

Submitted electronically to the [Convention Input Portal](#)

May 31, 2024

Jaap Venema, Ph.D.
Chief Science Officer & EVP
Chair, Council of Experts
Officer, USP Convention
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Re: To Provide Input On The Proposed Number And Types Of Expert Committees

Dear Dr. Venema,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to USP on the proposed number and types of Expert Committees.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a \$94 billion healthcare marketplace, employ 230,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

NCPA submits the following comments regarding the [memorandum](#) from Jaap Venema, Chair of the Council of Experts, that includes a summary of the proposed list of Expert Committees and the Council of Experts for the 2025-2030 cycle:

"Healthcare Quality and Safety" will have four new expert committees, including Compounding. According to [USP's FAQ](#) on USP Council of Experts and USP Expert Committees, under the question "What expertise is required?," USP states the following:

While each Expert Committee requires specific expertise in either analytical chemistry, analytical biochemistry, measurement science, food and dietary supplement science, or other applied sciences, candidates should have advanced degrees (doctoral degrees or the equivalent based on extensive experience), and should be actively working in related scientific and/or regulatory disciplines.

NCPA asks that USP further clarify its definition of what is an "expert" for the purposes of serving on the expert committees. NCPA is dismayed that in the past, such experts on the

compounding committee are consultants with no day-to-day practical experience with compounding. **NCPA advises USP that for purposes of compounding, USP should clarify that an expert should be a current compounding pharmacist with at least ten years recent and relevant compounding experience in a 503(A) pharmacy.**

To this end, NCPA believes that the Article VIII, Section I (“Conflicts of Interest”) and Section 2. (“Recusal”) of the [2020-2025 USP Bylaws](#) is overly broad, barring current compounders from serving on an expert committee regarding compounding. **NCPA advises that the following sections be amended with the following edits, to enable active compounders to serve on the expert committees:**

Section 1. Conflicts of Interest: Strike “preclude or”

Section 2. Recusal. Strike “No Officer, Trustee, or Expert shall cast a vote, nor take part in the final deliberation in any matter in which he or she has a Conflict of Interest.”

Please let us know how we can assist further, and should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

A handwritten signature in black ink, appearing to read 'Steve Postal', with a long horizontal stroke extending to the right.

Steve Postal, JD
Director, Policy & Regulatory Affairs
Staff Liaison, NCPA Compounding Committee
National Community Pharmacists Association