



EXCERPT FROM 2015-2020 USP BYLAWS

Article VII. Council of Experts

Section 1. Duties.

There shall be a Council of Experts which together with its 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 (including translations and line extensions of the *USP-NF*) and any reference standards associated therewith in accordance with the rules and procedures established by the Council of Experts.

Section 2. Election, Term and Removal.

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

Section 3. Number and Types.

The number and types of Expert Committees for the next cycle shall be determined as follows:

- a. Not less than twelve (12) months prior to each Regular Membership Meeting, the Council of Experts shall recommend to the Board the number and types of Expert Committees for the next cycle.
- b. Voting Members shall be given not less than ninety (90) days to provide comment on the proposed number and types of Expert Committees. All comments shall be acknowledged as received.
- c. Within ninety (90) days following the Voting Member comment deadline, the Board of Trustees shall review the comments received and approve the list of Expert Committees for the next cycle. The Board shall issue a report summarizing the comments provided and the decisions of the Board of Trustees.
- d. Upon notification by the Board, the Nominating Committee of the Council of Experts shall develop a list of appropriately qualified candidates for the chairs of such Expert Committees.

Section 4. Additional Expert Committees.

At any time during the cycle, the Council of Experts may recommend to the Board that additional Expert Committees be established to carry out the work of the Convention. If approved by the Board, the chairs of such additional Expert Committees shall be appointed by majority vote of the Council of Experts.

Section 5. Rules.

The Council of Experts shall make such rules and adopt such procedures, not in conflict with these Bylaws, as are sufficient to ensure the accuracy and adequacy of the content of the *United States Pharmacopeia*, the *National Formulary*, and other authorized publications, and to provide for adequate notice and opportunity for public comment and full and impartial consideration of all proposed changes in, and additions to, the content of such publications. Such rules and procedures shall include provisions for the governance of the Council

of Experts (including, but not limited to: filling of vacancies, appointment of additional chairs, conflict of interest rules, the election and operation of Expert Committees and the creation and operation of advisory bodies within the Council of Experts) and rules to carry out its areas of responsibility. Prior to adoption, the proposed rules and procedures shall be submitted to the Governance Committee of the Convention and the Board for review and approval as set forth in Article X, Section 1c.

Section 6. Vacancies.

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

Section 7. Appeals.

The Council of Experts shall adopt rules and procedures for appealing any standard adopted by the Council. The appeals process shall be consistent with the following provisions:

- a. A request for an appeal shall be made in writing within sixty (60) days after the date of publication of the standard as official text.
- b. The Council or Expert Committee establishing the standard shall work with a sense of urgency and have up to ninety (90) days to reconsider the standard and issue a decision.
- c. The appellant shall have thirty (30) days following receipt of the decision to request in writing further review by a panel consisting of three members of the Council of Experts appointed by the Chair, three members of the Board of Trustees appointed by the Chair of the Board, and up to three additional experts appointed by the President in consultation with the Chair of the Council of Experts. The panel shall be chaired by the President.
- d. The panel shall be convened within ninety (90) days after the request for further review is received, and the appellant shall be given the right to appear at a hearing of the panel. The decision of the panel shall be final.
- e. The date by which conformance with the standard is required shall be postponed while the appeal is pending. If the standard is upheld, the date by which conformance is required shall be reestablished so that the period allowed for implementation is not less than that provided for upon original publication of the standard.