California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

COMPOUNDING COMMITTEE
MEETING MINUTES

DATE:	February 20, 2019
LOCATION:	Department of Consumer Affairs First Floor Hearing Room 1625 N. Market Blvd. Sacramento, CA 95834
COMMITTEE MEMBERS PRESENT:	Maria Serpa, Licensee Member, Chairperson Victor Law, Licensee Member Allen Schaad, Licensee Member
COMMITTEE MEMBERS NOT PRESENT:	Shirley Kim, Public Member Stan Weisser, Licensee Member
STAFF MEMBERS PRESENT:	Anne Sodergren, Interim Executive Officer Julia Ansel, Chief of Enforcement Peg Panella-Spangler, Supervising Inspector Anna Kalantar, Supervising Inspector Laura Freedman, DCA Staff Counsel Kelsey Pruden, DCA Staff Counsel Debbie Damoth, Administration Manager

1. **Call to Order and Establishment of Quorum and General Announcements**

   Chairperson Serpa called the meeting to order at 10:05 am. Board members present: Allen Schaad, Maria Serpa and Victor Law. A quorum was established.

2. **Public Comment on Items not on the Agenda/Agenda Items for Future Meetings**

   Danny Martinez of the California Pharmacists Association commented on the availability of the meeting materials and requested meeting materials be provided in advance of the meeting.

   Marie Cottman of Pacific Compounding requested the board consider adding to the agenda autologous serum eye drops that require both compounding and a biologics licenses.

3. **Presentation on the Current Proposed Revisions to USP General Chapter 795, Regarding Pharmaceutical Compounding – Nonsterile Preparations**

The committee heard a presentation on the current proposed revisions to USP General Chapter <795> regarding pharmaceutical compounding for nonsterile preparations by Supervising Inspectors Peg Panella-Spangler and Anna Kalantar.

Supervising Inspector Panella-Spangler provided an overview of the United States Pharmacopeia (USP) 2015-2020 Council of Experts including Healthcare Quality Standards Collaborative Group which includes compounding. USP maintains resolutions to work with stakeholders in the development and maintenance of practice and quality standards in sterile and non-sterile compounding. USP includes General Chapters: <795> – Pharmaceutical Compounding – Nonsterile Products; <797> – Pharmaceutical Compounding – Sterile Preparations; <800> – Hazardous Drugs – Handling in Healthcare Settings; and <825> – Radiopharmaceutical Preparation, Compounding, Dispensing, and Repackaging. Ms. Panella-Spangler updated the committee on the status of USP revising Chapter <795> and subsequent revisions.

Supervising Inspector Panella-Spangler provided a synopsis of the proposed changes to the draft Chapter <795> to reflect new science and evidence based on updated guidance documents, best practices, and new learnings from investigations. The intent of the current draft is to respond to stakeholder input, clarify confusing topics and align with published Chapters <800> and revision efforts for Chapter <797>. The current Chapter <795> served as a template, and many of the summary statements were expanded to add clarity to requirements.

The committee was provided with a summary of the changes made in draft Chapter <795> based on the 14 sections.

Draft section Introduction and Scope added information on compounded nonsterile preparations (CNSP) and moved all hazardous drugs to General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings. A designated person was added and defined as one or more individuals responsible and accountable for the facility and personnel. Definitions for compounding and reconstituting were added.

Draft section Personnel Qualifications delineated training, competency and proficiency requirements prior to preparing CNSPs. Proficiency steps and minimum core competencies that must be demonstrated are noted.

Draft section Personal Hygiene and Garbing specified requirements prior to entering a designated compounding area and hand hygiene procedures. The draft section noted gloves are required and outlined appropriate garb.

Draft section Buildings and Facilities required a designated compounding area and outlined facility requirements (e.g., source of hot/cold water and accessible sink, etc.).

Draft section Cleaning and Sanitizing defined cleaning and sanitizing agent. Minimum frequencies for cleaning and sanitizing surfaces in nonsterile compounding areas were added.

Draft section Equipment and Components added the requirement for using a containment ventilated enclosure (CVE) for the weighing, measuring, or other manipulation of an active pharmaceutical ingredient (API). Minimum frequency for cleaning and sanitizing the CVE and equipment were defined. Certification requirements for the CVE were added. Requirements for components were added.

Draft section Standard Operating Procedures (SOP), Master Formulation and Compounding Records established the requirement for SOPs, master formulation records and compounding records.

Draft section Release Testing required visual inspection prior to release of any CNSPs and all checks/inspections for CNSPs detailed in SOPs.

Draft section Labeling defined and detailed requirements for labeling.

Draft section Establishing Beyond-Use Dates (BUD) defined and established parameters for BUDs. Maximum BUDs and package requirements were defined as well as the extension and shortening of the BUD. Microbial limit testing strategy for representative pharmaceutical and OTC drug products based on water activity was added to UPS <112>.

Draft section Quality Assurance and Quality Control defined quality assurance (QA) and quality control (QC) as well as outlined requirements for QA and QC.

Draft section CNSP Handling, Packaging, Storage and Transport outlined requirements for packaging materials, storage and shipping/transporting of CNSP.

Draft section Complaint Handling and Adverse Event Reporting detailed the requirements for developing and implementing SOPs for complaint receipt, acknowledgement and handling as well as defined the role of the designated person in the process.

Draft section Documentation defined the minimum requirements for electronic documentation for facilities where CNSPs are prepared.

Chairperson Serpa inquired about the labs used for stability testing for nonsterile compounding. Supervising Inspector Panella-Spangler provided that the same labs used for sterile compounding testing can be used for nonsterile compounding testing.

Committee Member Schaad confirmed the gloving and garbing requirement would be for any compounding. Supervising Inspector Panella-Spangler confirmed gloves are required and garbing is recommended at this time.

Joe Grasela of University Compounding Pharmacy recommended the board release the presentation to all compounders. Mr. Grasela confirmed that a study was not needed for a tablet as 180 days is the maximum. Mr. Grasela recommended the committee remove current compounding pharmacy law and replace with the USP when adopted.

DCA Counsel Freedman commented this meeting is for the educational purposes of the committee members. Chairperson Serpa encouraged Mr. Grasela to continue to attend the committee meetings to participate throughout the process.

Pharmacist Ranel Larsen commented on the quality of the presentation. Ms. Larsen noted there is a difference between water content and water activity. Ms. Larsen referred the committee to USP <659> for the temperature definitions.

Marie Cottman from Pacific Compounding Pharmacy shared she has no problem with the updated chapter and making changes to adhere to new requirements. Ms. Cottman shared her concern with the committee as an owner of a sterile compounding pharmacy about the fiscal impact of implementation. Ms. Cottman reminded the committee as a sterile compounding pharmacy, her pharmacy is inspected annually whereas pharmacies who do nonsterile compounding are not inspected annually. Ms. Cottman requested the committee consider this when developing implementation.

Board President and Committee Member Law confirmed it is the board's intent to ensure pharmacies are inspected every four years. Mr. Law advised the public the board can be notified if an inspection is needed or illegal activity is occurring at a pharmacy.

Mr. Grasela commented the out of state pharmacies will not be inspected. Mr. Grasela commented the committee may consider requiring accreditation to be licensed as a compounding pharmacy to ensure out of state pharmacies are inspected.

Clara Brown of Animal Solutions Pharmacy recommended and requested the committee to require pharmacists filling veterinary compounds know how to counsel and know species specific data of animals they are compounding for in order to reduce error rates. California Veterinary Medical Association and Veterinary Medical Association now requires counselling by a veterinarian when medication is provided to an animal. Ms. Brown requests the board protect animal patients as well as human patients. Ms. Brown expressed concern on the feasibility of implementation.

DCA Counsel Freedman reminded the committee and public this meeting is for the educational purposes of the committee members. Chairperson Serpa reminded the committee and public that board inspectors are inspecting to the current board regulation. The information presented today is draft USP <795> and not current board regulation.

Christine Versichele of Dynalabs commented to the committee that lab results completed by Dynalabs are provided online for customers for up to five years.

Chairperson Serpa inquired about testing for QA. Supervising Inspector Panella-Spangler provided her understanding was that testing was required to extend the BUD and not for routine QA. Interim Executive Officer Anne Sodergren indicated the committee could look at the release testing provisions in the chapter.

Jenny Partridge, a pharmacist and inspector for ACHC doing nonresident inspections for Texas, Louisiana and Florida and a surveyor for ACHC for specialty infusion sterile/nonsterile compounding

pharmacies, supports the adoption of draft USP <795> with consideration of comments to the cleaning, BUDs and garbing.

Paul Mahan of PETNET Solutions advised the committee he participated as a panel member on writing USP <825>. Mr. Mahan commented that USP <795> will not include nonsterile radiopharmaceuticals as it has been moved to USP <825>. Mr. Mahan reminded the committee that USP Chapters are the minimum standards that should be followed. Additionally, he commented that the audience of the USP Chapters extends beyond pharmacists/pharmacies.

Marie Cottman commented that the draft USP <795> is written for a larger audience and shared her concern with adopting draft USP <795> in its entirety. Ms. Cottman expressed concerns on the requirement that certificates of analysis (COA) meet all of the requirements of USP monographs.

4. Future Committee Meeting Dates

Chairperson Serpa announced the committee's next meeting is scheduled for March 13, 2019, in Sacramento.

5. Adjournment

Chairperson Serpa adjourned the meeting at 11:31 am.