



**USP STATEMENT**  
**Rules and Procedures of the 2010-2015 Council of Experts**

**April 1, 2011**

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The Rules and Procedures of the Council of Experts (Rules) is the primary governing document for USP's standards-setting body, the Council of Experts and its Expert Committees. The 2010-2015 Council of Experts provisionally adopted Rules at its first meeting in June 2010. Prior to final adoption by the Council of Experts, the provisionally adopted Rules were submitted to the Governance Committee of the USP Convention for review. Through this process, both the Governance Committee and the Council of Experts proposed changes to the provisionally adopted Rules. The Rules, with these changes incorporated, were subsequently approved by the Board of Trustees and then adopted by the Council of Experts.

The following outlines those changes to the Rules, which become effective April 1, 2011.

**2.04 Disclosure Statements**

The title of this section was changed from "Conflict of Interest" Statements to "Disclosure Statements," emphasizing that the purpose of these statements is to ensure disclosure of all relevant interests that potentially could become a conflict of interest.

**2.05 Identification and Resolution of Conflict Issues.**

The changes in this section require that all Expert Committee members' potential conflicts be disclosed to the rest of the Expert Committee, so that all members are aware of potential conflicts that exist within the Expert Committee and can take these into account as standards come before the Expert Committee for discussion.

**5.04 Expert Committee Work Plan**

Language was added to this provision to affirm that all work of the Expert Committee is consistent with the Work Plan, including work of its subcommittees and Expert Panels. At the same time, it makes clear that in the event of a public health crisis, the CoE Chairperson may direct an Expert Committee to work outside of its existing Work Plan to respond to the crisis.

**7.03 High Impact Revisions**

Language was added to clarify that each Expert Committee is responsible for determining if a proposed standard or revision constitutes a High Impact Revision and whether or not a design phase approach is warranted.

**7.06b Public Notice: Consideration of Comments**

Language was modified to clarify that the comment period for High Impact Revisions may be extended with the approval of the CoE Chairperson to allow stakeholders additional opportunity to review and comment on such proposals.

**7.06d Comment Summary**

Language was added to indicate that the summary of comments that is posted on USP's website does not include any information marked as confidential by the submitter, consistent with the USP's Document Disclosure Policy which requires that USP maintain the confidentiality of such information.

**7.07b Revised Documentary Standards: Ballot by Consent**

This provision was eliminated as the use of USP's traditional balloting process was viewed as important to the Council of Expert's decision-making processes and the credibility of USP standards.

**8.02 Non-U.S. Monographs; Standards for Articles Legally Marketed Outside of the U.S.**

This provision for Non-U.S. Standards was removed and a provision for the USP *Medicines Compendium* was added in its place. The *Medicines Compendium* is USP's new online compendium that provides standards (documentary and reference materials) for suitable chemical and biological medicines and their ingredients legally marketed in countries other than the U.S. This section of the Rules provides for the Request for Revision Process, the Notice and Comment Period, Approval by Expert Committee, and Publication of the *Medicines Compendium*. All Non-U.S. Monographs will be incorporated into the *Medicines Compendium*.

**8.04 Medicare Model Guidelines**

Language was added to emphasize that USP develops the Medicare Model Guidelines consistent with the statutory role given to USP under the Medicare Modernization Act of 2003. Detailed language was removed that outlined the USP Model Guidelines Expert Panel, to allow flexibility for the specific process used for development of the Model Guidelines to evolve over time.