

**2020-2025 Council of the Convention (CoC)  
Meeting #2  
Thursday, January 28, 2021**

**Minutes - Final**

**Goals and anticipated outcomes**

- Review activities from Convention Sectors and Regional Chapters
- Discuss and approve proposed changes to USP governance documents
- Gain insights on Convention Membership composition and future direction thereof

**Attendees:** See addendum for a list of CoC and USP staff attendees.

**1. Welcome, Opening Remarks, Confirmation of Quorum and Agenda Approval**

**Welcome**

Convention Secretary Anthony Lakavage confirmed that a quorum was present and **opened the meeting at 7:00 a.m. ET**. Mr. Lakavage welcomed everyone to the second meeting of the CoC for the 2020-2025 cycle, noting that he was filling in for CoC Chair Dennis E. Doherty to chair the meeting. Ordinarily, the CoC's Vice-Chair fulfills this role when the CoC Chair cannot lead the meeting. The CoC Chair typically appoints a Vice-Chair after they have had some time to get to know members of the CoC, and this usually takes place after roughly a few meetings. For meetings when neither the Chair nor Vice-Chair is able to chair a meeting, the Convention Secretary has chaired the meeting. This can occur once the CoC Chair identifies the Secretary as their designee to chair the meeting. Dr. Doherty's email to the CoC prior to the meeting served as this designation. Dr. Doherty was able to attend the meeting, though it was only in a listening-capacity, as he was recovering from a recent surgery.

**Overview of Agenda and Meeting Goals**

Mr. Lakavage reviewed the meeting agenda and objectives, noting that the purpose of the meeting was largely fourfold: 1) to share USP's COVID-19 updates; 2) to review activities from Convention Sectors and Regional Chapters; 3) to discuss and approve proposed changes to USP governance documents; and 4) to gain insights on Convention Membership composition and future direction thereof. Mr. Lakavage then called on the CoC to approve the meeting's agenda.

**Motion to Approve Agenda**

Dr. Emmanuel Akala moved to approve the agenda, and the motion was seconded. The motion carried by unanimous consent, and the agenda was approved.

**2. Approval of Minutes from Previous Meeting**

Mr. David Gaugh moved to approve the minutes from the previous meeting, and the motion was seconded. The motion carried by unanimous consent, and the agenda was approved.

**3. Biologics Sector Meeting Report**

Convention Biologics Sector Chair Susan Cantrell, CEO of the Academy of Managed Care Pharmacy, provided a report on the first Biologics Sector meeting of the 2020-2025 cycle.

This meeting was held on December 14, 2020. Due to the timing of this kick-off meeting related to the authorizations of both the Pfizer and Moderna COVID-19 vaccines, the sector meeting mainly focused on COVID-19 vaccines. Future meetings will address other topics in biologics. The goals of this meeting were to: 1) provide a foundational understanding of the Convention Biologics Sector; 2) capture insights about priority topics, including safety and quality in the development and distribution of COVID-19 vaccines and treatments; and 3) establish a connection with and between sector members around priority biologics topics.

Dr. Stephen Ostroff, the Medical Sciences Trustee of the USP Board of Trustees, and former leader from within the FDA and CDC, was the featured guest speaker for this sector meeting. He spoke on the importance of building public trust in vaccine quality. Twenty-six representatives from across 15 Convention Member organizations, attended with several sharing their perspectives on the need for increased coordination of vaccine-related communication to build public trust in both the science and the healthcare delivery systems. Participants came from Member organizations representing healthcare practitioners, patients, pharmaceutical manufacturers and scientists, and U.S. regulatory bodies.

Learnings and recommendations from this first meeting include:

- There is a need to further foster Member-driven dialogue at future sector meetings.
- Structure future sector meetings to enable robust participation among Members with concrete outcomes for continued dialog; this includes logistical and technical approaches to participation in a virtual setting.
- Incorporate USP and Member updates beyond COVID-19; broader topics are more likely to sustain engagement in the long-term.

#### **4. Sector and Regional Chapter Previews**

Ms. Shelley Whiddon reminded CoC members of the new sector and regional chapter model for engaging Convention Membership in the 2020-2025 cycle. The model is designed to harness the full breadth and depth of perspectives of the USP Convention around priority issues. The Biologics Sector meeting was the first sector meeting held this cycle. At this point in time, there are six sectors (Generic Medicines, Healthcare Practice, Biologics, Excipients, Innovation, and Dietary Supplements) and four regional chapters (Latin America, South Asia, Greater China, and Asia Pacific). Ms. Whiddon also briefly previewed a schedule of the upcoming sector and regional chapter meetings, noting that later in the day the Healthcare Practice Sector was set to hold its first meeting.

#### **5. COVID-19 Updates from USP**

USP Chief Science Officer and Chair of the Council of Experts Dr. Jaap Venema shared updates from USP's efforts related to COVID-19 in the areas of standards, advocacy, capability-building, and "last-mile" work. USP's work to address challenges surfaced by the COVID-19 pandemic has taken shape in two areas: 1) strengthening supply chain resilience; and 2) supporting, vaccines, treatments, and preventatives for COVID-19. Efforts to date have included:

- Supporting scientists and manufacturers through making documentary standards freely available to support COVID-19 therapeutics and offering free technical expertise to help support the development and manufacturing of new therapies

- Supporting regulators around the world by collaborating with international regulators and U.S. FDA and bringing transparency to the supply chain
- Supporting healthcare workers by providing resources for quality manufacturing of hand sanitizer and guidance on Personal Protective Equipment

### Discussion

CoC members made the following comments; USP responses are in sub-bullets:

- How is USP communicating its work addressing the COVID-19 pandemic?
  - This has occurred on USP's social media channels; more promotions are coming in the future.
- Many organizations and individuals in the healthcare field are not on social media; consider other ways to promote. Also consider partnering with organizations who can help carry these messages and announcements.

## 6. CoC Rules

Dr. Scott Kuzner shared a summary of staff-initiated proposed changes to the *Rules and Procedures of the Council of the Convention (CoC Rules)* from the previous cycle, as well as an overview of the topics covered in the *CoC Rules*. He noted that following this meeting and the CoC's approval of the proposed changes, the revised *CoC Rules* will go to Convention Membership for a 90-day comment period. Those comments will then come back to the CoC at their next meeting for consideration of any additional changes to the *CoC Rules* before they are then sent to the Board of Trustees for final approval. Dr. Kuzner emphasized that the CoC, as representative of Membership categories, regions, and sectors is the first and central point during the revision of the *CoC Rules*. USP's Bylaws indicate that the CoC is responsible for developing its own rules and procedures for carrying out its governance duties listed in the Bylaws.

The proposed revisions were developed by staff who worked with the CoC throughout the previous cycle. This included USP's Senior Counsel, Deborah Biswas who works on all USP governance documents to ensure they are in sync with one another. There are a few general drivers for the changes: 1) Bylaws Amendments passed at the 2020 Convention Meeting that resulted in a need for bringing the *CoC Rules* into alignment with the Bylaws due to content or citations changes; 2) general changes for grammar, clarity, and consistency; and 3) changes needed to make the CoC's work more efficient or reflective of needs discovered during the past five years.

A summary of changes to the *CoC Rules* as well as a red-lined copy of edits containing all changes was provided to the CoC in advance of the meeting to review. Dr. Kuzner presented the summary of changes at the meeting which included six major categories of changes:

- **Convention Governance Committee Rules added:** The CoC absorbed the governance responsibilities of the Convention Governance Committee, following revisions to USP's Bylaws at the 2020 Convention Governance Meeting. The following three sections from the *Rules and Procedures of the Convention Governance Committee* are now included in the CoC's Rules: i) the subsection on Amendments from the General section; ii) Ensuring the Integrity, Accuracy, and Security of the Convention's Voting Process; iii) Developing and Reviewing Proposed Amendments to the Bylaws; and iv) Reviewing Proposed Rules and

Procedures of the CoE and CoC. These new sections were presented in highlighted text, so that any inline edits to new text could be seen.

- **Observer Organization designation replaced with Associate Member (Section 3):** Revisions to USP's Bylaws at the 2020 Convention Governance Meeting replaced the Observer Organization Member category with a new Associate Member category for both organizations and individuals; corresponding changes were made to sections in the *CoC Rules*.
- **The process for consideration of invited membership (Section 2.02B):** This section was updated to include a step for reaching out to potential Convention Members to assess their interest before proceeding with the invitation steps that follow. This section also is streamlined to read as a process for each organization considered for Membership.
- **The resolution process (Section 4.02) now includes two additional steps:** i) a pre-open hearing comment period; and ii) the steps taken by the CoC to review open hearing comments on proposed resolutions.
- **Citations updated throughout:** Citations were updated for either specificity or a change in designation caused by other revisions.
- **Revisions made throughout for clarity and precision.**

### Discussion

CoC members made the following comments; USP responses are in sub-bullets:

- How often are the *CoC Rules* updated?
  - The *CoC Rules* are updated every five years following the Convention Meeting. If the *CoC Rules* need to be updated before the next Convention Meeting, the same process used for these revisions would be followed (e.g., CoC review, 90-day Member comment, CoC review of comments, Board approval).

### Motion

Ms. Hanan Sboul moved to approve sending the proposed *CoC Rules* forward to full Convention Membership for a 90-day comment period as outlined in USP's Bylaws. The motion was seconded and then carried by unanimous consent.

## 7. CoE Rules

Mr. Lakavage opened the topic of the *Rules and Procedures of the Council of Experts (CoE Rules)* by noting that at the last meeting, the CoC cleared the provisionally-approved *CoE Rules* to be sent to Convention Membership for a 90-day Member comment period. During that period, USP received comments from three Members. These comments as well as recommendations from staff, and approved by the CoE, on how to address these comments were included in the CoC's briefing materials. He noted that Ms. Biswas's presentation will review comments that were most substantial, particularly those that resulted in significant changes to the *CoE Rules* since the CoC last saw them. He reminded the CoC that their role is to review these comments, the subsequent changes, and the rationales for the changes before they are sent to the Board of Trustees for final approval.

USP Senior Counsel Deborah Biswas reviewed the scope and purpose of the *CoE Rules* as well as the timeline for revising them. USP received requests for revisions to the *CoE Rules* from three Convention Members: 1) New Jersey Pharmaceutical Quality Control Association (NJPQCA); 2) Parenteral Drug Association (PDA); and 3) Food and Drug

Administration (FDA). USP shared the source letters of the comments with Convention Membership following this open comment period. Ms. Biswas reviewed noteworthy comments from Convention Members regarding the provisionally-approved *CoE Rules* as well as the recommended responses and any necessary revisions to the *CoE Rules* proposed by the CoE.

### Convention Member comments – general

The following noteworthy comments and the CoE's responses were shared during the meeting:

- **60-day timeframe:** NJPQCA believes that the 60-day timeframe for requesting a postponement is too short and should be changed to 120 days after the date of publication to allow sufficient time for stakeholders to assess impact and determine if compliance is feasible by the official date. NJPQCA also recommends using the wording from last cycle to state that “A request for postponement received within sixty (60) days prior to the official date...may be refused for consideration...”
  - **Proposed CoE response:** We propose maintaining the 60-day timeframe. At 120 days many stakeholders will likely have already implemented or begun implementing changes consistent with the new or revised standard. For the same reason, we recommend not reverting to the previous language of “60 days prior to the official date.” In the event that an issue is discovered after the 60-day time period has passed, USP would still be able to make changes using the accelerated revision process, as appropriate.
- **Postponements:** The processes for postponements and appeals do not address accelerated revisions. NJPQCA recommends including a note in the Rules that recognizes that accelerated revisions may need expedited timeframes for requesting and reviewing postponements and appeals.
  - **Proposed CoE response:** We agree that the postponement section did not specify whether it applied to accelerated revisions. Given that accelerated revisions can become official in a matter of days, we recommend clarifying the text in the *CoE Rules* to explain that items advanced under the Accelerated Revision Guidelines are not eligible for postponement and that requests related to such items will instead be considered as a new request for revision or an accelerated revision.
- **Expert Advisors:** PDA suggests defining procedures to assure fair and unbiased selection of Expert Advisors, including a requirement that they demonstrate commitment to rigorous scientific inquiry. This would help the Expert Committee or Expert Panel feel confident in accepting the final input and prevent the inadvertent selection of Expert Advisors with a predetermined outcome in mind.
  - **Proposed CoE response:** Like all USP staff and volunteers Expert Advisors must comply with USP's Code of Ethics. As such, Expert Advisors will be required to disclose conflicts of interest that will be made known to other volunteers. Additionally, USP has established guidelines for the engagement of expert advisors that are designed to ensure identification of a diverse set of experts that can effectively contribute to USP's work. Given these factors, we think that Expert Panel and Expert Committee members will be able to have confidence in the qualifications of the Expert Advisors while being able to appropriately consider any potential conflicts of interest.
- **Sharing comments:** PDA urges USP to continue to use caution in publicly releasing comments. USP may want to check with the commenter before making

public any comment on a monograph, any comment containing data, and any comment on which there is any question about whether the content was intended by the commenter to be confidential.

- **Proposed CoE response:** We agree that it is important that stakeholders have a high level of confidence that data submitted confidentially will remain confidential, and we think that this can be achieved without having to reach out to each commenter. As a practical matter, in many circumstances reaching out to each commenter would be prohibitively costly in terms of USP staff time and resources. USP intends to provide clear messaging to stakeholders to explain their responsibility to unambiguously designate comments (or portions thereof) as confidential. In the event that USP is unsure of a commenter's intent with respect to confidentiality, USP could reach out to the commenter under that limited circumstance.

### **Convention Member comments – Final Discussion topic**

The following are comments from PDA and FDA on the topic of final discussion and government liaisons (GLs) in the *CoE Rules* that were shared at the meeting:

- PDA: Close collaboration between USP and governmental authorities is critical to the ongoing utility of USP-NF standards.
- PDA: Omit the sentence, "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."
- FDA: Changes to final discussion in the Rules and Procedures of the CoE will fundamentally alter the relationship between USP and FDA.
- FDA: Any perceived conflict of interest with FDA is mitigated, if not cured, and accounted for in other provisions of the Rules governing GLs.
- FDA: The recent practice of categorically excluding FDA GLs from final discussions does not align with USP's public-facing statements regarding transparency and collaboration.
- FDA: Final discussion provisions make it impossible for FDA GLs to participate in meaningful activities of their respective committees.
- FDA: USP should continue to use the mechanisms already in place to address actual conflicts of interest as they arise.

The CoE's proposed response to the comments from PDA and FDA on the topic of final discussion and government liaisons were the following:

- USP agrees that FDA government liaisons play a critically important role in the development of standards by providing expert input and regulatory context.
- After careful consideration, USP is proposing to remove the final discussion step from the process in order to maintain transparency in the standard-setting process.
- The Chairperson of an Expert Committee maintains the authority to close an official meeting and excuse any members or non-voting participants for standards of conduct reasons, or other reasons.

### **Other revisions to CoE Rules**

USP also implemented other revisions to the provisional *CoE Rules* to:

- Correct cross-references to sections of the Rules and Procedures, as well as references to sections in USP's Bylaws.

- Clarify the breadth of stakeholder engagement activities that may be undertaken.
- Expand the flexibility in the role of project teams as well as the flexibility to create project teams.
- Clarify the role of the CoE Chairperson in assessing requests for postponement.
- Make clear the steps in the appeals process and standard of review during the appeal process.

### **Discussion**

There were no comments or questions on the recent revisions to the *CoE Rules*.

### **Motion**

Dr. Emmanuel Akala moved to approve the forwarding to the Board of Trustees: (a) the provisionally-approved *CoE Rules*; (b) all comments from CoC membership; (c) any responses to the comments from the CoE; and (d) a recommendation for approval. The motion was seconded and then carried by unanimous consent.

## **8. Convention Membership Overview**

Dr. Kuzner provided an overview of Convention Membership composition and previewed upcoming activities related to composition. He noted this was not a decisional topic during this meeting, but the information will set the stage for decisions to come at future CoC meetings and in discussions that will take place throughout the five-year cycle. Before entering those decisional discussions, it's essential to have a full picture and history of Convention Membership and some time to reflect on that. Dr. Kuzner reminded the CoC that this topic is being brought to them since Membership is one of the CoC's main responsibilities described in USP's Bylaws – the rules, criteria for Membership consideration, and recommendations for invitation. His presentation covered Membership's importance, Membership composition, requirements for Membership, the future state of Membership, and what's next for the CoC.

Dr. Kuzner noted that inactive Membership hinders USP's ability to engage with the depth and breadth of the Membership, compromises reaching quorum at the USP Convention Meeting and suggests low attendance and engagement at the event, and can be a drain on staff time used for outreach efforts to Membership during contact audits, registration drives for the Convention Meeting, and other upcoming engagement efforts for the current cycle (e.g., events of Convention Sectors and Regional Chapters as well as the Call for Resolutions). Organizations may potentially be removed after failing to attend two consecutive Regular Membership Meetings or by failing to appoint a Delegate.

Dr. Kuzner emphasized that the broader evaluation of Membership aims to create a Convention Membership representative of USP's contemporary stakeholders and strategic vision, and inclusive of under-represented populations. Ultimately, all of this aims to foster active engagement from Membership throughout a five-year cycle and to help advance the current cycle's strategic goals adopted at the USP Convention Meeting.

At future meetings, the CoC will address potential removals, new organizations for potential membership, and plans for establishing new goals for Convention Member categories based on USP's strategic vision.

## Discussion

CoC members made the following comments; USP responses are in sub-bullets:

- How many organizations are eligible for removal?
  - There are 136 organizations eligible for removal. The CoC will evaluate these before recommending them for removal. Recommendations for removal are then forwarded to the Board of Trustees for final approval to remove.
- Where did the future state goals come from?
  - These were developed at the start of the 2015-2020 cycle by a cross-governing body consisting of members from USP's governing bodies and senior-level staff at USP. They will need to be re-evaluated by the CoC for alignment with USP's new strategic plan for the 2020-2025 cycle. USP plans to establish a CoC Membership committee to help develop these new goals and evaluate new potential members and organizations eligible for removal.
- Where does the combined 60 percent minimum from the two membership categories of "Health Practitioner Professional and Scientific Associations" and "Academic Institutions and Associations Thereof" come from?
  - This requirement comes from USP's Bylaws.

## 9. USP Code of Ethics

Mr. Lakavage introduced the topic of the *USP Code of Ethics (Code)* by noting that the *Code* is a guideline that provides the baseline standard of conduct for all USP employees, volunteers, and representatives to follow. This helps ensure that everyone connected to USP has the information they need to do what is expected of them. Given the unique nature of the CoC's role as representatives of both the Convention and their organization's constituencies, not everything in the *Code* applies to CoC members, but there are some general terms in the *Code* to be aware of. He noted that USP will share the *Code* with everyone following the meeting.

Ms. Biswas presented on the *Code* and certain portions applicable to CoC members. She noted that the *Code* sets forth principles that have made USP a trusted and respected standard-setting organization since its inception, demonstrates an ongoing commitment to legal and ethical behavior, and is available on USP's website.

She explained that CoC members are expected to:

- Consistent with the *Code*, act with integrity and hold themselves to high ethical standards when they are acting on behalf of USP.
- Be generally familiar with the *Code* and know where to find it:  
<https://www.usp.org/ethics>.

Specific portions of the *Code* may not be applicable to all CoC members in the course of their duties, but some provisions of the *Code* are generally applicable. For example:

- CoC members are expected to act respectfully to others in the course of their duties.
- CoC members must not speak on behalf of USP unless authorized to do so.
- CoC members must not disclose confidential information (e.g., in-process revisions to the Bylaws, submissions for the Call for Resolutions, membership applications, and any other CoC work that has not yet been made public).

Lastly, CoC members who are also CoE members will have additional ethical concerns applicable to Expert Volunteers that they need to be familiar with.

#### **10. What's Next**

Dr. Kuzner noted that following the meeting, USP staff will send presentation slides and the *USP Code of Ethics* to CoC members. Also, staff will soon reach out to CoC members to poll meeting dates for some time during the beginning of May.

#### **11. Adjourn and Closing Remarks**

Mr. Lakavage thanked CoC members for their work both during the meeting and in pre-meeting assignments. He also thanked those joining from the U.S. since it was an early start time in the morning for them. The start time will rotate with each meeting, given this is a global committee. Lastly, Mr. Lakavage noted that going forward CoC meetings will be less process-oriented and USP plans to include guest speakers and other dynamic programming elements.

**The Chair adjourned the meeting at 9:00 a.m. ET.**

## ADDENDUM

### Attendees

#### CoC Members

##### **CoC Chair and President of the Convention**

1. Dennis E. Doherty, M.D., Convention President and CoC Chair

##### **USP Convention Sector Chairs**

2. Generics Sector Chair: David Gaugh, R.Ph., Association for Accessible Medicines
3. Healthcare Practice Sector Chair: Amy Cadwallader, Ph.D., American Medical Association
4. Biologics Sector Chair: Susan Cantrell, BS Pharm., Academy of Managed Care Pharmacy
5. Excipients Sector Chair: Mary Kirchhoff, Ph.D., American Chemical Society
6. Dietary Supplements Sector Chair: Jay Sirois, Ph.D., Consumer Healthcare Products Association

##### **USP Convention Regional Chapter Chairs**

7. South Asia Region Chapter Chair: Bhojraj Suresh, M.Pharm., Ph.D., D.Sc. Pharmacy Council of India
8. Latin America Region Chapter Chair: Caroline Weinstein, Ph.D., Chilean Pharmacopeia
9. Greater China Region Chapter Chair: Mingzhe Xu, National Institutes for Food and Drug Control
10. Asia Pacific Region Chapter Chair: John Chien-Wei Lim, M.D., M.S., Centre of Regulatory Excellence, Duke-NUS Medical School

##### **At-Large Members**

11. Emmanuel Akala, R. Ph., Ph.D., DIM, Howard University College of Pharmacy
12. Lynette Bradley-Baker, Ph.D., R.Ph., American Association of Colleges of Pharmacy
13. Keysha Brooks-Coley, M.A., American Cancer Society/Cancer Action Network
14. Barbara Exum, PharmD, Virginia Commonwealth University/Medical College of Virginia School of Pharmacy
15. Stephen Mullenix, BS Pharm., R.Ph., National Council for Prescription Drug Programs
16. Pallavi Nithyanandan, Ph.D., FDA Center for Drug Evaluation and Research
17. Sue Peschin, M.H.S., Alliance for Aging Research
18. Hanan Sboul, M.B.A., B. Pharm, CAE, Jordanian Association of Pharmaceutical Manufacturers
19. Kanecia Zimmerman, M.D., American Academy of Pediatrics

##### **Council of Experts Representatives**

20. Martin Coffey, Ph.D., USP General Chapters—Dosage Forms Expert Committee
21. Stephanie Crawford, M.P.H., Ph.D., USP Nomenclature and Labeling Expert Committee
22. Kim Huynh-Ba, M.S., B.Sc., USP Small Molecules 4 Expert Committee
23. Xiaorong He, MBA, Ph.D., M.S., B.S., USP General Chapters—Physical Analytical Methods Expert Committee

**USP staff**

1. Anthony Lakavage, J.D., Convention and Board Secretary and Senior Vice President, Global External Affairs
2. Shelley Whiddon, M.A., Senior Director, Operations, Convention and Stakeholder Engagement
3. Scott Kuzner, Ph.D., Director, Board and Convention Operations
4. Amy Sonderman, Director, Convention and Stakeholder Engagement
5. Mario Sindaco, M.S., M.B.A., Vice President, Volunteer and Compendial Operations
6. Deborah Biswas, J.D., Senior Counsel