California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES

DATE:	September 26, 2018
STAFF LOCATION:	Department of Consumer Affairs – 1st Floor Hearing Room 1625 N. Market Blvd. Sacramento, CA 95834
ADDITIONAL TELECONFERENCE LOCATIONS:	1235 Buena Vista Duarte, Ca 91010 550 Montgomery Street San Francisco, Ca 94111 401 N. Garfield Ave. Monterey Park, Ca 91754 2029 H Street Sacramento, Ca 95811
BOARD MEMBERS PRESENT:	Victor Law, Licensee Member, President Lavanza Butler, Licensee Member Deborah Veale, Licensee Member Ricardo Sanchez, Public Member Albert Wong, Licensee Member Stanley Weisser, Licensee Member Maria Serpa, Licensee Member Valerie Munoz, Public Member
BOARD MEMBERS NOT PRESENT:	Allen Schaad, Licensee Member Shirley Kim, Public Member Ryan Brooks, Public Member Amjad Khan, Public Member Gregory Lippe, Public Member
STAFF PRESENT:	Virginia Herold, Executive Officer Anne Sodergren, Assistant Executive Officer Laura Freedman, DCA Staff Counsel Kelsey Pruden, DCA Staff Counsel Laura Hendricks, Staff Analyst

Wednesday, September 26, 2018

Call to Order 9:30 a.m.

I. Call to Order, Establishment of Quorum and General Announcements

President Law called the meeting to order at 9:30 a.m. He apologized for the late start of the meeting and thanked the public for their patience.

Board members present: Victor Law, Lavanza Butler, Ricardo Sanchez, Deborah Veale, Valerie Munoz, Maria Serpa, Stanley Weisser and Albert Wong.

President Law asked if there were any members of the public at the teleconference locations. Mr. Sanchez indicated that there was a member of the public at his location in Sacramento. It was also announced that there was a member of the public at the San Francisco location.

President Law asked board member Stanley Weisser to lead the meeting.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

There were no comments from the public or from the board.

III. Discussion and Consideration of Proposal to Modify Pharmacy Compounding Regulations (Title 16, California Code of Regulations, Sections 1735.1, 1735.2, 1735.6, 1751.1, & 1751.4), Including Review of Public Comments and, Potentially, Modified Text

Board member Weisser explained that at the July 2017 Board Meeting, the board approved proposed text to amend Sections 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4 of Title 16 CCR, related to Compounded Drug Preparations. This proposal formally amends the board's regulations regarding the establishment of compounding beyond use dates as it relates to sterile and non-sterile compounded drug preparations. Additionally, this regulation allows for the use of a double filtration system and further aligns the board's regulations with The United States Pharmacopeia - National Formulary (USP), which is the professional industry standards used across the nation.

Mr. Weisser stated that USP contains standards developed by a committee of experts that, among other things, help ensure the quality of compounded medications. USP's General Chapters for compounding establish procedures, methods and practices that are utilized by practitioners to help ensure the quality of compounded preparations. Mr. Weisser explained that the General Chapters for compounding include Chapter 795 (Pharmaceutical Compounding – Nonsterile Compounding), Chapter 797 (Pharmaceutical Compounding – Sterile Preparations) and Chapter 800 (Hazardous Drugs – Handling in Healthcare Settings). Further, the U.S. Federal Food, Drug, and Cosmetics Act designates the USP as the official compendia for drugs marketed in the United States. Mr. Weisser noted that all drug products within the U.S. market must conform to the standards in USP to avoid possible charges of adulteration and misbranding.

Mr. Weisser explained that as required by the Administrative Procedure Act, board staff released the proposed text for the 45-day comment period on August 3, 2018, which ended on September 17, 2018 following review by the Department of Consumer Affairs and the Business, Consumer Services, and Housing Agency.

Mr. Weisser reported that the comments received during the 45-day comment period were included as an attachment to the meeting materials. Also included are: board staff prepared recommendations in response to the comments and a proposed modified text.

Mr. Weisser explained that at this meeting the board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue. Among its options:

1. Amend the regulation to address any concerns raised by stakeholders.
2. Adopt the regulation as noticed by the Board on August 3, 2018.

Board member Deborah Veale thanked board staff for reviewing the comments and providing detailed recommendations.

Compounding pharmacist Marie Cotman stated that 1751.4(k) should be modified to remove the upper temperature limit for the sterile compounding room because some compounding staff may need the room temperature warmer or cooler based on their personal body chemistry. She added that if the board did not want to remove the upper temperature entirely they then could use the term “should” instead of “shall.” This would make the language more permissive, allowing the room temperature to be set at a temperature that is both ideal for the employees working in the room and for maintaining sterility.

Anne Sodergren stated that two comments had been received during the comment period regarding the temperature of the sterile compounding room. She explained that the language mirrors the temperature limits in USP.

Board member Maria Serpa recommended simplifying the language by removing the upper temperature limit from 1751.4 as room temperature is defined in another section of the regulation. She added that two degrees Celsius up or down is not clinically significant, the critical consideration for the temperature is if the product will be contaminated by sweat from staff working in the room. The board agreed with Dr. Serpa and directed staff to remove the upper limit from 1751.4(k).

BJ Bartleson and Candace Fong stated that the California Hospital Association supports the removal of the upper temperature limit in 1751.4(k).

Ms. Fong stated that the board should modify 1735.1(c) because USP does not require that each biological safety cabinet be individually vented. Ms. Sodergren responded that the regulation uses the term “should” not “shall.” Ms. Fong thanked her for the clarification.

Ms. Bartleson and Ms. Fong stated that many of their members are concerned with the amount of time and expense that modifying their sterile compounding rooms will take

(particularly in regard to regulating the temperature) and asked the board to delay implementation for a year to allow time to make the modifications. Mr. Weisser stated that the board has been working on these regulations for well over a year and many of the requirements are already in USP, so hospitals should have already been working towards compliance.

Sung Choy representing Cardinal Health stated that the board should reconsider 1735.2(i)(3) regarding beyond use date extension testing. Mr. Weisser responded that this section was not part of the comment period and recommended that Mr. Choy attend the newly formed Compounding Committee meetings where the committee will be reviewing the USP language and the board's regulations.

Motion: Adopt the staff recommended modified text, dated September 19, 2018, and remove the temperature upper limit in 1751.4(k). Notice the language for a 15-day comment period.

M/S: Sanchez/Wong

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Khan				x
Kim				x
Law	x			
Lippe				x
Munoz	x			
Sanchez	x			
Schaad				x
Serpa	x			
Veale	x			
Weisser	x			
Wong	x			

Motion: Should no negative comments be received, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

M/S: Veale/Law

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Khan				x
Kim				x
Law	x			
Lippe				x

Board Member	Support	Oppose	Abstain	Not Present
Munoz	x			
Sanchez	x			
Schaad				x
Serpa	x			
Veale	x			
Weisser	x			
Wong	x			

President Law thanked Mr. Weisser for running the meeting and adjourned the meeting at 10:42 a.m.