointed by the Executive Vice President-CEO with the advice and consent of the Board of Trustees. Staff may participate

in the Committee's deliberations but shall not be permitted to participate in Committee votes. The five members of the Convention, appointed by the President, who serve on the Nominating Committee for the Council of Experts may not be members of the Council of Experts, Expert Committees, the Board of Trustees, salaried employees, or officers of the Pharmacopeial Convention.

The President of the Pharmacopeial Convention shall serve as the chairperson of the Committee. The Executive Vice President-CEO shall be a member, *ex officio*, of the Committee. The Committee shall elect a Vice Chairperson. The Secretary of the Convention shall serve as Secretary of the Committee.

The Committee shall be organized at least six months after the stated meeting of the Pharmacopeial Convention, and shall continue until its successor committee is appointed.

Section 2

Not later than seven months prior to the stated meeting of the Pharmacopeial Convention, the Secretary of the Committee shall issue to all who are entitled to representation in the Pharmacopeial Convention, as provided in Article II, Section 1, of the Constitution, to all members of the Convention and to the members of the Council of Experts, its Expert Committees and its advisory panels, a request that they submit the names of persons whose qualifications entitle them to consideration as nominees for membership on the Council of Experts. Each name submitted shall be accompanied by a statement on an official form supplied by the Committee indicating affiliations, academic and professional backgrounds, and the qualifications for the specific classification or classifications of membership on the Council of Experts as set forth in the outline referred to in Chapter VII, Section 17, of these Bylaws. All recommendations shall be mailed to the Secretary of the Pharmacopeial Convention not later than one hundred and twenty days prior to the stated meeting.

All recommendations received by the Secretary shall be submitted to the Committee not later than ninety days prior to the stated meeting and shall be given primary consideration by the Committee in selecting nominees for membership for the Council of Experts.

Section 3

At the stated meeting of the Pharmacopeial Convention, the Committee shall submit, through the Secretary, to each member, a list of names of persons whom it deems qualified to serve on the Council of Experts, together with a statement covering the classification for which each nominee is deemed best qualified, and the affiliations, academic and professional backgrounds and specific qualifications of each nominee.

The Committee shall nominate, insofar as possible, twice the number of qualified persons to be elected to meet each need shown in the outline referred to in Chapter VII, Section 17, of these Bylaws.

Additional nominations may be made from the floor for membership on the Council of Experts and shall be seconded on the floor by at least ten members of the Pharmacopeial Convention. Each such nomination shall be submitted on the official form and presented at once to the Secretary of the Pharmacopeial Convention.

Section 4

Between meetings of the Convention, the Committee will operate on a continuing basis and will be the source of providing the names of nominees for election to the Council of Experts, if needed. The Committee shall also provide the names of qualified experts as potential nominees for election to Expert Committees, in accordance with Chapter VII, Section 5 of the Bylaws.



Section 5

The Committee shall provide advice and consent to the Executive Vice President-CEO prior to the appointment of individuals to advisory panels to the Council of Experts.

CHAPTER XI—THE MEMBERSHIP COMMITTEE

Section 1

The Membership Committee shall consist of not less than seven and not more than ten members and shall be appointed by the President. Six members shall represent the organizational membership categories as defined in Article II of the Constitution and additional members shall be appointed without regard to their affiliation. The President shall appoint the Committee and name the chairperson, not later than sixty days after the stated meeting of the Pharmacopeial Convention. The Chairperson of the Board of Trustees, the President, and the Executive Vice President-CEO shall be members, ex officio, of the Membership Committee. The Secretary of the Pharmacopeial Convention shall serve as the secretary. Members of the Membership Committee shall retain their Pharmacopeial Convention membership until their successors are appointed.

Section 2

The Membership Committee shall identify and recommend organizations eligible to appoint a delegate for the Board of Trustees' consideration. Such recommendations shall take into account any guidelines provided by the Convention at the previous stated meetings. The Membership Committee shall adopt such procedures and criteria as are sufficient to ensure the fair and orderly consideration in the identification and recommendation of organizations eligible to appoint a delegate. The Board of Trustees shall approve such procedures. The Membership Committee shall report to the Board of Trustees at least annually on the composition of the Pharmacopeial Convention and the work of the committee since its last report.

Section 3

The Membership Committee shall also examine carefully the credentials of all delegates or alternate delegates in the absence of delegates. Credentials issued in blank, with the names of the delegates and alternate delegates to be inserted subsequently by other than the regularly constituted officers of the appointing eligible organization shall not be accepted. Credential forms presented for the first time at a meeting shall be independently verified before acceptance. Immediately prior to the opening of the stated meeting of the Pharmacopeial Convention, the Committee shall furnish to the Secretary of the Pharmacopeial Convention a list of delegates whose credentials have been approved by the Committee and a list of alternate delegates whom it has approved in lieu of delegates who are absent.

Section 4

The Membership Committee shall make a report to the Pharmacopeial Convention concerning all credentials that have not been approved. A majority vote of the members of the Pharmacopeial Convention shall be required to overrule a decision approving or disapproving the credentials of any person by the Membership Committee.

Section 5

The Membership Committee shall make a report to the Pharmacopeial Convention regarding the composition of the Convention and the work of the committee since the last stated meeting. The Membership Committee shall also provide to the Resolutions Committee guidelines for the types of institutions and bodies that should be invited to appoint a delegate for the following stated meeting.

CHAPTER XII—MEMBERS

Section 1

Each delegate shall present his or her credentials to the Membership Committee and, upon report by that Committee that the credentials are approved, shall be accredited and be seated as a member. If a member is absent from the stated meeting the alternate delegate shall present credentials as Alternate Delegate to the Membership Committee and, upon report that the credentials are approved, shall be accredited and be seated as the member for that stated meeting.

Section 2

The Officers of the Pharmacopeial Convention, the Board of Trustees, and the Chairpersons of Committees directed to report at the stated meeting, serving by authority of the preceding stated Pharmacopeial Convention or the Constitution and Bylaws shall be members, ex officio, of the Pharmacopeial Convention. The Membership Committee and the persons selected by the Board of Trustees as members-at-large shall be members of the Convention.

Section 3

Nominees selected by the Nominating Committee for Officers and Trustees for the Board of Trustees, the office of President and the office of Treasurer shall be members of the Pharmacopeial Convention for the stated meeting when their names are presented as nominees in accordance with Chapter IV, Section 1(g), of the Bylaws, whether present or not.

Section 4

A member of the Pharmacopeial Convention appointed by an organization named in the Constitution shall continue to be a member unless he or she dies, resigns, or fails to meet the requirements as provided in Article II, Section 6, of the Constitution or until his or her successor has been authorized by the eligible organization and his or her successor's credentials have been approved by the Membership Committee. The term of members appointed by organizations designated by the Board of Trustees shall end six months following the stated meeting.

Section 5

A member shall represent not more than one educational institution, organization, or designated division of the Federal Government.

Section 6

A member may be expelled for improper conduct or for violation of the Constitution and Bylaws, by a vote of not less than two-thirds of the members present and voting.

Section 7

Resignations of membership in the Pharmacopeial Convention shall be submitted in writing to the Secretary of the Convention. All resignations shall be acknowledged in writing by the Secretary and shall be reported to the Board of Trustees.

CHAPTER XIII—COMMITTEE OF TELLERS

Section 1

The Committee of Tellers shall consist of not more than six members and shall be appointed by the President. The President shall appoint the Committee and name the chairperson, not later than ninety days before the stated meeting of the Pharmacopeial Convention; the Committee shall serve until its successor shall have been appointed as provided herein. The Secretary of the Pharmacopeial Convention shall serve as the



secretary. Members of the Committee of Tellers shall retain their Pharmacopeial Convention membership until their successors are appointed.

Section 2

The Committee shall be responsible for ensuring the distribution, collection and counting of ballots, and reporting the vote to the Convention. The tellers' report shall be entered in full in the proceedings of the stated meeting or the minutes of the organization.

Section 3

On all questions related to voting, the latest edition of Robert's Rules of Order, Newly Revised, shall prevail, unless otherwise specified herein.

CHAPTER XIV—MEETINGS

Section 1

Meetings of the Pharmacopeial Convention shall be held as provided in Article VII of the Constitution.

The call for a stated meeting of the Pharmacopeial Convention shall be issued as provided in Chapter I, Section 7, of these Bylaws.

The call for a special meeting of the Pharmacopeial Convention shall state the purpose for which the meeting is called and shall be mailed by the Secretary to all members and to all those entitled to representation under the Constitution, not later than sixty days prior to the meeting. The business of a special meeting shall be limited to the purpose for which the meeting has been called.

Section 2

Each stated or special meeting of the Pharmacopeial Convention shall consist of an opening and a final session and such number of intervening sessions as the Convention may direct in order to conduct the business of the Convention. At least one hour shall elapse between any two sessions, and no session shall be opened at a time earlier than that announced at the session immediately preceding.

Any session may be recessed by a majority vote and shall be reconvened at the time specified in the recess motion.

Section 3

The Secretary, with the advice and consent of the President and the Executive Vice President-CEO, shall prepare the order of business for each stated meeting and shall distribute it to the Members, Delegates, and Alternate Delegates at least thirty days prior to the meeting. That order of business shall govern unless otherwise directed by the affirmative votes of not less than two-thirds of the members present and voting.

On all questions of procedure, the latest edition of Robert's Rules of Order, Newly Revised, shall prevail, unless otherwise specified herein.

CHAPTER XV—THE CORPORATE SEAL

The seal of the Corporation shall contain the words: "The United States Pharmacopeial Convention. Corporate-1900-seal, D.C."



CHAPTER XVI—AMENDMENTS

Section 1

Every proposition to amend these Bylaws, except as hereinafter provided, shall be submitted in accordance with the procedures to amend the Constitution as set forth in Article VIII, Sections 1 and 2, of the Constitution, and shall, under either procedure, upon receiving the affirmative votes of not less than three-fourths of the members present and voting, become a part of these Bylaws.

Section 2

The Board of Trustees may at its discretion mail to the members of the Pharmacopeial Convention a proposition to amend or alter these Bylaws. A period of sixty days shall be allowed for the submission of comments on the proposition. A summary of the comments shall accompany the mail ballot by which the vote of the member may be recorded and returned within ninety days of the date printed on the ballot. Upon receiving the affirmative vote of seven-eighths of the members voting, with a total of not less than one hundred and thirty members voting, it shall become a part of these Bylaws.

CHAPTER XVII—DISSOLUTION

In the event of dissolution of the corporation, the Board of Trustees shall after paying or making provision for the payment of all of the liabilities of the corporation, dispose of all of the assets exclusively for the purposes of the corporation in such manner as the Board of Trustees shall determine to such organization or organizations, organized and operated exclusively for charitable, educational, or scientific purposes as at the time shall qualify as an exempt organization or organizations under Section 501(c)(3) of the Internal Revenue Code of 1954 (or the corresponding provision of any future United States Internal Revenue Law.