

**RULES AND PROCEDURES
OF THE
2025-2030 COUNCIL OF EXPERTS
APPROVED February 9, 2026**

SECTIONS**1. GENERAL**

- 1.01 Governance and Authority
- 1.02 Code of Ethics; Standards of Conduct
- 1.03 Procedural Questions
- 1.04 Approval, Adoption, and Amendment

2. STANDARDS OF CONDUCT

- 2.01 Representation of Interests
- 2.02 Conflict of Interest
- 2.03 Disclosure Statements
- 2.04 Conflict Issue Management for Expert Committee Members
- 2.05 Conflict Issue Management for Expert Panel Members and Expert Advisors
- 2.06 Conflict Issue Management for Cross-Committee or Cross-Panel Collaboration
- 2.07 Identification and Resolution of Conflict Issues
- 2.08 Confidentiality
- 2.09 Dispute Resolution

3. COUNCIL OF EXPERTS (CoE)

- 3.01 CoE Chairperson
- 3.02 Election and Duties
- 3.03 Removal
- 3.04 Executive Secretariat

4. EXPERT COMMITTEES

- 4.01 Number of Committees
- 4.02 Expert Committee Composition, Function, and Work Plan
- 4.03 Chair and Vice Chair
- 4.04 Appointment of Expert Committee Members
- 4.05 Removal and Vacancies
- 4.06 Subcommittees and Joint Subcommittees
- 4.07 Joint Standards-Setting Subcommittees

5. EXPERT PANELS

- 5.01 Charge and Scope
- 5.02 Formation
- 5.03 Reporting Requirements

6. GOVERNMENT PARTICIPATION

- 6.01 Role of Government Liaisons
- 6.02 Government Liaison Responsibilities and Confidentiality
- 6.03 Participation of Government Liaisons and Other Government Employees

7. EXPERT ADVISORS

- 7.01 Role of Expert Advisors

8. MEETINGS

- 8.01 Expert Body Official Meetings
- 8.02 Public Announcement of Meeting Agendas and Sharing of Minutes
- 8.03 Meetings not Considered Official: Working Sessions
- 8.04 Other Participants in Expert Body Meetings

9. SHARING OF INFORMATION AND EXPERTS ACROSS EXPERT BODIES

9.01 Information Exchange Across Expert Bodies

9.02 Participation Across Expert Bodies

10. OFFICIAL USP-NF STANDARDS

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

10.02 Accelerated Revision Processes

10.03 International Harmonization

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

10.05 Publication in the *Pharmacopeial Forum*

10.06 Approval

10.07 Postponement of Official Date of New or Revised Standard

10.08 Appeals

11. OTHER DOCUMENTARY STANDARDS

11.01 Effective Food Chemicals Codex Standards

11.02 Medicare Model Guidelines

11.03 USP Herbal Medicines Compendium

12. EXTERNAL STAKEHOLDER ENGAGEMENT ACTIVITIES

12.01 General

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*), other compendia, 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 6 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*, other authorized publications, associated reference standards, 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, Expert Committees, Expert Panels, Subcommittees, Joint Subcommittees, Joint Standard Setting Subcommittees (hereafter individually or collectively, “Expert Body” or “Expert Bodies”), and related standards-setting activities. USP staff may periodically also issue official USP Guidelines publicly accessible on the USP website (e.g., Guidelines for *USP-NF* Submissions, Accelerated Revisions, Guideline for Submitting Requests for Revision to the *USP-NF*, 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 are required to adhere to the USP Code of Ethics, which is available on USP's website, and to the Standards of Conduct as outlined in Section 2 of these Rules. Failure to adhere may result in removal consistent with Sections 3.03 and 4.05 of these Rules. USP **Expert Volunteers** are individuals (e.g., Expert Committee members, Expert Panel members, Expert Advisors) with the required expertise who have been invited to participate in an Expert Body and who have completed the required onboarding.

1.03 Procedural Questions

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

1.04 Approval, 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 in accordance with Article VII, Section 6 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 USP five-year **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 by the Council of Experts, in accordance with Article IX, Section 1 of the Bylaws.

2. STANDARDS OF CONDUCT

2.01 Representation of Interests

(a) Expert Committee Members. Expert Committee members serve as individual experts on behalf of USP; they must not represent any outside interest during their participation in any USP activities and duties (e.g., participating in an Expert Panel, engaging in USP stakeholder groups). An Expert Committee member shall not use their membership in any way that is, or appears to be, motivated by private gain or any outside interest, including the interest of their employer.

(b) Expert Panel Members and Expert Advisors. During their performance of USP activities and duties in the furtherance of standards-setting, Expert Advisors and Expert Panel members who do not otherwise serve as Expert Committee members may represent an outside interest provided such interest is disclosed consistent with Section 2.03(a) of these Rules. For activities external to their role with USP, an Expert Panel member or Expert Advisor shall not

use their membership in any way that is, or appears to be, motivated by any personal interest, including the interest of their employer.

2.02 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 Volunteers shall adhere to the Conflicts of Interest provisions set forth in these Rules.

(b) Conflict of Interest. 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.

2.03 Disclosure Statements

(a) Requirement. Expert Volunteers shall submit to USP a disclosure statement(s) disclosing all relevant interests, which may include, but are not limited to, employment, professional research, and organizational memberships. The disclosure statement(s) 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 Body 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 Government Liaisons 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 Volunteer 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.

2.04 Conflict Issue Management for Expert Committee Members

(a) Participation. No Expert Committee member shall cast a vote on any matter in which they have a Conflict of Interest in accordance with Article VIII, Section 2 of the Bylaws.

(b) Assignment of Work. No Expert Committee member shall be assigned the primary responsibility to work on an issue or question in which they have a Conflict of Interest. However, they may provide relevant scientific information and may participate in discussions regarding such issue or question provided they have disclosed their Conflict of Interest.

(c) Conflict of Chair. In the case where an Expert Committee Chair has a Conflict of Interest, the Vice Chair will serve. If the Vice Chair is also conflicted, a designated non-conflicted Expert Committee member shall be selected by a majority of the other non-conflicted members to lead the discussions.



2.05 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 they have a Conflict of Interest provided they have disclosed their Conflict of Interest.

(b) Assignment of Work. Expert Panel members or Expert Advisors who have a Conflict of Interest may be assigned work on any matter in which they have a Conflict of Interest provided they have disclosed their Conflict of Interest.

(c) Conflict of Chair. An Expert Panel Chair who has a Conflict of Interest may continue to serve as Chair provided they have disclosed their Conflict of Interest.

2.06 Conflict Issue Management for Cross-Committee or Cross-Panel Collaboration

As provided for in Section 9, Expert Committee members, Expert Panel members, and Expert Advisors may choose to collaborate across groups in pursuit of mutually beneficial standards-setting goals. In all cases where Expert Volunteers convene with others not on their Committee(s) or Panel(s), the disclosure and management of Conflicts of Interest must be executed consistent with Section 2.07 below.

2.07 Identification and Resolution of Conflict Issues

(a) Identification of Conflict Issues. Any Expert Volunteer who believes or should have reason to believe they may have a potential Conflict of Interest shall notify USP staff and the Expert Body Chair, as applicable, and ensure that such interest is reflected on such individual's disclosure statement described in Section 2.03 above, prior to any work on or discussion of the matter in question.

USP staff, together with the Expert Body Chair, may 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 by the Expert Committee 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 any resolution of such issue, including the abstention of an Expert Committee member due to Conflict of Interest.

2.08 Confidentiality

(a) Obligation to Maintain Confidentiality. Each Expert Volunteer shall maintain the confidentiality of all information gained in the course of their activities as an Expert Volunteer

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 Volunteers should use only their USP email address for sending any electronic communications related to their USP service. Expert Volunteers must not share access to their USP email address with their employer or any other third party.

(b) Confidentiality Agreement. Each Expert Volunteer shall sign a confidentiality agreement reflecting the confidentiality obligations set forth in Section 2.08(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.

2.09 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 or email correspondence).

(c) Escalation to Cross-Functional, USP-Mediated Discussion. Should the dispute persist despite efforts described in Subsection (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, along with USP staff responsible for the Committees. The Expert Committee Chairs 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 persists, despite efforts described in Subsection(c) above, the CoE Chairperson shall lead a discussion with the Expert Committee Chairs 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.



3. COUNCIL OF EXPERTS (CoE)

3.01 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, direct and facilitate the work of the CoE and its Expert Bodies, and execute other responsibilities consistent with these Rules. The CoE Chairperson shall preside over all meetings of the CoE. The CoE Chairperson shall designate another person to act in their stead in the event of their temporary absence. The CoE Chairperson may delegate any of their duties enumerated in these Rules unless the duty is specifically assigned in the Bylaws to the CoE Chairperson. 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.

3.02 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 pursuant to Article VII, Section 7 of the Bylaws.

3.03 Removal

Any member(s) of the CoE may be removed for cause by the Board, upon recommendation of the CoE pursuant to Article VII, Section 2 of the Bylaws. As used herein, "cause" may include, but is not limited to, unprofessional conduct, inattention to duties, failure to abide by USP's Code of Ethics or these Rules, or otherwise unreasonably impeding the standards-setting process.

3.04 Executive Secretariat

The **Executive Secretariat** shall serve as official correspondent on behalf of the CoE Chairperson, CoE, and its Expert Bodies. The Executive Secretariat is authorized to perform duties consistent with these Rules.

4. EXPERT COMMITTEES

4.01 Number of Committees

The Board shall approve the number of Expert Committees in accordance with Article VII, Section 4 of the Bylaws. The CoE may, at any time during the 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 5 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.

4.02 Expert Committee Composition, Function, and Work Plan

Expert Committees shall be comprised of voting members appointed to serve on a given committee, together with other Expert Volunteers and Government Liaisons, as appropriate. Expert Committees shall be 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.

Each Expert Committee shall work with the CoE Chairperson and other USP staff to develop a work plan which sets forth the standards-setting goals and objectives of the Expert Committee for the Cycle. 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.

4.03 Chair and Vice Chair

The Expert Committee Chair shall be determined in accordance with Section 3.02. Each Expert Committee Chair, in consultation with the CoE Chairperson, shall appoint a Vice Chair to serve in the temporary absence of the Expert Committee Chair and to provide supplementary leadership in support of the work of the Expert Committee. The appointment of the Vice Chair shall be for a term of one year and may be renewed. In the event of a permanent vacancy of the Chair's office, the Vice Chair shall serve as Chair *pro tem* until a new Chair is appointed by the CoE in accordance with Article VII, Section 7 of the Bylaws.

4.04 Appointment of Expert Committee Members

Each member of the CoE, in consultation with USP staff and the CoE Chairperson, shall nominate potential members with expertise across relevant areas for appointment to the Expert Committee they chair. The CoE Chairperson shall approve the appointment of any Expert Committee member on the roster, including the appointments of CoE members who seek to be appointed to more than one Expert Committee.

4.05 Removal and Vacancies

Any member(s) of an Expert Committee (with the exception of members of the CoE, who are subject to the provisions of Section 3.03) may be removed for cause by the CoE Chairperson, following consultation with or recommendation of the Chair of the applicable Expert Committee, 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 required on any Expert Committee, the CoE Chairperson shall approve appointment of new members.

4.06 Subcommittees and Joint Subcommittees

(a) Formation. Subject to the review of the CoE Chairperson, Expert Committees may form Subcommittees and Joint Subcommittees to advance their work, conditional on a majority vote by Expert Committee members and approval of the roster by the Expert Committee Chair. A **Subcommittee** is a group of Expert Committee members, meeting via Working Sessions, of a single Expert Committee assigned to perform a certain task of the Expert Committee. A **Joint Subcommittee** is a group of Expert Committee members, meeting via Working Sessions, from two or more Expert Committees assigned to perform a certain task of interest to such Expert Committees. Subcommittees and Joint Subcommittees may also include other individuals such as Government Liaisons and Expert Advisors to the Expert Committee(s), as defined in Sections 6 and 7 below.

(b) Responsibilities and Reporting Requirements. A 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 that Expert Committee. A Joint Subcommittee may make recommendations to one or more designated Expert Committees. All decision-making authority shall be retained and exercised by the Expert Committee(s) responsible for any standards associated with those recommendations. Expert Committees not charged with oversight and decision-making authority whose members have been assigned to the Joint Subcommittee shall be kept apprised of the work of the Joint Subcommittee. Any recommendations issued by a Subcommittee or Joint Subcommittee to the responsible Expert Committee(s) must be accompanied by a disclosure of Conflicts of Interest information identified under Section 2.03.

4.07 Joint Standards-Setting Subcommittees

The CoE Chairperson, in consultation with the CoE, may establish **Joint Standards-Setting Subcommittees** consisting of members from two or more Expert Committees. The Chair and members of the Joint Standards-Setting Subcommittee are elected by the CoE. The work and procedures of such Joint Standards-Setting Subcommittees shall be undertaken under the same rules applicable to Expert Committees. Unlike Subcommittees and Joint Subcommittees in Section 4.06, Joint Standards-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 as defined in Section 10.06 (d) below.



5. EXPERT PANELS

5.01 Charge and Scope

The CoE Chairperson may form an **Expert Panel** to provide additional expertise and perform an assigned task for a particular Expert Committee(s), Joint Standards-Setting Subcommittee(s), or the CoE Chairperson. 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.

5.02 Formation

An Expert Panel may include Expert Volunteers not otherwise serving on an Expert Committee, shall be advisory only, and shall have no authority to approve standards. For Expert Panels reporting to Expert Committee(s) or Joint Standards-Setting Subcommittee(s), at least one member of the Expert Committee(s) or the Joint Standards-Setting Subcommittee(s) to which the Expert Panel reports shall be a member of the Expert Panel. The CoE Chairperson shall appoint, and may remove at any time, the Chair of an Expert Panel. The CoE Chairperson, working in consultation with the Expert Committee and Expert Panel Chairs, shall appoint the members of the Expert Panel, who may be removed by the CoE Chairperson at any time. USP may recruit volunteers to obtain the broadest expertise and diverse membership on a particular topic or issue. An Expert Panel will continue until its assigned task has been completed or until dissolved by the CoE Chairperson.

5.03 Reporting Requirements

The Chair of the Expert Panel shall report on its progress as needed or as requested by the Expert Committee Chair(s), Joint Standards-Setting Subcommittee Chair(s), or the CoE Chairperson. The Expert Panel shall issue formal recommendations to the Expert Committee(s), Joint Standards-Setting Subcommittee(s), or CoE Chairperson upon the completion of its task, which shall be accompanied by a disclosure of relevant interests identified as described in Section 2.03. All decision-making authority shall be retained and exercised by the Expert Committee(s) or Joint Standards-Setting Subcommittee(s) responsible for any standards associated with those recommendations.

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 its formal recommendation. However, any Expert Panel may hold an informal vote (e.g., by online poll, by voice vote) to verify that a majority of the Expert Panel members support the formal recommendation prior to its finalization.

6. GOVERNMENT PARTICIPATION

6.01 Role of Government Liaisons

(a) Definition. **Government Liaisons** are representatives from government agencies who participate in USP standards-setting activities. Government Liaisons may offer opinions on all facets of USP standards including content and implementation, but they do not vote on USP standards. Government Liaisons are also 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 Body.

(b) U.S. Based Government Liaisons. USP works with FDA and other U.S. federal and state agencies, as applicable, to ensure the opportunity for appropriate Government Liaison representation on each Expert Body. Considering USP's role under U.S. law, USP may consult with U.S. government agencies individually (e.g., the FDA), as part of the Government Liaison program, and in furtherance of standards-setting activities.

(c) Other Government Liaisons. USP may collaborate with agencies outside of the U.S. to identify Government Liaison candidates in the interest of providing an international perspective on the development and application of USP standards.

6.02 Government Liaison Responsibilities and Confidentiality

Government Liaisons generally receive briefing materials and are allowed to participate in confidential discussions during Official Meetings or Working Sessions. Government Liaisons are required to sign confidentiality agreements allowing them to share information only within their agency as necessary to fulfill their Government Liaison responsibilities. Some information provided by USP to Government Liaisons may be proprietary, commercial, trade secret, confidential, or not available for public disclosure, unless such information is already publicly available. Government Liaisons are not permitted to attend meetings, or portions thereof, during which Expert Volunteers share or discuss confidential information related to their specific Conflicts of Interest. No Government Liaison shall be excused from a meeting for any other reason without approval by the CoE Chairperson.

6.03 Participation of Government Liaisons and Other Government Employees

A government official or employee is eligible to participate in USP standards-setting activities only as a Government Liaison unless otherwise permitted by their government agency to participate as an Expert Volunteer. A government employee serving as an Expert Volunteer serves USP as an individual expert, is not considered a Government Liaison, and their participation shall be governed by Section 2 of these Rules.

7. EXPERT ADVISORS

7.01 Role of Expert Advisors

An Expert Body may engage one or more individuals, known as **Expert Advisors**, to provide additional expertise and assist in the development of a standard by participating in Expert Body discussions and/or reviewing documents. An Expert Advisor shall not be deemed a member of the Expert Body nor vote on any Expert Body matter. Expert Advisors shall be appointed by the Expert Body Chair with the approval of the CoE Chairperson and may be removed by the CoE Chairperson at any time. The Expert Body Chair may ask an Expert Advisor to excuse themselves during any discussion in which the Expert Body Chair believes the Expert Advisor's participation would not be appropriate due to confidentiality, Conflict of Interest, or other reasons.

8. MEETINGS

8.01 Expert Body Official Meetings

(a) Official Meetings. An **Official Meeting** is a hybrid or entirely virtual meeting held by an Expert Body where decisions by a vote (e.g., Expert Committee) or formal recommendations (e.g., Expert Panel) are intended to be made if a quorum is reached. **Quorum** is achieved when a majority—greater than 50%—of voting Expert Body members are present.

Participation by any means, whether in person or virtually, shall constitute presence in an Official Meeting for all purposes, including for determining quorum. If a quorum is not reached, the meeting remains classified as an official meeting; however, no decisions or formal recommendations may be made. Abstentions from voting do not affect quorum for the purposes of making decisions or formal recommendations.

(b) Open Meeting Policy for Official Meetings. USP endeavors to allow any stakeholder to attend and observe Expert Body Official Meetings, subject to the conditions described in these Rules, thus providing equal opportunities for participation and creating greater transparency around the standards-setting process. A portion of an Official Meeting may be closed if the Expert Body Chair or the CoE Chairperson determines that there is sufficient reason for closure. Meetings of the CoE are closed to the public unless otherwise indicated.

(c) Closing Official Meetings. Sufficient reasons for meeting closure may include but are not limited to review or discussion of trade secret or confidential, commercial information; standards of conduct discussions; or review of matters in preliminary or exploratory discussion, the disclosure of which could be detrimental to USP. If the determination is made to close an Official Meeting, such determination and the specific reason for closure shall be announced at the beginning of the meeting or during the meeting and noted in the meeting minutes.

Government Liaisons may participate in closed portions of Official Meetings unless excused by the Expert Body Chair or CoE Chairperson for reasons related to Conflict of Interest

discussions. Consistent with Section 6.02, if closure to Government Liaisons is for any other reason, approval by the CoE Chairperson is required. Any other participants, as described in Section 8.04 (observers, invited guests, etc.), attending an Official Meeting shall be excused from the meeting.

(d) Logistic Considerations for an Official Meeting. All participants in Official Meetings must be able to hear each other and perceive comments through the use of effective electronic meeting platforms and equipment. The creation of electronic recordings during any Official Meeting is prohibited, unless specifically authorized in advance by the Expert Body Chair and USP staff. Meeting recordings will be captured by USP staff and used only for the stated purpose agreed upon at authorization. Any further distribution of meeting recordings requires written consent, discretion, and permission from USP.

Minutes of Official Meetings must capture sufficient information on Conflicts of Interest (Section 2.07 (b)), the specific reason for any closure (Section 8.01 (c)), the proceedings, the presence or absence of quorum for official decisions, and the attendees.

8.02 Public Announcement of Meeting Agendas and Sharing of Minutes

(a) Posting Agendas. USP will post agendas for all hybrid Expert Body Official 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 Official meetings shall be publicly available upon request, subject to USP's Document Disclosure Policy, from the USP Executive Secretariat, excluding minutes from any closed portion thereof.

8.03 Meetings not Considered Official: Working Sessions

(a) Working Sessions. Expert Bodies may hold **Working Sessions** for purposes that may include making recommendations, working on drafting standards, and reviewing the status of work performed by a subgroup (e.g., Subcommittee) or an ad hoc group of an Expert Body(ies). Working Sessions must include two or more Expert Volunteers, may include Government Liaisons, and are closed to the public to maintain confidentiality and facilitate discussion of matters that are preliminary or exploratory, the disclosure of which could be detrimental to USP. Decisions or formal recommendations shall not be made at a Working Session.

(b) Logistic Considerations for a Working Session. All participants in Working Sessions must be able to hear each other and perceive comments through the use of effective electronic meeting platforms and equipment. The creation of electronic recordings during any Working Session is prohibited, unless managed by USP staff. Meeting recordings will be used only for internal USP purposes. Any distribution of meeting recordings requires written consent, discretion, and permission from USP.

8.04 Other Participants in Expert Body Meetings

(a) General. When a USP meeting is open to the public, a party who is not an Expert Committee member, Expert Panel member, Government Liaison, or Expert Advisor may participate as described in Subsections (b), (c) and (d) below. These participants will be provided with an agenda. These participants will not be provided with briefing materials or confidential information. They may request meeting minutes consistent with USP's Document Disclosure Policy.

The Expert Body Chair shall ask these participants to excuse themselves during any closed portion of the meeting, with the exception outlined in 8.04 (d). These participants will be permitted to make presentations or otherwise speak at the meeting only if approved in advance by the Expert Body Chair.

(b) Observers. Observers, including press and representatives of government agencies not officially designated as Government Liaisons or serving as Expert Volunteers, are parties who themselves choose to attend an Expert Body Official Meeting. Observers should notify USP at least five (5) 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. Observer requests received less than five (5) days in advance of the meeting may be granted at the discretion of USP. USP retains the right to refuse a request to attend a meeting. The Expert Body Chair shall ask observers to excuse themselves during any closed portion of the meeting.

(c) Invited Guests. Invited guests are parties who are invited specifically to an Official Meeting to share a particular expertise or express their particular point of view. This shall be carried out under the control of the Expert Body Chair and shall be subject to these Rules. The Expert Body Chair shall ask invited guests to excuse themselves during any closed portion of the meeting.

(d) Technical Experts and Sponsors. **Technical experts** and sponsors are parties that have confidential information related to a proposed revision by an Expert Body. The Expert Body may, upon consultation with the Expert Body Chair, invite a sponsor of, or a technical expert on, a standard under development to attend a closed portion of an Official Meeting, Working Session, or portion thereof for the limited purpose of sharing their 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.

9. SHARING OF INFORMATION AND EXPERTS ACROSS EXPERT BODIES

9.01 Information Exchange Across Expert Bodies

More than one Expert Body may collaborate to share information in pursuit of mutually beneficial standards-setting goals (e.g., during joint Expert Body meetings). These informal

groups may make recommendations for further consideration and implementation within their constituent Expert Bodies but shall not be empowered with collaborative decision-making authority.

9.02 Participation Across Expert Bodies

In order to obtain additional expertise in a particular area, an Expert Body Chair may request that an Expert Committee member, Expert Panel member, Government Liaison, or Expert Advisor from another Expert Body participate in the requesting Expert Body's meetings or other work. Such a participating individual shall not be deemed a member of the requesting Expert Body nor vote on any requesting Expert Body matter. The Chair of the requesting Expert Body may ask such participating individual to excuse themselves during any discussion in which the Chair believes such individual's participation would not be appropriate due to confidentiality, Conflict of Interest, or other reasons.

10. OFFICIAL USP-NF STANDARDS

10.01 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 of a documentary standard 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 12.

10.02 Accelerated Revision Processes

In accordance with USP's Guideline on Use of Accelerated Processes for Revisions to the *USP-NF* and *Food Chemical Codex (FCC)* (Accelerated Revision Guideline), available on USP's website, USP may use Accelerated Revision processes to revise 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, including 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 the official date of a standard, per Section 10.07 below.

Accelerated Revisions require approval by balloting unless subject to an exception as described in the Accelerated Revision Guideline.

10.03 International Harmonization

USP participates in standards harmonization activities with other pharmacopeias around the globe. Any USP standard, or portion thereof, that a designated representative of USP agrees to harmonize with other pharmacopeia's standards must also be considered and approved by the relevant Expert Body before such standard or information is considered official, authorized, or adopted by USP.

A harmonized standard shall not be modified beyond the addition of locally applicable text without first obtaining agreement of the international harmonization collaborative group members, unless it is determined by the Expert Body that such modification is necessary in the interest of public health. In such cases, the Chair of the relevant Expert Body or USP staff designee, shall immediately notify the international harmonization collaborative group members and provide the reasons for making such changes.

10.04 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 an Expert Body and USP staff.

(b) Review of Requests. All Requests for New or Revised Standards shall be forwarded to USP staff supporting the relevant Expert Body(ies). USP staff shall evaluate the relevance, 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 its decision or Expert Panel for its formal 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.

10.05 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 *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.

(c) Consideration of Comments. After the comment period expires, the Expert Committee and USP staff review and consider the officially submitted comments received during the comment period, and revise the proposal as needed. Comments not provided in a timely manner may be considered prior to approval and publication of the standard as final text or treated as a Request for a New or Revised Standard. A proposal is not required to be republished in *PF* if the changes made to the proposal do not create additional or more stringent compendial requirements that were not contained in the prior *PF* proposal.

(d) Commentary. **Commentary** is a summary or abstract of each significant type of comment received and a succinct response to the comment from the Expert Body(ies) posted on USP's website for the final approved text of a revision published in *PF*. Commentary will not be published for previous versions of proposals that appeared in *PF* where the proposal did not advance to publication. Summaries shall be posted only for comments received on the most recent version of the proposal published in *PF*. Commentary shall not include any information unambiguously designated as confidential by the submitter, consistent with USP's Document Disclosure Policy.

(e) 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 standards-setting goals. Information contained in comments that is unambiguously designated as confidential is not subject to publication or public disclosure, consistent with USP's Document Disclosure Policy.

(f) Additional Mechanisms for Soliciting Public Feedback. In addition to publication in *PF*, and if determined appropriate by the Expert Body Chair or the CoE Chairperson, other means such as **Compendial Notices** posted on the USP website may be used to provide notice of and opportunity to comment on compendial policy issues. 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 (e) above.

10.06 Approval

(a) Expert Committee; New Standards and Accelerated Approvals; Balloting. Except as described in USP's Accelerated Revision Guideline and in Section 10.06(c) below, 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 and for determining quorum. Expert Committee 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 the quorum requirement.

(b) Council of Experts; Approval; Balloting. Except as described in USP's Accelerated Revision Guideline and in Section 10.06(c) below, prior to publication as final text, all new or revised standards under the responsibility of the CoE must be voted on and approved by the CoE. 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 must be completed and provided to the CoE to inform its consideration. Ballots must be returned by a majority of the members of the CoE by the specified due date for the vote to be valid and for determining quorum. CoE 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 the quorum requirement.

(c) USP Staff; Delegation of Approval Authority with Council Oversight. The CoE 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 CoE which provide for oversight by the Council. The CoE may also 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.

(d) Joint Standards-Setting Subcommittees; Approval; Balloting. Joint Standards-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 Standards-Setting Subcommittee by the specified due date for the vote to be valid and for determining quorum. Joint Standards-Setting Subcommittee 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 the quorum requirement.

(e) Responsibility for Standards. 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 for the same standard, each of which shall approve the standard.

10.07 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 portion of a standard may be filed by anyone and shall be accompanied by a statement of the grounds for postponement and appropriate supporting information. Items advanced under the Accelerated Revision Guideline per Section 10.02 are not eligible for postponement. Accelerated Revisions are published under a rapid timeline and a request for postponement will instead be considered as a Request for New or Revised Standard per Section 10.04.

(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) Review of Request for Postponement. The CoE Chairperson may postpone the official date of any standard or portion(s) thereof following consultation with the responsible Expert Committee or the CoE, as applicable. The CoE Chairperson shall have thirty (30) days following receipt of the request for postponement to decide whether to summarily dismiss on procedural grounds, deny, or grant the postponement. These decisions shall not be subject to further review.

10.08 Appeals

(a) Appeal. An appeal of a new or revised portion of a standard may be filed by anyone and shall be accompanied by a statement of the grounds for appeal and supporting information. Items advanced under the Accelerated Revision Guideline per Section 10.02 are not eligible for appeal. Accelerated Revisions are published under a rapid timeline and a request for appeal will instead be considered as a Request for New or Revised Standard per Section 10.04.

(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) Standard of Review. The standard of review is applicable to the initial assessment, appeal review, and final review. After a determination of the relevance and materiality of the evidence offered, the reviewing body will primarily consider the sufficiency of the process used by the responsible standards-setting Expert Body (e.g., whether the Expert Committee provided adequate notice and opportunity for public comment), but may also consider issues of fact that would justify reconsideration for approving the standard under appeal. The reviewing body may not consider issues of scientific judgment.



(d) 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 10.07 above.

(e) 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 Expert Body responsible for the standard under appeal. The CoE Chairperson shall work with a sense of urgency in performing this assessment and must render a decision within thirty (30) days after receipt of the appeal. If the CoE Chairperson determines that the appeal is procedurally deficient or raises no genuine or substantial issue of fact, they may summarily dismiss the appeal.

Otherwise, the CoE Chairperson may either: (1) grant the appeal (in whole or in part), including any textual modifications that result in reversion to previously official text (or portion(s) thereof) in accordance with guidelines approved by the CoE, and remand the standard (or portion(s) thereof) under appeal to the responsible Expert Body for reconsideration; or (2) refer the appeal (in whole or in part) to the CoE or appointed reviewing body, as applicable, for further deliberation as described below. The CoE Chairperson shall notify the appellant of their decision (i.e., summarily dismiss, grant, or referral for further deliberation) in writing.

(f) Appeal Review for Standards Balloted by an EC or Joint Standards-Setting Subcommittee. If the CoE Chairperson refers an appeal to the CoE for further deliberation, as described in Subsection (e) above, the appellant has the right to a hearing before the CoE if a request for a hearing is made to the USP Executive Secretariat within fifteen (15) days of notification of the CoE Chairperson's referral. The hearing must take place within 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 Expert Body whose decision is being appealed.

The CoE shall work with a sense of urgency to render its decision (based on a majority vote) whether to grant the appeal (in whole or in part) and remand it to the responsible Expert Body and/or deny the appeal in whole (or in part). The CoE Chairperson shall communicate the decision to the appellant in writing. A member of the Expert Body responsible for the standard under appeal may participate in the deliberation but shall abstain from voting on the appeal.

(g) Appeal Review for Standards Balloted by the CoE. For standards balloted by the CoE, the process for referring an appeal for further deliberation, as described in Subsection (e) will follow the process described in Subsection (f), except that the CoE Chairperson will refer the appeal to a reviewing body of five (5) to seven (7) Expert Volunteers with a representation from diverse technical areas, selected by the CoE Chairperson.

(h) Request for Final Review by an Appointed Panel. The appellant shall have thirty (30) days following receipt of the reviewing body's decision on the appeal review to submit a written request for final review to the USP Executive Secretariat. 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 Chair by majority vote. The panel shall work with a sense of urgency to render its decision (by majority vote) on the appeal, and such decision shall be final. If the panel upholds the appeal, it must remand the standard to the Expert Body responsible for approving the standard under appeal.

11. OTHER DOCUMENTARY STANDARDS

11.01 Effective *Food Chemicals Codex* Standards

(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 relevance, 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 (FI) Expert Committee 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 content of the *FCC*, subject to approval by the Food Ingredients Expert Committee.

(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 the *FCC Forum* will be allowed for public review and comment. The CoE Chairperson may alter the time specified for good cause.

(d) Designation and Disclosure of Comments. All comments submitted to USP in response to proposals or *Stimuli* articles published in the *FCC Forum*, 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 standards-setting goals. Information contained in comments that is unambiguously designated as confidential is not subject to publication or public disclosure, consistent with USP's Document Disclosure Policy.

(e) Approval and Publication. Except as described in USP's Accelerated Revision Guideline referenced in Section 10.02, following the notice and comment period, the FI Expert Committee 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 using the voting procedures and requirements provided in Section 10.06 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 Expert Committee, the *FCC* proposal shall be published in the next edition of the *FCC* or Supplement thereto, as applicable, and shall become effective ninety (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.

11.02 Medicare Model Guidelines

USP Expert Volunteers are responsible for providing proposed revisions to the Medicare Model Guidelines and related information and documents that pertain to Medicare Part D of prescription drug plans under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Act), 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.

11.03 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 herbal medicines may submit proposals to create new monographs or to revise monographs in the *Herbal Medicines Compendium (HMC)* for herbal articles. Herbal ingredients eligible for *HMC* standards include those that have been approved by a national authority for use in herbal medicines or are included in a national pharmacopoeia. 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 as **Proposed for Comment** monographs on the *HMC* website and provide at least ninety (90) days for public review and comment.

(c) Approval. Following the notice and comment process outlined above and in any applicable guideline, the *HMC* proposed monograph must be approved using the voting procedures provided in Section 10.06 above.

(d) Publication. After approval by the BDSHM Expert Committee, an *HMC* monograph 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 consistent with Subsections (a), (b), and (c) above. Any Errata will be corrected in the online version. A history of Errata will be maintained on the *HMC* website.



12. EXTERNAL STAKEHOLDER ENGAGEMENT ACTIVITIES

12.01 General

(a) Goal of Stakeholder Outreach. The goal of stakeholder engagement is to provide sufficient opportunities for input from stakeholders (any person with an interest in USP's activities) on USP standards-setting activities and other USP compendial activities. Stakeholder engagement activities help align USP Expert Volunteer work with stakeholder needs and ensure public health priorities are considered in formulating key compendial principles.

(b) Forms of Stakeholder Outreach. USP may engage in numerous forms of stakeholder outreach or engagement to solicit input in furtherance of public standards-setting goals and other USP compendial activities. Stakeholder engagement may be initiated from the exploratory phase to the post-publication phase of standards development.

Outreach methods may include hosting workshops and forums; convening roundtables, working groups, project teams, education, or advisory groups; publishing *Stimuli* articles; developing key issue web pages; and distributing drafts of standards prior to publication in *Pharmacopeial Forum*.

During the compendial development phase, USP Expert Bodies adhere to USP's Open Meeting Policy, which ensures that meetings are transparent to stakeholders as described in Section 8.01(b). During the standard development stage, stakeholders may provide informal feedback during meetings or other interactions, and this feedback should be shared with the responsible Expert Body and appropriately documented. These discussions are not a replacement for the compendial process, and stakeholders should still submit formal comments.

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

(d) Representation. Members of the CoE and Expert Committee members may participate in stakeholder engagement activities solely as representatives of USP as described in Section 2.01. Other members of stakeholder groups and participants in events may serve as representatives of an organization, company, service provider, or other outside interests.