



RULES AND PROCEDURES OF THE 2010–2015 COUNCIL OF THE CONVENTION

February 14, 2011

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1. GENERAL

1.01 Rules and Procedures

In accordance with Article IX, Section 3 of the 2010-2015 USP Bylaws (Bylaws), the Council of the Convention (CoC) shall adopt Rules and Procedures (Rules) for its own governance and to carry out its duties.

1.02 Approval of Rules

Prior to adoption, the proposed Rules shall be submitted to the Governance Committee of the Convention for review and the Board for approval as set forth in Article X, Section 1c of the Bylaws.

1.03 Review and Update of Rules

The Rules will be reviewed annually by the CoC for appropriate revisions and updating. Any revisions must be approved as set forth in Section 1.02 above.

1.04 Defined Terms

Capitalized terms appearing in these Rules and not defined herein will have the meanings given to such terms in the Bylaws.

1.05 Meetings; Notes

The CoC shall meet on a regular basis as it deems necessary to fulfill the duties described in these Rules. Meetings may be held in person or electronically, and participants not able to attend a face-to-face meeting will be allowed to participate electronically. Notes shall be kept of all meetings, and a summary of such notes including all actions and decisions taken by the CoC shall be made available to the Board and the Convention.



2. COUNCIL OF THE CONVENTION COMPOSITION

2.01 Number and Representation

As defined in Article IX, Section 2 of the Bylaws, the CoC shall be composed of not more than twenty-five (25) persons who are Delegates or other representatives of Voting Organizational Members, or Voting At Large Members. The Council shall include at least one Voting Organizational Member representative from each category of Voting Organizational Member specified in Article III, Section 1a(i). Namely:

- Academic institutions including accredited colleges and schools of allopathic, osteopathic, and veterinary medicine, pharmacy and nursing and other recognized academic institutions in health and science-related fields, and associations thereof;
- Health practitioner professional and scientific associations and organizations including those that represent medicine, pharmacy, and nursing;
- Consumer and other organizations representing the public interest;
- Manufacturer, trade, and affiliated associations;
- Governmental bodies or divisions or associations thereof; and
- Non-governmental standards setting and conformity assessment bodies.

2.02 Method and Term of Appointment

The CoC members shall be appointed by the President in consultation with the Executive Vice President – Chief Executive Officer (EVP-CEO) and subject to the approval of the Board of Trustees. The CoC shall be organized not later than six months after the Regular Membership Meeting and its members shall continue in office until adjournment of the next Regular Membership Meeting or until their successors are appointed. A general call will be issued to all Voting Organizational Members for volunteers to serve on the Council of the Convention. Based on the response to this call, the President and EVP-CEO may need to seek Voting Organizational Members from specific categories to achieve the balance required by the Bylaws. The President may appoint the members of the CoC incrementally; i.e., a small number of members initially, and at any time thereafter the President can make additional appointments up to the 25, providing the representation conditions are satisfied.

2.03 Chair

The President of the Convention shall be the Chair of the CoC.

2.04 Secretary

The Secretary of the Convention shall serve as Secretary of the CoC.

3. DUTIES

According to Article IX, Section 1 of the Bylaws, the CoC shall have the following duties:

3.01 Recommending New Voting Organizational Members

The CoC shall recommend to the Board of Trustees additional Voting Organizational Members for invitation to the USP Convention membership. Such recommendations shall be based on the criteria and procedures set forth in Sections 4 and 5 of these Rules.

3.02 Removing Voting Organizational Members

The CoC shall recommend to the Board of Trustees the removal of Voting Organizational Members for cause based on the criteria and procedures set forth in Section 6 of these Rules.



3.03 Inviting Observers to the USP Membership

The CoC shall have the authority to invite organizations as Observers to the Convention based on the criteria set forth in Section 7 of these Rules. Such Observers shall be allowed to participate in the Convention in accordance with the rules and procedures set forth in Section 8.

3.04 Developing Resolutions

The CoC shall be responsible for developing proposed resolutions that advance the purposes of the Convention set forth in Article II of the Bylaws and submitting such resolutions to the Voting Members for approval. Consideration of resolution proposals will be conducted in accordance with the process set forth in Section 9 of these Rules.

3.05 Engaging and Communicating with Membership

The Council shall develop approaches and mechanisms for engaging and communicating with the Membership in periods between Regular Membership Meetings in accordance with the provisions set forth in Section 10 of these Rules.

4. CONSIDERING VOTING ORGANIZATIONAL MEMBERS

4.01 Balance and Total

In recommending possible Voting Organizational Members to the Board of Trustees, the Council shall ensure that at all times not less than sixty percent (60%) of the Organizational Voting Members fall within the subcategories below.

- Academic institutions including accredited colleges and schools of allopathic, osteopathic, and veterinary medicine, pharmacy and nursing and other recognized academic institutions in health and science-related fields, and associations thereof; and
- Health practitioner professional and scientific associations and organizations including those that represent medicine, pharmacy, and nursing.

The CoC shall also ensure that the total number of Voting Organizational Members does not exceed six hundred (600).

4.02 Previously-Named Organizational Members

According to Resolution 1 adopted by the USP Convention on April 24, 2010, initial Voting Organizational Members of the USP Convention shall include all organizations that were *named* in the USP Constitution prior to the adoption of the 2010 Amended and Restated Bylaws. These organizations shall continue to be members until they resign or are removed for cause in accordance with the Bylaws.

4.03 Elements to Consider about Voting Organizational Members

The CoC will consider the following elements when making recommendations to the Board of Trustees. The Council will seek a broad range of perspectives within its Voting Organizational Members, while maintaining the balance noted in Section 4.01.

1. Mission/charter/statement of purpose
 - a) Clear applicability to USP core and allied compendial standards and other initiatives
 - b) Focus of the organization is relevant to USP's focus and priorities
 - c) Mission and vision is compatible with USP mission and vision
 - d) Stability – in existence for five years (preferred)
 - e) Proven performance – demonstrates significant accomplishments
2. Governance Structure
 - a) Accreditation status (if applicable)
 - b) Appropriate board, staff, committees, etc. – sound structure, size, interactions
 - c) Any obvious outside influences
 - d) Not-for-profit



3. Outreach/influence capacity
 - a) Type of advocacy/education offerings/ability to influence public policy
 - b) Scientific / practice influence
 - c) Regulatory/legal
 - d) Single/multi-issue
 - e) Broad geographic focus: national, international, regional
 - f) Size of organization/membership
 4. Differentiation from current members
 - a) Potential to add breadth rather than redundancy
 - b) Ability to integrate ethnic, minority, social perspectives into membership
 - c) Intellectual and experiential capacity to contribute
 - d) Specific constituency vs. broader community
 - e) If membership overlaps with other organizations is purpose significantly different
 6. Historical or potential future interactions with USP
 7. Re-invitation of previous membership – appropriate involvement and interest
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5. SELECTING AND INVITING VOTING ORGANIZATIONAL MEMBERS

5.01 Organizations for Consideration

Recommendations for potential Voting Organizational Members may come through the CoC, Council of Experts, Expert Committees, Board of Trustees, and Staff. Additionally, organizations may contact USP directly to be considered for membership. All organizations recommended for or requesting membership shall be subject to the selection and invitation process described in this Section 5.

5.02 Vetting Potential Voting Organizational Members

If identified as an organization of interest by the Council, Staff will prepare an organization “profile” for CoC consideration/discussion to ensure that the factors about the organization outlined in Section 4.03 are considered. Additional information will be provided as appropriate or requested by the CoC.

5.03 Approval by the CoC and Recommendation to the Board of Trustees

If approved by the CoC, a formal recommendation will be presented to the Board of Trustees by the CoC with the rationale for inviting the organization to become a Voting Organizational Member.

5.04 Non-Approval of Membership

If an organization that is formally considered for membership according to Section 5.02 is not recommended for membership by the CoC, the Board will be informed of the CoC’s decision and the rationale for the decision. The Board may request that the CoC reconsider its recommendation. If the Board agrees with the CoC’s recommendation, and the request came from the organization, the organization will be informed of the decision and rationale.

5.05 Approval by the Board of Trustees

The CoC’s recommendations for membership shall be subject to approval by the Board of Trustees, which under the Bylaws is responsible for selection of Voting Organizational Members based on such recommendations.



5.06 Method of Invitation to USP Convention Membership

Upon Board approval, a letter will be sent (in hard copy and by email, if available) to the organization's executive officer extending an invitation to become a Voting Organizational Member (copying any other individuals within the organization that might facilitate the process). The letter will be organization-specific and explain how USP perceives the two organizations working together and their relevance to one another, citing compatible missions, specific resolutions, strategic directions, and/or other initiatives. The letter will explain that there are no dues associated with USP membership. The letter will stipulate that the invitation remains valid for twelve months from the date of the letter.

5.07 Invitation Follow-up

If no acknowledgment of the invitation is received within one month of issuing the invitation, USP Staff will contact the addressee to confirm that the invitation was received. Additional copies will be sent if needed to ensure that the organization has received the letter of invitation.

If after six months there is no response, USP will contact the organization again to remind the invited Voting Organizational Member of the stipulations of the invitation; i.e., that the invitation will be rescinded one year from the date of the original letter of invitation and the organization will be removed as a Voting Organizational Member.

If it is determined during the six-month follow up that a change in leadership has occurred, another letter will be issued to the new or acting executive, noting that the invitation will be rescinded (and the organization removed as a Voting Organizational Member) one year from the date of the original letter of invitation. This notification will be conducted in accordance with the steps outlined in Section 6.

A 'not interested' response at any time will cause the removal of the organization from the list of Voting Organizational Members. This notification will be conducted in accordance with the steps outlined in Section 6.

5.08 Acceptance of Invitation; Designation of Delegate

Designation of a representative who is authorized to vote for the Voting Organizational Member (Delegate) constitutes acceptance of the USP's invitation. A suitable paper or electronic form will be provided for this purpose; however, any reasonable notification received by USP from a recognized executive of the organization will be deemed adequate for such designation.

A Voting Organizational Member may change its Delegate by notifying USP of such change. As above, while a paper or electronic form is preferred, any reasonable notification received by USP from a recognized executive of the organization will be accepted.

Voting Organizational Members also may name other representatives from the organization with whom USP may wish to interact; however, Convention related communications will be sent to the Delegate and the executive officer.

6. REMOVAL OF VOTING ORGANIZATIONAL MEMBERS

6.01 Authority to Remove Voting Organizational Members

According to Article III, Section 7 of the Bylaws, any Voting Organizational Member may be removed for cause from Membership by a two-thirds vote of the Board of Trustees upon the recommendation of the CoC, pursuant to rules and procedures developed by the CoC and approved by the Board of Trustees.



6.02 Definition of Cause for Removal

Article III, Section 7 of the Bylaws define “cause” as follows:

1. Failure by a Voting Organizational Member to name a Delegate within twelve (12) months after issuance of an invitation to become a Voting Organizational Member, or
2. Failure of a named Delegate to attend two (2) consecutive Regular Membership Meetings.

No. 1 above shall include the failure by a Voting Organizational Member to fill a Delegate vacancy for 12 months.

6.03 Notification of Removal

Before recommending removal of a Voting Organizational Member to the Board of Trustees for cause, the CoC will issue notification of such removal to 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 the intent of the CoC to recommend removal to the Board of Trustees.

The Voting Organizational Member subject to removal will be given 30 days in which to respond to the notification letter. It is expected that such response would come from a recognized executive of the Voting Organizational Member. If, in the judgment of the CoC, the response from the Voting Organizational Member adequately explains the lack of engagement, the CoC may choose to vacate its recommendation for removal. If there is no response from the organization, the CoC will recommend removal to the Board of Trustees.

6.04 Eligibility of Removed Member for Future Consideration.

An organization that has been removed from membership shall not be precluded from reapplying or being reconsidered for membership.

7. CRITERIA FOR SELECTION OF OBSERVER ORGANIZATIONS

7.01 Balance and Total of Observer Organizations

In selecting Observers to the USP Convention, the CoC shall make an effort to achieve balanced representation from academia, industry, professional and scientific organizations, governmental agencies, and non-governmental standards setting and conformity assessment bodies. In addition, Observers will be sought from all regions of the world, and a balance among regions shall also be sought. The CoC shall also ensure that the total number of Observers does not exceed one hundred (100).

7.02 General Criteria for Considering Observer Organizations

An organization may be recommended for observer status by the Council of the Convention, Board, Council of Experts, Staff, or an organization may request observer status. An invitation to be an Observer provides an opportunity for both the Observer organization and USP to gain experience on the extent to which the organization may wish to be considered for a Voting Organizational Member position.

Organizations that may be considered for Observers include, but are not limited to:

1. Organizations that are current members, where additional representation is desired by USP or requested by the organization;
2. Organizations that are invited to membership, but cannot accept due to internal procedures/ restrictions;



3. Organizations that are desirable to have in the Convention, but that do not completely meet member criteria or whose interest in and commitment to USP is not yet established; and
4. Organizations that meet all member criteria, but because of the requirements in Section 4.01 cannot be invited to membership.

Organizations identified for or requesting Observer status shall be vetted by the CoC and judged on:

- Value to USP;
- Unique perspective on issues relevant to USP's programs and activities; and
- Ability to meet criteria used for member consideration (would not need to meet all criteria)

7.03 Vetting Potential Observer Organizations

If identified as an organization of interest by the Council, Staff will prepare an organization "profile" for CoC consideration/discussion to ensure that as many criteria as can be determined about the organization (as for a Voting Organizational Member) are reviewed.

7.04 Approval of Observer Organizations

As stated in Article III, Section 8 of the Bylaws, the CoC has the authority to invite Observer organizations to the USP Convention.

7.05 Method of Invitation to Observer Status

A letter will be sent (in hard copy and by email, if available) to the organization's executive officer extending an invitation to become an Observer to the USP Convention (copying any other individuals within the organization that might facilitate the process). The letter will make it clear that the purpose of Observer status is to affirm USP's desire to establish or strengthen the relationship between USP and the organization. The rights of a USP Observer and rules for participation also will be defined in the invitation. The letter will stipulate that the invitation remains valid for six months from the date of the letter and that the organization must name a representative within the six month period.

7.06 Observer Invitation Follow-up

Within one month of issuing the invitation, USP Staff will contact the addressee to confirm that the invitation was received.

If after three months there is no response, USP will contact the organization again to remind the invited Observer organization of the stipulations of the invitation; i.e., it will be rescinded six months from the date of the original letter of invitation.

A 'not interested' response at any time will remove the organization from further consideration as an Observer.

7.07 Acceptance of Observer Invitation

Designation of a representative constitutes acceptance of the USP's invitation. Any reasonable notification received by USP from a recognized executive of the organization will be deemed adequate for such designation.

An Observer organization may change its representative by notifying USP of such change. As above, any reasonable notification received by USP from a recognized executive of the organization will be accepted.

7.08 Term of Observer Status

An organization that has been invited to and accepted Observer status shall remain an Observer until the end of the next Regular Membership Meeting, unless the organization voluntarily terminates its Observer status prior to that time.



8. PARTICIPATION BY OBSERVER ORGANIZATIONS

8.01 Purpose of Observer Status

Observer status was established within the USP Convention to allow limited participation by organizations that collaborate, assist, and share in USP's public health mission.

8.02 Observer Benefits and Restrictions

Observers will receive Member Memoranda and other member communications, have access to USP's Member Page, and will be invited to attend the 5-year meetings of the Convention. At the Regular Membership Meeting, Observers may participate in the Open Hearings for Resolutions and Bylaws.

Observers are not Members and do not have voting rights. Observers may not participate in sessions of the Regular Membership Meeting that are reserved for Delegates only.

9. RESOLUTIONS DEVELOPMENT

9.01 Source and Purpose of Resolutions

The CoC will solicit resolution proposals from any interested party and will be responsible for developing resolutions that advance the purposes of the Convention as stated in Article II of the Bylaws; namely, to develop and disseminate public standards for medicines and other articles, and engage in related public health programs.

9.02 Resolution Submission

The CoC will notify all Voting Organizational Members, Delegates, Representatives, and Observer Organizations no later than six months before the Regular Membership Meeting requesting submission of suitable resolution proposals for consideration by the CoC. To the extent possible, the CoC will attempt to facilitate easier submission of proposals through online forms, etc., and will ensure that the accompanying explanations and background information clearly describes USP's strategic priorities and direction so that submissions are aligned with USP's strategic focus.

9.03 Resolution Review Process

The CoC will utilize the following resolutions review process:

- Each submission will be acknowledged and evaluated for completeness by USP Staff. Staff will consult with the submitter to obtain additional information/rationale, if needed.
- Depending on volume and at reasonable intervals, complete submissions will be forwarded to the CoC with a completed evaluation form and recommendation.
- After reviewing the submissions and Staff recommendations, CoC members will indicate whether they agree or disagree with the assessment. Disagreements will be discussed further via email or at the next meeting of the CoC.
- Staff will develop background and rationale statements for any submissions that are approved by the CoC for consideration by the Membership.
- Staff will inform submitters of the final disposition of their submission.
- The CoC will assign a CoC member to each approved resolution, who will be responsible for understanding relevant details and important points of the resolution and who will respond to questions during debate at the Regular Membership Meeting.

9.04 Resolutions Reviewed by the Board of Trustees and Council of Experts

As provided for in Article IX, Section 1(d) of the Bylaws, resolutions developed by the CoC shall be submitted to the Board and Council of Experts for a resource assessment.



9.05 Resolutions Submitted to the USP Membership

In accordance with Article IX, Section 1(d) of the Bylaws, resolutions developed by the CoC will be provided to the Membership along with the findings of the Board and Council of Experts by electronic mail or by a link to the USP website not later than thirty (30) days prior to the Regular Membership Meeting.

10. ENGAGING AND COMMUNICATING WITH THE MEMBERSHIP

10.01 Approaches and Mechanisms

According to Article IX, Section 1(e) of the Bylaws, the CoC shall develop approaches and mechanisms for engaging and communicating with the Membership in the periods between Regular Membership Meetings. The CoC shall review such approaches and mechanisms annually to assess their effectiveness. In fulfilling this duty, the CoC should clearly define the purpose of such engagement and communication, which could include the following:

- a) Build a better understanding of USP's mission and vision among the membership and raise awareness about the relevance and benefit of USP's activities, programs, and services to benefit Convention members;
- b) Build closer relationships with Convention member organizations, tap into their expertise on current and developing healthcare issues, and seek their input on USP's current activities and future direction;
- c) Create more frequent opportunities for exchanges of ideas and perspectives on USP's opportunities and challenges between/among Convention member organizations, USP Staff, and other USP governing and advisory bodies such as Stakeholder Forums, the Council of Experts and Expert Committees, and the Board of Trustees;
- d) Better fulfill USP's role as an unbiased convener, allowing it to more effectively reach out to and interact with organizations that are affected by USP standards and who in turn can affect USP's work;
- e) Help identify and recruit organizations and individuals as potential USP Voting Organizational Members and Observers; and
- f) Enable Voting Organizational Members, Delegates, and Voting At Large Members to exercise their USP governance responsibilities in a more informed and active way.

10.02 Board Report

The CoC shall provide an annual report to the Board of Trustees on its membership engagement and communication activities.

