

RULES AND PROCEDURES OF THE 2015–2020 COUNCIL OF EXPERTS

APPROVED 2018-06-01

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1. GENERAL

1.01 Governance and Authority

As set forth in Article VII, Section 1 of the Bylaws, the Council of Experts and its Expert Committees are responsible for determining and approving content of the *United States Pharmacopeia and National Formulary (USP-NF)* and other compendia and information that may be published on behalf of the Council of Experts or an Expert Committee (including translations and line extensions of the *USP-NF*) and any associated reference standards. In order to fulfill these responsibilities, the Council of Experts is authorized under Article VII Section 5 of the Bylaws to make such Rules and Procedures, not in conflict with the Bylaws, that are sufficient to ensure the accuracy and adequacy of the content of the *USP-NF* and other authorized publications, and to provide for adequate notice and opportunity for public comment and full and impartial consideration of all proposed changes to such publications. These Rules and Procedures of the Council of Experts (Rules) govern the activities of the Council of Experts and those bodies related to the Council of Experts, including the Expert Committees, Expert Panels, Joint Standard-Setting Subcommittees, Stakeholder Forums and Project Teams. USP staff may periodically also issue Guidelines publicly accessible on the USP website (e.g., Guidelines for *USP-NF* Submissions; Accelerated Revisions, and others) consistent with the Rules to promote transparency of USP's internal processes and procedures.

1.02 Procedural Questions

On procedural questions, the 11th Edition of *Robert's Rules of Order, Newly Revised* shall prevail where the Rules are silent.

1.03 Adoption and Amendment

Prior to adoption by the Council of Experts, these Rules shall be submitted to the Governance Committee of the Convention (Governance Committee) and the Board of Trustees (Board) for review and approval as provided in Article VII, Section 5 of the Bylaws. These Rules may be amended at any time during the cycle, provided that any proposed amendment also shall be submitted to the Governance Committee and the Board for review and approval prior to adoption.

2. STANDARDS OF CONDUCT

2.01 Code of Ethics

Members of the Council of Experts, Expert Committees (COE/EC Expert) and Expert Panels shall be required to adhere to the USP Code of Ethics, which is available on USP's website.

2.02 Representation

COE/EC Expert members serve USP as individual experts; they do not serve any outside interest. A member of an Expert Panel may serve an outside interest provided such interest is disclosed pursuant to Section 5.05(a) of these Rules. A COE/EC Expert or Expert Panel member shall not use his or her membership in any way that is, or appears to be, motivated by private gain or any outside interest.

2.03 Conflict of Interest

- (a) General. Pursuant to Article VIII, Section 1, of the Bylaws and the Conflicts of Interest Policy in the Code of Ethics, all CoE/EC Expert members shall adhere to the Conflicts of Interest provisions set forth in this section. Expert Panel members are subject to the Conflict of Interest requirements contained in Section 5.05(a) of these Rules. As used in these Rules, "Conflict of Interest" includes, but is not limited to, any matter in which an Expert has a direct or indirect financial interest or any other personal interest of any kind which would preclude or appear to preclude such individual from exercising impartial judgment or otherwise acting in the best interest of USP.
- (b) Recusal. No CoE/EC Expert shall vote nor take part in the final discussion or deliberation of any matter in which he or she has a Conflict of Interest. An Expert Panel member may participate in deliberations or recommendations regarding matters in which he or she has a Conflict of Interest provided disclosure of a Conflict of Interest is made pursuant to Section 5.05(a) of these Rules.
- (c) Assignment of Work. No CoE/EC Expert shall be assigned the primary responsibility to work on an issue or question in which he or she has a Conflict of Interest. He or she may, however, provide relevant scientific information and may participate in discussions regarding such issue or question.; providing, however, that final discussion, deliberation and vote on such issue or question shall be conducted without such member present in person or by telephone. Expert Panel members who have a Conflict of Interest may be assigned work on matters in which they have a Conflict of Interest provided disclosure of such Conflict of Interest is made pursuant to Section 5.05(a) of these Rules.
- (d) Conflict of Chair. In the case where the chairperson of an Expert Committee has a Conflict of Interest, the vice chairperson will serve. If the vice chairperson also is conflicted, a designated non-conflicted member shall be selected by a majority of the other non-conflicted members to lead the discussions. The chairperson of an Expert Panel that has a Conflict of Interest may continue to serve as chairperson provided disclosure of such Conflict of Interest is made pursuant to Section 5.05(a) of these Rules.

2.04 Disclosure Statements

- (a) Requirement. Each COE/EC Expert and Expert Panel member shall submit to USP a Disclosure Statement disclosing all employment, professional research, organizational memberships, and other relevant interests. The Disclosure Statement, shall be updated by the member as necessary to keep it current or as requested periodically by USP, and the member is also obligated to advise the Expert Committee or Expert Panel chair and USP staff of changing or emerging interests. Except as specified in Section 2.05 below (e.g., periodic disclosure to fellow Expert Committee or Expert Panel members), the information provided in Disclosure Statements shall be kept confidential.

- (b) Failure to Submit Statement. If a CoE/EC Expert or Expert Panel member fails to submit a Disclosure Statement, that member will not be allowed to participate in CoE/EC or Expert Panel activities until such statement is submitted to USP.

2.05 Identification and Resolution of Conflict Issues.

- (a) USP Responsibility. USP staff, together with the chairperson of an Expert Committee or Expert Panel shall review Disclosure Statements on a periodic basis identify potential Conflicts of Interest and to ensure that all interests disclosed on the Disclosure Statements are disclosed to the other members of the Expert Committee or Expert Panel. Where an apparent or potential Conflict of Interest is identified by a CoE/EC Expert and cannot be resolved through voluntary recusal and/or intervention by the EC chair, the matter shall be referred to the Chair of the Council of Experts (CoE Chairperson) and the USP Executive Secretariat for resolution. The CoE Chairperson shall have final authority for resolving matters involving Conflicts of Interest. The minutes of any meeting at which a Conflict of Interest issue has been identified shall reflect disclosure and resolution of such issue, including any recusal of a CoE/EC Expert due to Conflict of Interest.
- (b) Expert Responsibility. Any CoE/EC Expert or Expert Panel member who believes or should have reason to believe that he or she may have an apparent or potential Conflict of Interest shall notify USP staff and the chairperson of the Expert Committee or Expert Panel, as applicable, prior to any work on or discussion of the matter in question. Conflict of Interest issues identified by a CoE/EC Expert shall be resolved as described in Section 2.05(a) above.

2.06 Confidentiality

- (a) Obligation to Maintain Confidentiality. Each CoE/EC Expert member shall maintain the confidentiality of all information gained in the course of his or her activities as a CoE/EC Expert, and shall not use or disclose such information for any purpose, unless such information is already publicly available. In case of doubt as to whether information is deemed confidential, the information shall be treated as confidential until otherwise indicated by the USP Executive Secretariat or USP Secretary. Expert Panel members are obligated to maintain confidentiality of materials in accordance with Section 5.05(b) of these Rules. CoE/EC Experts and Expert Panel members should receive and send any confidential electronic communications (i.e. all communications in the case of Expert Committee members) from a private email address, not shared with or accessible to their employer or any other 3rd party.
- (b) Confidentiality Agreement. Each CoE/EC Expert and Expert Panel member shall sign a confidentiality agreement reflecting the confidentiality obligations set forth in Section 2.06(a). If a CoE/EC Expert or Expert Panel member fails to sign and submit a confidentiality agreement, that member will not be allowed to receive any confidential information or participate in the Council of Experts, Expert Committee or Expert Panel activities until such agreement is submitted to USP. Where it is agreed upon formation of an Expert Panel that the Panel will not receive confidential information and will work solely in a non-confidential manner, the members of such Panel will be exempted from the requirement to sign and submit a confidentiality statement to USP as provided in Section 5.05(b).

3. THE COUNCIL OF EXPERTS

3.01 CoE Chairperson

In accordance with Article IV Section 11 of the Bylaws of USP, the Executive Vice President-Chief Executive Officer (EVP-CEO) or the EVP-CEO's designee shall serve as CoE Chairperson and establish policies and Work Plans (as defined in Section 4.05

below), assign responsibilities, and otherwise direct the work of the Council of Experts and its Expert Committees. The CoE Chairperson shall chair all meetings of the Council of Experts. In the event of the temporary absence of the CoE Chairperson, the CoE Chairperson shall designate another person to act in his or her stead. The CoE Chairperson may also appoint USP staff members to act as scientific liaisons to Expert Committees (Scientific Liaisons) to work on behalf of the CoE Chairperson to support and assist the Council of Experts, Expert Committees and Joint Standard-Setting Subcommittees in carrying out their Work Plans and other assigned responsibilities.

3.02 Election and Duties

The Council of Experts shall be elected in accordance with Article VII, Section 2 of the Bylaws. Each member of the Council of Experts shall chair an Expert Committee. In the event of a vacancy in the Council of Experts the Council of Experts shall appoint a replacement as provided in Article VII, Section 6 of the Bylaws.

3.03 Removal

A member of the Council of Experts may be removed for cause by the Board of Trustees, upon recommendation of the Council of Experts as provided in Article VII, Section 2 of the Bylaws. As used herein, “cause” may include, but is not limited to, unprofessional conduct, inattention to duties, or failure to abide by USP’s Code of Ethics or these Rules.

4. EXPERT COMMITTEES

4.01 Number of Committees

The Board of Trustees shall approve the number of Expert Committees in accordance with Article VII, Section 3 of the Bylaws. The Council of Experts may at any time during a current cycle recommend to the Board that additional Expert Committees be established to carry out the work of the Convention, in accordance with Article VII, Section 4 of the Bylaws. If approved by the Board, the chairs of such additional Expert Committees shall be appointed by a majority vote of the Council of Experts.

4.02 Election of Expert Committee Members

Members of each Expert Committee shall be elected by the Council of Experts. Each member of the Council of Experts, working with staff, shall nominate individuals for election to his or her Expert Committee. An individual may be elected to more than one Expert Committee. A member of the Council of Experts may be elected to serve as a member of any other Expert Committee.

4.03 Removal and Vacancies

A member of an Expert Committee may be removed for cause by the CoE Chairperson, upon the recommendation of the Expert Committee chairperson, and cause shall have the meaning set forth in Section 3.03 above. In the event of a vacancy on an Expert Committee or if additional members are determined to be needed on any Expert Committee, the CoE Chairperson shall appoint new members.

4.04 Vice Chairperson

The chairperson of each Expert Committee, in consultation with the CoE Chairperson, shall appoint a vice chairperson to serve in the temporary absence of the chairperson. Such appointment shall be for a term of one year and may be renewed. In the event of a permanent vacancy of the chairperson’s office, the vice chairperson shall serve as chairperson until a new chairperson is appointed by the Council of Experts in accordance with Article VII, Section 6 of the Bylaws.

4.05 Expert Committee Work Plan

Each Expert Committee shall work with the CoE Chairperson and other USP staff to develop a work plan which sets forth the standard setting goals and objectives of the Expert Committee for the cycle (Work Plan). The Work Plan shall be revised as needed subject to the approval of the CoE Chairperson. The Work Plan and any revisions thereto shall be made publicly available. Reports of progress made under the Work Plan shall be provided to the CoE Chairperson and made publicly available on a regular basis.

4.06 Subcommittees

Expert Committees may form subcommittees to advance their work. A subcommittee is a group of members of a single Expert Committee assigned to perform a certain task of the Expert Committee. A joint subcommittee is a group of members from two or more Expert Committees assigned to perform a certain task of interest to such Expert Committees. Unlike a Joint Standard Setting Subcommittee described in section 4.07, a subcommittee or joint subcommittee may only make recommendations to the Expert Committee responsible for a particular task or issue and all decision-making authority shall be retained and exercised by the Expert Committee. A joint subcommittee shall only make recommendations to, and be directed by, one Expert Committee, which shall be designated by the CoE Chairperson and exercise decision-making authority with respect to the task. Expert Committees not charged with oversight and decision-making authority shall be kept apprised of the work of a joint subcommittee by their members that have been assigned to the joint subcommittee.

4.07 Joint Standard-Setting Subcommittees

The CoE Chairperson, in consultation with the Council of Experts, may establish Joint Standard-Setting Subcommittees consisting of members from two or more Expert Committees. The chair and members of the Joint Standard-Setting Subcommittee are elected by the Council of Experts. Such Joint Standard-Setting Subcommittees shall be empowered to develop and approve compendial standards, including the use of certain reference standards consistent with the guideline approved by the Council of Experts. The work and procedures of such Joint Standard-Setting Subcommittees shall be undertaken under the same rules applicable to Expert Committees.

4.08 Expert Consultations

From time to time, an Expert Committee (Requesting Expert Committee) may request that a CoE/EC Expert from another Expert Committee participate in the Requesting Expert Committee's meetings or other work in order to obtain additional expertise in a particular area. Such participating CoE/EC Experts shall not be deemed members of the Requesting Expert Committees or vote on any Requesting Expert Committee matter. An Expert Committee may also request assistance from an individual who is not a CoE/EC Expert to participate in discussions or review documents where such individual provides necessary expertise not available within the Council of Experts or Expert Committees. Such individual shall be required to sign a confidentiality agreement requiring that the confidentiality of all information provided to such individual be maintained.

5. EXPERT PANELS

5.01 Formation

The CoE Chairperson may form an advisory Expert Panel to provide additional expertise and perform an assigned task for a particular Expert Committee, Expert Committees, or CoE Chairperson. The CoE Chairperson shall appoint the members of the Expert Panel, who may be removed by the CoE Chairperson at any time. USP may issue a Call for Candidates to obtain the broadest expertise and diverse membership on a particular topic or issue. At least one member of the Expert Committee to which the Expert Panel reports shall be a member of the Expert Panel. Any Expert Committee member that

becomes a member of an Expert Panel or participates at an Expert Panel meeting may do so only as a representative of USP. An Expert Panel will continue until its assigned task has been completed or until dissolved by the CoE Chairperson.

5.02 Chairperson, Charge and Scope

The CoE Chairperson shall appoint, and may remove at any time, the chairperson of an Expert Panel. The CoE Chairperson shall provide an Expert Panel with a specific charge, including scope of work (advisory only), deliverables, and timelines for completion of work, and dissolve such Expert Panel at the conclusion of the specified work.

5.03 Reporting Requirements.

The chairperson of the Expert Panel shall report on its progress as needed or as requested by the Expert Committee chairperson or the CoE Chairperson. The Expert Panel shall issue advisory recommendations to the Expert Committee(s) or CoE Chairperson upon the completion of its task, which shall be accompanied by a disclosure of Conflicts of Interest information identified under Section 5.05(a) below. Expert Panel members will strive to reach consensus on their compendial topic and are expected to complete their task within the specified timeframe, but are not required to achieve unanimity. Dissenting views of Expert Panel members may be expressed in writing and accompany the Expert Panel's advisory recommendations to the Expert Committee.

5.04 Joint Expert Panels

A Joint Expert Panel advisory to two or more Expert Committees may be established. However, the CoE Chairperson shall designate a lead Expert Committee responsible for the oversight of such Joint Expert Panel. In selecting members of a Joint Expert Panel and appointing a Chairperson, the CoE Chairperson shall consider the advice of the chairs of each involved Expert Committee. The formation, charge and reporting for the Joint Expert Panel shall be the responsibility of the lead Expert Committee.

5.05 Conflict of Interest and Confidentiality.

- (a) Conflicts. Conflicts of Interest, as defined in Section 2.03(a), will not be a bar to participation on an Expert Panel or in any deliberations or recommendations of the Expert Panel, including voting, provided the Expert Panel member timely and adequately discloses any Conflict of Interest as required by Sections 2.03, 2.04 and 2.05 of these Rules to other members of the Expert Panel including the chairperson.
- (b) Confidentiality. Expert Panel members are not necessarily obligated to maintain confidentiality of materials obtained and issues discussed during the course of the Expert Panel's task. However, pursuant to Section 2.06(b) and except as otherwise provided therein, Expert Panel members must sign and submit confidentiality agreements to USP because confidentiality may be required in certain instances as identified by the Expert Panel Chairperson and USP staff including, but not limited to, protecting third party confidentiality obligations, preventing the premature disclosure of a standard, or maintaining the confidentiality of proprietary, business, or trade secret information.

6. GOVERNMENT LIAISONS

6.01 Role in Standards-Setting Process

Government Liaisons (GLs) are representatives from the United States (U.S.) Food and Drug Administration or other federal or state governmental agencies in the U.S., or from government agencies in other countries. GLs participate in the setting of USP compendial standards of a USP Expert Committee or Expert Panel to which they are assigned and may offer opinions on all facets of the standards including content and implementation. GLs also may be tasked with seeking information or opinions from the agency they represent, and

with identifying other representatives of their agency who may have specific subject matter expertise that might be helpful to the Expert Committee or Expert Panel.

6.02 Responsibilities and Confidentiality

GLs generally receive briefing materials and are allowed to participate in confidential discussions during an Expert Committee or Expert Panel meeting, but they do not vote on USP standards. GLs are required to sign confidentiality agreements allowing them to share information only within their agency as necessary to fulfill their GL responsibilities. Some information provided by USP to GLs may be proprietary, commercial, trade secret and confidential and not subject to public disclosure unless such information is already publicly available. The chair of an Expert Committee or Expert Panel may ask a GL to excuse him or herself during any discussion or deliberation in which the chairperson believes such GL's participation would not be appropriate due to confidentiality, conflict, or other reasons.

6.03 Participation of Government Liaison

A government official or employee is eligible to participate in USP standards-setting activities only as a GL unless otherwise granted permission by his or her government agency to participate as an Expert Committee member. A government employee serving as an Expert Committee member serves USP as an individual expert, is not considered a GL, does not represent the views of his or her agency and is subject to all of the provisions of these Rules applicable to CoE/EC Experts.

7. USP-NF STANDARDS

7.01 Official Publication of *United States Pharmacopeia* or *National Formulary* Standards

The final approved text of a revision to the *United States Pharmacopeia (USP)* or *National Formulary (NF)* shall be published and distributed to the public via print and/or electronic means through the following vehicles: annual editions of the *USP-NF*, *Supplements* to the annual edition, *Interim Revision Announcements*, *Revision Bulletins* and *Errata*. Unless otherwise determined by the CoE Chairperson, a revision that includes the use of a new USP reference standard shall not be published as final approved text until the required USP reference standard is available. All revisions shall become official six (6) months after publication, unless otherwise specified in the publication vehicle.

Prior to development, chairs and members of USP Expert Committees are to consider the impact of USP's standards on stakeholders, including affected industry and regulators. When USP identifies the potential for the development of or revision to standards to have a broad and significant impact on stakeholders, USP will employ appropriate mechanisms to allow input and dialogue with stakeholders, including, but not limited to, a workshop, web meeting, Stimuli article, key issue web page, prepublication of proposed and/or official text, training, and/or delayed implementation to mitigate such impact.

7.02 Accelerated Revision Processes

Accelerated revision processes are used to make revisions to the *USP-NF* official more quickly than through USP's standard revision process when necessary to correct errors, address patient safety issues, or resolve compliance issues. Accelerated revisions, which include *Interim Revision Announcements*, *Revision Bulletins* and *Errata* do not always require notice and comment and allow for a revision to become official prior to the next *USP-NF* or *Supplement*. All accelerated revisions other than *Errata* require approval by balloting as provided in Section 7.06 below. Accelerated revisions may be used only in the circumstances described in USP's Guideline on the Use of Accelerated Processes for Revisions to the *USP-NF*, which is posted on USP's website.

7.03 International Harmonization

In USP's effort to harmonize the *USP-NF* with the *European Pharmacopoeia* and the *Japanese Pharmacopoeia* through the Pharmacopeial Discussion Group (PDG), any harmonized standard that has been agreed to by a designated representative of USP shall be approved by the relevant Expert Committee in order for such standard or information to be considered official or authorized or adopted by USP. If a standard has been harmonized, such a standard shall not be modified beyond the addition of locally applicable text without first obtaining agreement of the partners in PDG, unless it is determined by the Expert Committee that such modification is necessary in the interest of public health. In such case, the Chair of the relevant Expert Committee or designee, shall immediately notify the PDG partners and provide the reasons for making such changes.

For all other harmonization activities outside of PDG, any harmonized standard that has been agreed to by a designated representative of USP shall be approved by the relevant Expert Committee of that standard.

7.04 Requests for New or Revised USP-NF Compendial Standards

- (a) Submission of Requests. Any request to develop new or revised existing *USP-NF* standards (Request for New or Revised Standards) must be submitted in accordance with the USP Guideline for Submitting Requests to Develop or Revise *USP-NF* Standards (Guideline), available on USP's website, and may be refused if it does not substantially conform to the Guideline. Requests for New or Revised Standards may be initiated by anyone including Expert Committees and USP staff.
- (b) Review of Requests. All Requests for New or Revised Standards shall be forwarded to the appropriate Scientific Liaison. The Scientific Liaison shall evaluate the relevancy, supportability, and urgency of the Request in accordance with established policies and procedures. The Scientific Liaison may initiate work on the Request or provide the Request to the relevant Expert Committee for decision or Expert Panel for its recommendations.
- (c) Notice of Intent to Revise. Upon request of any party, a Notice of Intent to Revise may be posted on USP's website indicating USP's intent to revise existing *USP-NF* standards subject to approval by the relevant Expert Committee(s).
- (d) Approved for Inclusion. As set forth in USP's Guideline on Drugs Approved for Inclusion, available on USP's website, upon the written commitment from a party to submit a Request for New or Revised Standards, together with adequate supporting data and the bulk material required for any accompanying reference standard, USP shall notify the Centers for Medicare and Medicaid Services (CMS) that such article has been "approved for inclusion" in the *USP-NF*. Such "approved for inclusion" status may be revoked at USP's discretion upon the party's failure to fulfill such commitment in a timely fashion.

7.05 Publication in the *Pharmacopeial Forum*

- (a) Publication in *Pharmacopeial Forum*. Except as provided in Section 7.02 above, all proposals for revisions to the *USP-NF* shall, at the direction of either an Expert Committee, or the Scientific Liaison (following notice to the appropriate Expert Committee), be published in the *Pharmacopeial Forum (PF)* for public review and comment. Unless otherwise determined by the CoE Chairperson, a proposal that includes the use of a new USP reference standard shall not be scheduled for publication in *PF* until a suitable reference standard bulk candidate has been received by USP.
- (b) Public Notice and Comment. Except as provided in Section 7.02 above, a period of at least ninety (90) days from the date of publication will be allowed for public review and

comment. The time allowed for public comments shall be noted in the publication in the *PF*. The comment period for proposals with the potential for broad stakeholder impact may be extended with approval of the CoE Chairperson to allow stakeholders additional opportunity to review, consider and comment on such proposals. Comments not provided in a timely manner may either be considered prior to approval and publication as final text, or instead treated as a Request for a New or Revised Standard. All comments submitted to USP during the comment period shall be considered to be public information unless designated as confidential by the submitter. Comments designated as confidential are not subject to public disclosure in accordance with USP's Document Disclosure Policy.

- (c) Consideration of Comments. After the comment period expires, the Expert Committee and Scientific Liaison review and consider the comments, and revise the proposal as needed. A proposal is not republished in *PF* if the changes made to the proposal are in response to comments received and do not create new compendial requirements that were not contained in the initial *PF* proposal.
- (d) Comment Summary. Where a proposal appears in the *PF* and is approved for publication in the *USP-NF*, a summary or abstract of each significant type of comment received and a succinct response to the comment from the Expert Committee or CoE Chairperson shall be posted on USP's website. Such summary shall not include any information designated as confidential by the submitter, consistent with USP's Document Disclosure Policy. Comments received on text that is not the subject of a proposed revision generally are not considered for inclusion in the comment summary unless the comments result in a change to the text.
- (e) Additional Notice and Comment. In addition to publication in *PF* as provided herein, other means such as the USP website may be used to provide notice of and an opportunity to comment on proposals, if determined appropriate by the Expert Committee, or the CoE Chairperson.

7.06 Approval by Expert Committee

- (a) New Standards and Accelerated Approvals; Balloting. Except as described in Section 7.06(b) below, prior to publication as final text, all new or revised documentary standards (including all accelerated revisions other than *Errata*) and the suitability for use of any reference standard in such documentary standards must be voted on and approved by the responsible Expert Committee. Voting shall be accomplished by ballot and may occur either by line-item or for a standard in its entirety. To be eligible for balloting all pertinent supporting information for the documentary standards and basis of suitability for use of any associated reference standards, must be completed and provided to the Expert Committee to inform its consideration. Ballots must be returned by a majority of the members of the Expert Committee by the specified due date for the vote to be valid. Members who are abstaining from voting due to Conflict of Interest or other reasons shall indicate such abstention on their ballots and be counted towards this majority requirement. The Council of Experts may delegate to USP staff or Joint Standards-setting Subcommittees the authority to approve the suitability for use of reference standard continuation and replacement lots, in accordance with guidelines approved by the Council of Experts which provide for oversight by the Council.
- (b) USP Staff; Delegation of Approval Authority with Council Oversight. The Council of Experts may delegate to USP staff or Joint Standards-setting Subcommittees the authority to approve the suitability for use of reference standard continuation and replacement lots, in accordance with guidelines approved by the Council of Experts which provide for oversight by the Council. The Council of Experts may delegate to USP staff the authority to approve limited revisions and monograph omissions, in accordance

with guidelines approved by the Council of Experts which provide for oversight by the Council.

- (c) Joint Standard-Setting Subcommittees; Approval; Balloting. Joint Standard-Setting Subcommittees shall vote and approve compendial standards and reference standards by ballot where delegated by the Council of Experts. Ballots must be returned by a majority of the members of the Joint Standard Setting Subcommittee by the specified due date for the vote to be valid. Members who are abstaining from voting due to Conflict of Interest or other reasons shall indicate such abstention on their ballots and be counted towards this majority requirement.
- (d) Responsibility for Approvals. When more than one Expert Committee collaborates on a particular standard, one Expert Committee shall be designated by the CoE Chairperson as the lead Expert Committee and will be responsible for approvals. The other collaborating Expert Committee(s) shall be notified of the approval. The CoE Chairperson may authorize exceptions and designate two or more Expert Committees, each of which shall approve the standard.

7.07 Postponement

- (a) Request for Postponement. A request for postponement of a USP standard may be filed by anyone and shall be accompanied by a statement of the grounds upon which the postponement is requested and appropriate supporting data. A request for postponement submitted under this section shall be clearly distinguished from a Request for New or Revised Standards. A postponement shall be in effect until lifted or canceled by the appropriate Expert Committee.
- (b) Untimely Requests. A request for postponement received within thirty (30) days prior to the official date of a *USP-NF* standard may be refused for consideration by the CoE Chairperson if, solely within his or her discretion, he or she considers the request untimely or lacking adequate supporting data. Such decision shall not be subject to further review, and the matter instead will be considered as a Request for New or Revised Standards.
- (c) Granting of Postponement. The Expert Committee responsible for approving the *USP-NF* standard for which postponement is sought shall have the authority to postpone, revise, or reinstate the official date of any requirement or textual material in such standard; provided that all decisions on postponement requests shall require review and approval by the CoE Chairperson.

7.08 Appeals

All appeals shall be received and considered as provided in Article VII, Section 7 of the Bylaws. All appeals shall clearly specify the grounds for the appeal and contain appropriate supporting documentation.

8. OTHER DOCUMENTARY STANDARDS

8.01 Food Chemicals Codex

- (a) Requests for New or Revised Standards. Proposals to create new standards or to revise standards in the *Food Chemicals Codex (FCC)* shall be submitted in accordance with any applicable guidelines developed by USP. The Scientific Liaison shall evaluate the relevancy, supportability, and urgency of the request in accordance with the Council of Experts' established policies and procedures and determine whether to proceed with the requested revision. The Scientific Liaison may notify the Food Ingredients Expert Committee (FI EC) of a pending *FCC* request for revision, and may also provide the request to other relevant Expert Committees or Expert Panels.

- (b) Notice and Comment Period. Except as provided in subsections (e) and (f) below, all proposals to revise the *FCC* shall be published in the *FCC Forum* on the USP website for public review and comment. Unless otherwise determined by USP, a proposal that includes the use of a new USP reference standard shall not be scheduled for publication in the *FCC Forum* until a suitable reference standard bulk candidate has been received by USP. A period of at least ninety (90) days from the date of publication in *FCC Forum* will be allowed for public review and comment. For good cause shown, the CoE Chairperson may alter the time specified.
- (c) Approval by Expert Committee and Publication. Following the notice and comment period, the FI EC shall review all comments, accept or reject them, and make any final changes to the proposal it deems appropriate. Prior to publication in final form, the proposal must be approved by the FI EC using the voting procedures and requirements provided in Section 7.06 above, including access to all pertinent supporting information for the documentary standards and the basis of suitability for use of any reference standard. After approval by the FI EC, the *FCC* proposal shall be published in the next edition of the *FCC* or *Supplement* thereto, as applicable, and shall become effective 90 days from the date of publication unless otherwise provided. Unless otherwise determined by the CoE Chairperson, a revision to the *FCC* that includes the use of a new USP reference standard shall not be published as final approved text until the required USP reference standard is available. In the event the CoE Chairperson decides in exceptional circumstances to publish a revision prior to the availability of a required USP reference standard, that portion of the standard containing the requirement shall not be effective until the specified USP reference standard is available.
- (d) Expedited Standards. If the FI EC determines that for public health or other appropriate reasons, a new or revised standard should be made available prior to publication of the next edition of the *FCC* or *Supplement*, it may be posted as final on the USP website following notice and comment under subsection (b) and approval by the FI EC under subsection (c) of this section. Such a standard (Expedited Standard) will be effective upon website publication after the ninety (90) days comment period, unless a delayed effective date is specified therein. Upon publication of the next edition of the *FCC* or *Supplement* thereto, as applicable, any Expedited Standard that has become effective since publication of the last edition or *Supplement* will be included in such volume and removed from the USP website.
- (e) Immediate Standards. In those rare cases where the FI EC determines that a new or revised standard should be made available immediately because of an urgent public health need, a standard may be approved by the FI EC and posted as final on the USP website without the notice and comment period specified in subsection (b) above. Such a standard (Immediate Standard) will be effective upon website publication, unless a delayed effective date is specified therein. Upon publication of the next edition of the *FCC* or *Supplement* thereto, as applicable, any Immediate Standard that has become effective since the last edition or *Supplement* will be included in such volume and removed from the USP website.
- (f) Errata. Errata are considered to be text erroneously published in the *FCC* or its *Supplements* that do not accurately reflect the intended requirements as approved by the FI EC. A list of errata and corresponding corrections to an edition of the *FCC* or to a *Supplement* shall be published on USP's website, until the publication of the next edition of the *FCC* or *Supplement*, which shall then reflect such corrections. Errata shall not be subject to notice and comment and shall not require approval by the FI EC.

8.02 Medicare Model Guidelines

The Council of Experts shall be responsible for developing and approving revisions to the Model Guidelines and related information and documents that pertain to formularies and plan designs that may be used by prescription drug plans under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, consistent with the statutory role given to USP under the Act. Such work will be performed from time to time when requested by the Centers for Medicare and Medicaid Services.

8.03 USP Herbal Medicines Compendium

- (a) **Requests for Revision.** The public, USP staff, members of the USP Botanical Dietary Supplements and Herbal Medicines (BDSHM) Expert Committee, and members of Expert Panels associated with the USP *Herbal Medicines Compendium (HMC)* may submit proposals to create new monographs or to revise monographs in the *HMC* for herbal articles that are approved by a national authority for use as ingredients of herbal medicines, or are included in a national pharmacopeia. Such proposals for revision of *HMC* standards shall be submitted in accordance with any applicable guidelines developed by USP.
- (b) **Notice and Comment Period.** Except in rare cases where the BDSHM Expert Committee determines that a new or revised standard should be made available immediately because of an urgent public health need, all proposals to revise the *HMC* shall be published in draft on the *HMC* website, and provide at least ninety (90) days for public review and comment.
- (c) **Approval by Expert Committee.** Following the notice and comment process outlined above and in any applicable guideline, the *HMC* proposal must be approved by the BDSHM Expert Committee members using the voting procedures provided in Section 7.06(a) above.
- (d) **Publication.** After approval by the BDSHM Expert Committee, a *HMC* proposed standard shall be published and maintained on the *HMC* website as a final authorized standard. Any subsequent comments received shall be treated as proposed revisions of an *HMC* monograph in accordance with subsections (a), (b), and (c) above. Any Errata will be corrected in the online version. A history of Errata will be maintained in a table on the *HMC* website.

9. Advisory Stakeholder Forums and Project Teams

9.01 Formation

Stakeholder Forums and Project Teams may be formed by the CoE Chairperson.

9.02 General

- (a) **Membership.** Stakeholder Forum and Project Team members shall serve as representatives of an organization, company, or service provider. Members of the Board of Trustees, Council of Experts, and Expert Committees may participate in Stakeholder Forum and Project Team discussions, but only as representatives of USP.
- (b) **Advisory Nature.** Stakeholder Forum and Project Team deliberations are advisory and are not binding in any way on the Council of Experts, its Expert Committees, or USP staff.
- (c) **Travel Expenses.** When attending a meeting, Stakeholder Forum and Project Team members' travel and accommodation arrangements and costs are the responsibility of the individual Stakeholder Forum or Project Team member, unless otherwise indicated by USP.

9.03 Stakeholder Forums

- (a) Purpose. Stakeholder Forums shall be formed to enable an exchange of information and perspectives, with the ultimate goal of improving USP standards and information. Stakeholder Forums may exist in any region in which USP operates and may focus on any general compendial offering.
- (b) Formation. The decision to form a Stakeholder Forum will be made by the CoE Chairperson. When establishing a Stakeholder Forum, the CoE Chairperson shall develop a specific charge for the Stakeholder Forum, including goals and expected outcomes. Multiple Stakeholder Forums can be formed and will continue until dissolved by the CoE Chairperson.
- (c) Participants. Participants of Stakeholder Forums will consist of representatives of organizations, companies, and service providers, and other stakeholder groups that may be affected by USP actions and that, in turn, might affect USP activities. The CoE Chairperson shall have the right to limit or adjust the number of attendees from each stakeholder group to ensure balanced representation across constituencies. Participants may also include other individuals that the CoE Chairperson determines may provide useful insight or perspective on USP activities. The CoE Chairperson shall assign one or more USP staff liaisons to each Stakeholder Forum to serve as the USP contact and facilitate the work of the Stakeholder Forum.
- (d) Planning Committee. If the participants of a particular Stakeholder Forum elect to convene a planning committee, the CoE Chairperson shall determine the stakeholder groups or individuals that may be a member of that planning committee.
- (e) Chair. With the advice and consent of the CoE Chairperson, the Stakeholder Forum planning committee will select the chairperson(s) of such Stakeholder Forum. Subsequent rotation of chairperson(s) of a Stakeholder Forum is at the Stakeholder Forum's discretion. If there is not a planning committee, the CoE Chairperson may select the chairperson(s). The chairperson(s) of a Stakeholder Forum shall work with the USP liaison(s) and any planning committee to create agendas for each meeting. The chairperson(s) will preside over the Stakeholder Forum meetings.
- (f) Meetings. Stakeholder Forum meetings may be held as face-to-face meetings at USP Headquarters or other locations, and/or via Web meeting. Dates and times will be posted on the USP website and are open to attendance by any other interested individuals.

9.04 Project Teams

- (a) Purpose. Project Teams generally shall be formed to address a specific compendial topic (primarily process-oriented). Project Teams will function under a particular Stakeholder Forum.
- (b) Formation. The formation of a Project Team may be initiated by the CoE Chairperson. A Stakeholder Forum may recommend formation of a Project Team to the CoE Chairperson. When forming a Project Team, the CoE Chairperson shall develop a specific charge for the Project Team, including goals and expected outcomes, with input from the related Stakeholder Forum. Project Teams will continue until completion of their charge or until dissolved by the CoE Chairperson.
- (c) Membership. Members of Project Teams shall be appointed by the CoE Chairperson, based on recommendations from the related Stakeholder Forum and/or on their scientific or technical expertise. The CoE Chairperson shall determine the appropriate number and type of representatives on the Project Team, with input from the Stakeholder Forum. The CoE Chairperson shall assign a USP staff liaison to each Project Team to serve as the USP contact and help facilitate the work of the Project Team.

- (d) Chair. Each Project Team, with consent of the CoE Chairperson, shall select a Project Team chairperson or co-chairpersons. Subsequent rotation of chairpersons or co-chairpersons of a Project Team is at the Project Team's discretion. The chairperson or co-chairpersons shall preside over the Project Team's meeting(s) and will interact with the USP staff liaison and other USP staff on behalf of the Project Team.
- (e) Meetings. Upon formation of a Project Team, an initial kick-off meeting shall be held with the Project Team and appropriate USP staff and Council of Experts or Expert Committee members. Subsequent meetings of the Project Team will occur as determined necessary by the Project Team, and may be face-to-face, via teleconference, or via Web meeting. USP staff shall attend such subsequent meetings as requested by the Project Team.
- (f) Reports. Project Teams shall report progress to the appropriate Stakeholder Forum. The Project Team shall provide periodic reports as requested by USP staff and on completing its charge. USP staff will respond to any issues raised by the Project Team, in writing, as appropriate and necessary.

10. MEETINGS

10.01 Expert Committee and Expert Panel Meetings

- (a) Open Meetings. In accordance with USP's Open Meeting Policy, all official meetings of an Expert Committee, Expert Panel and Joint Standard Setting Subcommittee shall be open to the public, except that a meeting or a portion of a meeting may be closed if the chairperson of the Expert Committee, Expert Panel, Joint Standard Setting Subcommittee, or the CoE Chairperson determines that there is good and sufficient reason for closure. Such reasons may include, and are not limited to: review or discussion of trade secret or confidential, commercial information; or review or discussion of matters the premature disclosure of which could be detrimental to the USP. An official meeting is a face-to-face meeting or teleconference held by an Expert Committee, Expert Panel or Joint Standard Setting Subcommittee where decisions or formal recommendations are intended to be made if a quorum is reached.
- (b) Closed Meetings. If the determination is made to close an official meeting, such determination and the reason for closure shall be announced at the beginning of the meeting or during the meeting and noted in the meeting minutes. Any non-member participants (observers, invited guests, etc. described in section 10.03 (a) and (b) below) attending such meeting shall be excused from the meeting. Government Liaisons may participate in closed meetings unless excused by the chairperson for the reasons described in section 6.02 above. All ballot teleconferences held by an Expert Committee, Expert Panel or Joint Standard Setting Subcommittee are considered to be closed meetings to maintain the confidentiality of the information discussed. Meetings of the Council of Experts shall be closed unless otherwise indicated.
- (c) Teleconferences. An Expert Committee, or Expert Panel or Joint Standard Setting Subcommittee may hold an official meeting by means of a teleconference, Web meeting, or other communications mechanism by which all persons participating in the meeting can hear one another or perceive each other's comments. Participation by such means shall constitute presence in person at a meeting. An official meeting held by means of a teleconference, Web meeting, or other communications mechanism shall provide an opportunity for public participation unless the meeting is closed as provided in section 10.01(b).
- (d) Visual/Audio Recording Devices. The use of audio or visual/video recording devices during any Expert Committee, Expert Panel or Joint Standard Setting Subcommittee

meeting is prohibited, by Experts, Observers, or other attendees, unless specifically authorized in advance by the Expert Committee, Expert Panel or Joint Standard Setting Subcommittee Chairperson.

10.02 Announcement of Public Meetings and Minutes

- (a) Posting Agendas. USP will post agendas for all official, face-to-face Expert Committee, Expert Panel or Joint Standard Setting Subcommittee meetings on the USP website (USP.org) calendar as far in advance of the meeting as possible. Closed meetings or closed agenda topics will be indicated as such on the agenda.
- (b) Minutes. The final approved version of minutes of Expert Committee and Expert Panel meetings shall be publicly available upon request from the USP Executive Secretariat, excluding minutes from any closed portion thereof.

10.03 Non-member Participants in Expert Committee or Expert Panel Meetings

When a USP meeting is open to the public, a non-member or non-Government Liaison may participate in one of two ways:

- (a) Invited Guest. Invited guests are non-members who are invited specifically to share a particular expertise or express their particular point of view. This shall be carried out under the control of the chairperson of the Expert Committee, Expert Panel or Joint Standard Setting Subcommittee and shall be subject to these Rules. These non-members may be provided with appropriate briefing materials, excluding confidential information. The Expert Committee, Expert Panel, or Joint Standard Setting Subcommittee chairperson shall ask the invited guest to be excused during a closed session of the meeting.
- (b) Observers. Observers, including press and representatives of government agencies not officially designated as Government Liaisons, are non-members who themselves choose to attend an Expert Committee, Expert Panel, or Joint Standard Setting Subcommittee meeting. Observers must notify USP **at least five business days** in advance of the meeting (or as soon as possible after posting of the meeting notice and agenda) of their proposed attendance, and provide necessary background information about themselves. At the discretion of the chairperson of the Expert Committee, Expert Panel, or Joint Standard Setting Subcommittee, observers may or may not receive briefing materials. USP retains the right to refuse permission for an observer to attend a meeting. The Expert Committee, Expert Panel, or Joint Standard Setting Subcommittee chairperson shall ask the observer to excuse him or herself during a closed session of the meeting. Observers will be permitted to make presentations or otherwise speak at the meeting only if approved in advance by the chairperson of the Expert Committee, Expert Panel, or Joint Standard Setting Subcommittee.

10.04 Working Sessions and Status Conferences

Two or more members of an Expert Committee, Expert Panel or Joint Standard Setting Subcommittee may engage in informal dialogue and working sessions as part of their work. An Expert Committee, Expert Panel or Joint Standard Setting Subcommittee may hold informal teleconferences and online discussions to review the status of work being performed by members, without the need to call or conduct an official meeting as defined in Section 10.01(a). Working sessions are closed to the public to maintain confidentiality and facilitate discussion. Except as provided in Section 7.06 above, any decision on any substantive issue shall be made by an Expert Committee, Expert Panel or Joint Standard Setting Subcommittee only at an official meeting called and conducted in accordance with the provisions of Sections 10.01 through 10.03 above.