RULES AND PROCEDURES
OF THE
2020-2025 COUNCIL OF EXPERTS

PROVISIONALLY APPROVED 2020-06-08

Sections

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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, the Expert Committees, Expert Panels, Joint Standard-Setting Subcommittees (hereafter individually or collectively, “Expert Body” or “Expert Bodies”), 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 Code of Ethics; Standards of Conduct

All USP expert volunteers (Expert Committee members, Expert Panel members, Expert Advisors) are required to adhere to the USP Code of Ethics, which is available on USP’s website; and to the Standards of Conduct, per Section XI of these Rules.

1.03 Procedural Questions

On procedural questions, the current edition of Robert's Rules of Order Newly Revised shall prevail where the Rules are silent.

1.04 Adoption and Amendment

Prior to final adoption by the Council of Experts, these Rules shall be submitted to the Council of the Convention and the Board of Trustees (Board) for review and approval as provided in Article VII, Section 5 of the Bylaws. Rules shall be provisionally adopted by the Council of Experts upon taking office, and such provisionally adopted Rules shall govern the activities of the Council of Experts on an interim basis during the review and approval process. These Rules may be amended at any time during the cycle, provided that any proposed amendment also shall be submitted to the Council of the Convention and the Board for review and approval prior to adoption.

2. COUNCIL OF EXPERTS (CoE)

2.01 CoE Chairperson

In accordance with Article IV Section 11 of the Bylaws, the Chief Executive Officer (CEO) or the CEO's designee shall serve as CoE Chairperson and direct and facilitate the work of the CoE and its Expert Committees and shall execute other responsibilities consistent with these Rules. The CoE Chairperson shall chair all meetings of the CoE. 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 work on behalf of the CoE Chairperson to support and assist the CoE and Expert Bodies in carrying out their Work Plans and other assigned responsibilities.

2.02 Election and Duties

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

2.03 Removal

A member of the CoE may be removed for cause by the Board, upon recommendation of the CoE 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.

2.04 Executive Secretariat

The Executive Secretariat shall serve as official correspondent and secretary on behalf of the CoE Chairperson, CoE, Expert Bodies, Stakeholder Forums, and Project Teams. The Executive Secretariat is authorized to perform duties consistent with these Rules to facilitate the operational functions of the CoE, Expert Bodies, Stakeholder Forums, and Project Teams, as well as implementation of USP processes and policies.

3. EXPERT COMMITTEES

3.01 Number of Committees

The Board shall approve the number of Expert Committees in accordance with Article VII, Section 3 of the Bylaws. The CoE 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 CoE.

3.02 Election of Expert Committee Members

Members of each Expert Committee shall be elected by the CoE. Each member of the CoE, 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 CoE may be elected to serve as a member of any other Expert Committee.

3.03 Removal and Vacancies

A member of an Expert Committee may be removed for cause by the CoE Chairperson, upon the recommendation of the Chairperson of the Expert Committee, and cause shall have the meaning set forth in Section 2.03 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.

3.04 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 and to provide supplementary leadership in support of the work of the Expert Committee. 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 CoE in accordance with Article VII, Section 6 of the Bylaws.

3.05 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.

3.06 Subcommittees

(a) Formation. 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. Subcommittees may also include Expert Advisors to the Expert Committee(s), as defined in Section V below.

(b) Responsibilities and Reporting Requirements. Unlike a Joint Standard-Setting Subcommittee described in Section 3.07, 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. Any advisory recommendations issued by a subcommittee or joint subcommittee to the responsible Expert Committee must be accompanied by a disclosure of Conflicts of Interest information identified under Section 11.03 below.

3.07 Joint Standard-Setting Subcommittees

The CoE Chairperson, in consultation with the CoE, 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 CoE. 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 CoE, defined in Section 9.06(b) below. The work and procedures of such Joint Standard-Setting Subcommittees shall be undertaken under the same rules applicable to Expert Committees.

4. EXPERT PANELS

4.01 Formation

The CoE Chairperson may form an Expert Panel to provide additional expertise and perform an assigned task for a particular Expert Committee, Expert Committees, Joint Standard-Setting Subcommittee, or the CoE Chairperson. An Expert Panel may include expert volunteers not otherwise on an Expert Committee, shall be advisory only, and shall have no authority to approve standards. 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(s) or the Joint Standard-Setting Subcommittee to which the Expert Panel reports shall be a member of the Expert Panel. An Expert Panel will continue until its assigned task has been completed or until dissolved by the CoE Chairperson.

4.02 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, deliverables, and timelines for completion of work, and dissolve such Expert Panel at the conclusion of the specified work.

4.03 Reporting Requirements.

The Chairperson of the Expert Panel shall report on its progress as needed or as requested by the Expert Committee Chairperson(s), Joint Standard-Setting Subcommittee Chairperson, or the CoE Chairperson. The Expert Panel shall issue advisory recommendations to the Expert Committee(s), Joint

Standard-Setting Subcommittee, or CoE Chairperson upon the completion of its task, which shall be accompanied by a disclosure of Conflicts of Interest information identified under Section 11.03 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. An Expert Panel is not required to vote by ballot to approve the advisory recommendation it is tasked with developing. However, any Expert Panel may hold an informal vote (e.g., by online poll, by voice vote) to verify that a majority of the members of the Expert Panel support the recommendation prior to its finalization.

4.04 Joint Expert Panels

A Joint Expert Panel advisory to two or more Expert Committees may be established and is subject to the reporting requirements described immediately above in Section 4.03. 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. EXPERT ADVISORS

5.01 Role of Expert Advisors

An Expert Body may engage one or more individuals to provide additional expertise and assist in the development of a standard by participating in Expert Body discussions and/or reviewing documents. Such participating individual shall be deemed an Expert Advisor and shall not be deemed a member of the Expert Body or vote on any Expert Body matter. Expert Advisors shall be appointed by the Chair of the Expert Body, with the approval of the CoE Chairperson. The Chair of the Expert Body may ask an Expert Advisor to excuse him or herself during any discussion in which the Chairperson believes the Expert Advisor’s participation would not be appropriate due to confidentiality, conflict, or other reasons.

6. GOVERNMENT LIAISONS

6.01 Role of Government Liaisons

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 are 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 official or working meetings, 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. GLs are not permitted to attend official meetings, or portions thereof, during which experts share or discuss confidential information related to their specific conflicts of interest, and during final discussions, as defined in section 12.01(d) below. Additionally, the Chair may ask a GL to excuse him or herself during any discussion 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 standard-setting activities only as a GL unless otherwise permitted by his or her government agency to participate as an Expert Committee or Expert Panel member, or as an Expert Advisor. 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 Expert Committee members. A government employee serving as an Expert Panel member may represent the views of his or her agency and is subject to all of the provisions of these Rules applicable to Expert Panel members. A government employee serving as an Expert Advisor may represent the views of his or her agency and is subject to all of the provisions of these Rules applicable to Expert Advisors.

7. SHARING OF INFORMATION AND EXPERTS ACROSS EXPERT BODIES

7.01 Information Exchange Across Expert Bodies

More than one Expert Body may collaborate to share information and to participate in each other's meetings in pursuit of mutually beneficial standard setting goals. These informal collaborative groups may make recommendations for further consideration and implementation within their constituent Expert Bodies, but shall not be empowered with collaborative decision-making authority.

7.02 Participation Across Expert Bodies

From time to time, the Chairperson of an Expert Body may request that an Expert Committee member, Expert Panel member, GL, or Expert Advisor from another Expert Body participate in the requesting Expert Body's meetings or other work in order to obtain additional expertise in a particular area. Such participating individual shall not be deemed a member of the requesting Expert Body or vote on any requesting Expert Body matter. The Chair of the requesting Expert Body may ask such participating individual to excuse him or herself during any discussion in which the Chairperson believes such individual's participation would not be appropriate due to confidentiality, conflict, or other reasons.

8. EXTERNAL STAKEHOLDER ENGAGEMENT ACTIVITIES

8. Advisory Stakeholder Forums and Project Teams

8.01 General

(a) Formation. Stakeholder Forums and Project Teams may be formed by the CoE Chairperson.

(b) Representation. Stakeholder Forum and Project Team members shall serve as representatives of an organization, company, or service provider. Members of the Board, CoE, and Expert Committees may participate in Stakeholder Forum and Project Team discussions, but only as representatives of USP.

(c) Advisory Nature. Stakeholder Forum and Project Team discussions are advisory and are not binding in any way on the CoE, its Expert Committees, or USP staff.

(d) 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.

8.02 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 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, via teleconference, or via virtual meeting. Dates and times will be posted on the USP website and these meetings are open to attendance by any other interested individuals.

8.03 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 CoE or Expert Committee members. Meetings of the Project Team will occur as determined necessary by the Project Team, and may be face-to-face, via teleconference, or via virtual 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.

8.04 Other Forms of Stakeholder Outreach

USP may engage in additional forms of stakeholder outreach or engagement to solicit input in furtherance of public standard-setting goals. These include, but are not limited to, hosting workshops, convening roundtables, working groups or advisory groups, publishing *Stimuli* articles, developing key issue web pages, and pre-publishing drafts of standards prior to publication in *Pharmacopeial Forum* as described below.

9. OFFICIAL *USP-NF* STANDARDS

9.01 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 through periodic updates to the *USP-NF*. 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 of a new or revised standard, USP may employ appropriate mechanisms to allow input and dialogue with stakeholders, including those described in Section VII above.

9.02 Accelerated Revision Processes

In accordance with USP's Guideline on Use of Accelerated Processes for Revisions to the *USP–NF* and *FCC* (Accelerated Revision Guideline), available on USP's website, USP may use accelerated revision processes to make revisions to the *USP-NF* or *FCC* more quickly than through USP's standard revision process. Accelerated revisions do not always require notice and comment and allow for a revision to become official more expeditiously than six (6) months after publication. Pursuant to the Accelerated Revision Guideline, such accelerated revision processes may be used when necessary to correct errors; update outdated or superseded factual information; address patient safety issues (including access issues, such as the prevention of drug shortages); resolve compliance issues; or postpone, revise, or reinstate the official date of a standard per Section 9.07 below. Accelerated revisions require approval by balloting unless subject to an exception as described in the Accelerated Revision Guideline.

9.03 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 in order for such standard or information to be considered official or authorized or adopted by USP.

9.04 Requests for New or Revised *USP-NF* Compendial Standards

(a) Submission of Requests. Any request to develop new or revised *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 (Submission Guideline), available on USP's website, and may be refused if it does not substantially conform to the Submission Guideline. In addition to Requests for New or Revised Standards submitted by third parties, the development of new or revised standards may be initiated by Expert Committees and USP staff.

(b) Review of Requests. All Requests for New or Revised Standards shall be forwarded to the appropriate USP staff supporting the responsible Expert Committee(s). The responsible USP staff shall evaluate the relevancy, supportability, and urgency of the Request in accordance with established policies and procedures. USP staff 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.

9.05 Publication in the *Pharmacopeial Forum*

(a) Publication in *Pharmacopeial Forum*. Except as described in USP's Accelerated Revision Guideline, all proposals for revisions to the *USP-NF* shall, at the direction of either an Expert Committee, or USP staff (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. For revisions published in PF, 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.

(c) Designation and Disclosure of Comments. All comments submitted to USP in response to proposals or *Stimuli* articles published in PF, as well as the identities of commenters, are considered public information unless clearly and specifically designated as confidential. USP may publish or otherwise disclose comments in furtherance of standard-setting goals. In accordance with USP's Document Disclosure Policy, information contained in comments that is designated as confidential is not subject to publication or public disclosure.

(d) Consideration of Comments. After the comment period expires, the Expert Committee and USP staff review and consider the comments, and revise the proposal as needed. A proposal is not required to be republished in PF if the changes made to the proposal are in response to comments received and do not create additional or more stringent compendial requirements that were not contained in the initial PF proposal.

(e) Commentary. 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 and called Commentary. 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 Commentary unless the comments result in a change to the text.

(f) Additional Mechanisms for Soliciting Public Feedback.

In addition to publication in PF as provided herein, other means such as Compendial Notices and/or the USP website may be used to provide notice of and an opportunity to comment on compendial policy issues, if determined appropriate by the Expert Committee or the CoE Chairperson. The time period allowed for public comment shall be noted in the specific publication. The policy regarding designation and disclosure of comments shall be the same as for comments received through PF, per subsection (c) above.

9.06 Approval by Expert Committee

(a) New Standards and Accelerated Approvals; Balloting. Except as described in USP's Accelerated Revision Guideline, prior to publication as final text, all new or revised documentary standards 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.

(b) USP Staff; Delegation of Approval Authority with Council Oversight. The CoE may delegate to USP staff or Joint Standard-Setting Subcommittees the authority to approve the suitability for use of reference standard continuation and replacement lots, in accordance with guidelines approved by the CoE which provide for oversight by the Council. The CoE may delegate to USP staff the authority to approve limited revisions and monograph omissions, in accordance with guidelines approved by the CoE 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 CoE. 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.

9.07 Postponement of Official Date of New or Revised Standard

(a) Request for Postponement. A request for postponement of the official date of a new or revised USP standard may be filed by anyone and shall be accompanied by a statement of the grounds for postponement and appropriate supporting information.

(b) Submission Process. A request for postponement shall be made in writing to the USP Executive Secretariat within sixty (60) days after the date of publication of the standard as final approved text.

(c) Granting of Postponement. Following consultation with the responsible Expert Committee, the CoE Chairperson shall have the authority to postpone, revise, or reinstate the official date of any requirement or textual material in such standard. The CoE Chairperson shall have thirty (30) days following receipt of the Request for Postponement to decide whether or not to grant the postponement. Such decision shall not be subject to further review.

9.08 Appeals

(a) Appeal. An appeal of a USP standard may be filed by anyone and shall be accompanied by a statement of the grounds for appeal and supporting information.

(b) Submission Process. An appeal must be submitted in writing to the USP Executive Secretariat within sixty (60) days after the date of publication of the standard as final approved text.

(c) Postponement of Standard Under Appeal. To seek postponement of the official date of a standard under appeal, the appellant must also submit a request for postponement, which will be adjudicated using the process and timeline described in Section 9.07 above.

(d) Initial Assessment of Appeal by CoE Chairperson. The CoE Chairperson shall perform an initial assessment of any appeal submitted under this section, in consultation with the Chair of the Expert Committee responsible for the standard under appeal. The CoE Chairperson must work with a sense of urgency in performing this assessment and must render a decision within thirty (30) days of receipt of the appeal. If the CoE Chairperson determines that the appeal is substantively or procedurally deficient (e.g., untimely filed), he or she is authorized to deny the appeal summarily. Otherwise, the CoE Chairperson shall have the authority either to: (1) grant the appeal and remand the standard (or portion(s) thereof) under appeal to the responsible Expert Committee for reconsideration; or (2) refer the appeal to the CoE for further deliberation on its merits, as described below. The CoE Chairperson shall notify the appellant of his or her decision (i.e., to deny, to grant, or to refer for further deliberation) in writing.

(e) Appeal Review by CoE. If the CoE Chairperson refers an appeal for further deliberation on its merits, as described in subsection (d) above, the appellant has the right to request a hearing before the CoE, which must take place within the first sixty (60) days of the CoE Chairperson's referral of the appeal. The CoE may invite other parties that it deems to have substantial expertise in the matter being appealed to provide input, including the Committee whose decision is being appealed. The CoE shall work with a sense of urgency to render their decision on the appeal and shall communicate this decision to the appellant in writing.

(f) Request for Final Review by an Appointed Panel. The appellant shall have thirty (30) days following receipt of the CoE's decision to submit to the USP Executive Secretariat in writing a request for final review. Such final review shall be conducted by a panel consisting of the President of the USP

Convention, three (3) members of the CoE appointed by the CoE Chairperson, and three (3) members of the Board appointed by the Chair of the Board. The panel shall be appointed within thirty (30) days of receipt of the written request for final review and shall elect its own Chairperson by majority vote. The panel shall work with a sense of urgency to render its decision on the appeal, and such decision shall be final.

(g) Standard of Review. In conducting its review of an appeal, the CoE or the panel determines the relevancy and materiality of the evidence offered. The CoE or the review panel primarily considers the sufficiency of the process used by the Expert Committee responsible for approving the standard under review (e.g., whether the Expert Committee provided for adequate notice and opportunity for public comment and engaged in full and impartial consideration of the information available).

The CoE or the panel shall deny an appeal unless it finds that: (1) the Expert Committee responsible for approving the standard did not fully adhere to the requirements of these Rules in the development of the standard, and that such nonconformance materially affected the development or approval of the standard; (2) the Expert Committee responsible for approving the standard under appeal failed to fully and impartially consider public input into the standard, including comments received pursuant to Section 9.05 above; or (3) additional scientific information or other evidence has been presented that justifies reconsideration by the Expert Committee responsible for approving the standard under appeal.

If the CoE or the panel upholds the appeal, it must remand the standard to the Expert Committee responsible for approving the standard under appeal.

10. OTHER DOCUMENTARY STANDARDS

10.01 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. USP staff shall evaluate the relevancy, supportability, and urgency of the request in accordance with the CoE's established policies and procedures and determine whether to proceed with the requested revision. USP staff 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 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 *FCC* standards subject to approval by the FI EC.

(c) Notice and Comment Period. Except as described in USP's Accelerated Revision Guideline, all proposals to revise the *FCC* shall be published in the *FCC* Forum on the USP website for public review and comment. 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.

(d) Approval by Expert Committee and Publication. Except as described in USP's Accelerated Revision Guideline, 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 9.06(a) 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. A revision to the *FCC* that includes the use of a new USP reference standard may be published as final approved text before the required USP reference standard is available; in such cases, that portion of the standard containing the requirement shall not be effective until the specified USP reference standard is available.

10.02 Medicare Model Guidelines

The CoE 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.

10.03 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 9.06(a) above.

(d) Publication. After approval by the BDSHM Expert Committee, an 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.

11. STANDARDS OF CONDUCT

11.01 Representation

(a) Expert Committee Members. Expert Committee members serve USP as individual experts; they do not serve any outside interest. An Expert Committee 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. Expert Committee

members participating in other USP activities (e.g., Expert Panels, Stakeholder Forums, USP workshops) do so as representatives of USP and do not represent any other interest.

(b) Expert Panel Members and Expert Advisors. A member of an Expert Panel or Expert Advisor may serve an outside interest provided such interest is disclosed pursuant to Section 11.03(a) of these Rules. An Expert Panel member or Expert Advisor shall not use his or her membership in any way that is, or appears to be, motivated by private gain or any outside interest.

11.02 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 Expert Committee and Expert Panel members and Expert Advisors shall adhere to the Conflicts of Interest provisions set forth in these Rules.

(b) Conflict of Interest; Definition. 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.

11.03 Disclosure Statements

(a) Requirement. Each Expert Committee and Expert Panel member and Expert Advisor 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 individual as necessary to keep it current or as requested periodically by USP, and the individual is also obligated to advise the relevant Expert Committee or Expert Panel Chair and USP staff of changing or emerging interests. The information provided in Disclosure Statements shall be considered confidential and shared only among USP staff and expert volunteers to facilitate Conflict of Interest management. USP will not disclose the information provided in Disclosure Statements to GLs or to members of the public unless compelled to do so by law, e.g., under subpoena or court order.

(b) Failure to Submit Statement. If an Expert Committee or Expert Panel member or Expert Advisor fails to submit a Disclosure Statement, that individual will not be allowed to participate in any Expert Body activities until such statement is submitted to USP.

11.04 Conflict Issue Management for Expert Committee Members

(a) Participation. No Expert Committee member shall vote nor take part in the final discussion of any matter in which he or she has a Conflict of Interest.

(b) Assignment of Work. No Expert Committee member 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 and vote on such issue or question shall be conducted without such member present in person or by telephone.

(c) 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.

11.05 Conflict Issue Management for Expert Panel Members and Expert Advisors

(a) Participation. An Expert Panel member or Expert Advisor may participate in discussions or make 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 11.03(a) of these Rules.

(b) Assignment of Work. Expert Panel members or Expert Advisors 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 11.03(a) of these Rules.

(c) Conflict of Chair. 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 11.03(a) of these Rules.

11.06 Conflict Issue Management for Cross-Committee or Cross-Panel Collaboration.

As provided for in Section VII above, Expert Committee members, Expert Panel members and Expert Advisors may choose to collaborate across groups in pursuit of mutually beneficial standard setting goals. In all cases where Experts convene with others not on their Committee(s) or Panel(s), the disclosure and management of Conflicts of Interest must be executed in accordance with Section 11.07 below.

11.07 Identification and Resolution of Conflict Issues.

(a) Identification of Conflict Issues. Any Expert Committee or Expert Panel member or Expert Advisor who believes or should have reason to believe that he or she may have a potential Conflict of Interest shall notify USP staff and the Chairperson of the Expert Body, as applicable, and ensure that such interest is reflected on such individual's disclosure statement described in Section 11.03 above, prior to any work on or discussion of the matter in question.

USP staff, together with the Chairperson of an Expert Body shall review Disclosure Statements on a periodic basis to identify potential Conflicts of Interest and to facilitate the dissemination of information on the Disclosure Statements to the members and/or Expert Advisors of the Expert Body.

(b) Resolution of Conflict Issues. Where a potential Conflict of Interest is identified by an Expert Committee member and cannot be resolved through voluntary recusal and/or intervention by the EC Chair, the matter shall be referred to the CoE Chairperson 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 an Expert Committee member due to Conflict of Interest.

11.08 Confidentiality

(a) Obligation to Maintain Confidentiality. Each Expert Committee or Expert Panel member and Expert Advisor shall maintain the confidentiality of all information gained in the course of his or her activities as an expert, and shall not use or disclose such information for any purpose, unless such information is already publicly available. Confidential treatment serves purposes that include, but that are 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. In case of doubt as to whether information is deemed confidential, the information shall be treated as confidential until

otherwise indicated by USP staff. Expert Committee and Expert Panel members and Expert Advisors should receive and send any electronic communications related to their USP service from a private email address, not shared with or accessible to their employer or any other 3rd party.

(b) Confidentiality Agreement. Each Expert Committee and Expert Panel member and Expert Advisor shall sign a confidentiality agreement reflecting the confidentiality obligations set forth in Section 11.08(a). If an Expert Committee or Expert Panel member or Expert Advisor fails to sign and submit a confidentiality agreement, that individual will not be allowed to receive any confidential information or participate in any Expert Body activities until such agreement is submitted to USP.

11.09 Dispute Resolution

(a) Cross-Cutting Issues. For cross-cutting compendial policy issues, there may be times when two or more Expert Committees take different positions or propose to adopt different approaches.

(b) USP staff as Primary Dispute Resolution Agents. Where a potential dispute between two or more Expert Committees is identified, the USP staff supporting the Committees involved first attempt to resolve the dispute through collaborative engagement (e.g., special meetings, email correspondence, teleconferences).

(c) Escalation to Cross-Functional, USP-Mediated Discussion. Should the dispute persist despite efforts described in (b) above, a cross-functional, USP-mediated discussion group shall be convened. The group shall consist of representatives of each of the involved Expert Committees selected by the Chairs, along with USP staff responsible for the Committees. The Chairs of the Expert Committees involved shall select representatives from each of their Committees, as well as USP staff to mediate the discussion.

(d) Escalation to CoE Chairperson. If a dispute persist despite efforts described in (c) above, the CoE Chairperson shall lead a discussion with the Chairs of the Expert Committees involved, along with members of the Expert Committees and USP staff selected at the discretion of the CoE Chairperson. The CoE Chairperson shall have final adjudicatory authority to resolve the dispute and to prescribe the compendial approach to be adopted by the Committees.

12. MEETINGS

12.01 Expert Body Meetings

(a) Open Meetings. In accordance with USP's Open Meeting Policy, all official meetings of an Expert Body 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 Body, 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 Body where decisions or formal recommendations are intended to be made if a quorum is reached. If a quorum is not reached, the meeting remains classified as an official meeting; however, no decisions or formal recommendations may be made.

(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 12.03 (a) and (b) below) attending such meeting shall be excused from the meeting. GLs may participate in closed meetings unless excused by the Chairperson for the reasons described in Section 6.02 above, related to confidential conflict of interest discussions, final discussion, or other reasons determined by the Chairperson. The Chairperson may invite a sponsor of, or a technical expert on, a standard under development, to attend a closed meeting, or portion thereof, for the limited purpose of sharing confidential information related to a proposed revision with the Expert Body. In such limited cases, the invited sponsor or technical expert shall not be given access to any USP-confidential or third-party confidential information. Meetings of the CoE shall be closed unless otherwise indicated.

(c) Teleconferences. An Expert Body may hold an official meeting by means of a teleconference 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 or other communications mechanism shall provide an opportunity for public participation unless the meeting is closed as provided in Section 12.01(b).

(d) Final Discussions. Before an item is advanced for final balloting by an Expert Committee or a Joint Standard-Setting Subcommittee, the responsible Expert Body must engage in a final discussion. Per Section 11.04(a) and (b), no Expert Committee member shall take part in the final discussion of any matter in which he or she has a Conflict of Interest. Final discussion may be conducted in person or by teleconference, with any members with Conflicts of Interest recusing themselves from the discussion. To promote full and frank deliberation, final discussions are closed to the public and limited only to non-conflicted voting members of the responsible Expert Committee or Joint Standard-Setting Subcommittee.

(e) Visual/Audio Recording Devices. The use of audio or visual/video recording devices during any Expert Body meeting by experts, observers, or other attendees is prohibited, unless specifically authorized in advance by the Expert Body Chairperson.

12.02 Announcement of Public Meetings and Minutes

(a) Posting Agendas. USP will post agendas for all official, face-to-face Expert Body 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 Body meetings shall be publicly available upon request from the USP Executive Secretariat, excluding minutes from any closed portion thereof.

12.03 Other Participants in Expert Body Meetings

When a USP meeting is open to the public, a party who is not an Expert Committee member, Expert Panel member, GL, or Expert Advisor may participate in one of two ways:

(a) Invited Guests. Invited guests are parties 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 Body and shall be subject to these Rules. These nonmembers may be provided with appropriate briefing materials, excluding confidential information. The Expert Body Chairperson shall ask the invited guest to excuse himself or herself during a closed session of the meeting.

(b) Observers. Observers, including press and representatives of government agencies not officially designated as GLs or serving as expert volunteers, are parties who themselves choose to attend an Expert Body 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 Body, observers may or may not receive briefing materials. USP retains the right to refuse permission for an observer to attend a meeting. The Expert Body 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 Body.

12.04 Working Sessions and Status Conferences

Two or more members of an Expert Body or Expert Advisors may engage in informal dialogue and working sessions as part of their work. An Expert Body may hold informal teleconferences to review the status of work being performed by members, without the need to call or conduct an official meeting as defined in Section 12.01(a). Working sessions are closed to the public to maintain confidentiality and facilitate discussion. However, a sponsor of, or a technical expert on, a standard under development, may be invited to a working session for the limited purpose of sharing confidential information with the Expert Body. In such limited cases, the invited sponsor or technical expert shall not be given access to any USP-confidential or third-party confidential information. Except as provided in Section 9.06 above, any decision on any substantive issue shall be made by an Expert Body only at an official meeting called and conducted in accordance with the provisions of Sections 12.01 through 12.03 above.