TEXAS STATE BOARD OF PHARMACY

COMPOUNDING ADVISORY GROUP MEETING

Held via Videoconference

Thursday, June 24, 2021

MINUTES

I. Call to Order and Welcome

The meeting was called to order at 9:01 a.m.

Compounding Advisory Group members present via videoconference were Lisa Ashworth, R.Ph.; Jeff Carson, R.Ph.; Steve Hoffart, Pharm.D., R.Ph.; Jim Hrncir, R.Ph.; Jobby John, Pharm.D., R.Ph.; Cole Knutson, R.Ph.; Jasper Lovoi, Pharm.D., R.Ph.; Richie Ray, R.Ph.; Genee Schexnayder, Pharm.D., R.Ph.; Ray Solano, R.Ph.; Kelly Tran, Pharm.D., R.Ph. Board Member Liaison Donna Montemayor, R.Ph.; Amanda Lawrence, Pharm.D., R.Ph.; and Pamella Ochoa, Pharm.D., R.Ph., were not in attendance.

Board staff present via videoconference were Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director; Kerstin Arnold, General Counsel; Megan Holloway, Deputy General Counsel; Iona Grant, R.Ph., Senior Compliance Officer; Terri Burrows, Pharm.D., R.Ph., Compliance Officer; Adrienne Bauer, Ph.T.R., Senior Compliance Inspector; Jim Clark, R.Ph., Compliance Officer; and Kathy Salinas, R.Ph., Compliance Officer.

II. Announcements

Ms. Benz made general announcements.

III. Discussion and Approval of Minutes for Advisory Group Meeting held January 13, 2021

Ms. Benz advised that the group members had received drafted minutes from the meeting held January 13, 2021, for their review and called for a motion to approve the minutes or for the group members to indicate if any changes were needed. Dr. John motioned to approve the minutes as drafted. The motion was seconded by Dr. Schexnayder and passed unanimously.

IV. Discussion Concerning FDA Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products

Ms. Benz directed the group members to materials concerning the FDA Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products, including comments and a summary of issues from TSBP staff, and written comments from the following:

- Scott Brunner, CAE, Chief Executive Officer, Alliance for Pharmacy Compounding;
- Tom Siegenthaler, RPh, FACA, Owner, Pharmacy Solutions;
- Mike Sands, Co-Founder and CEO, SandsRx Pharmacy;
- Gretchen DuBeau, Esq., Executive and Legal Director, Alliance for Natural Health USA;
- Steven F. Hotze, M.D., Owner, Physicians Preference Pharmacy International, LLC;
- Alliance for Pharmacy Compounding, American Pharmacists Association, National Community Pharmacists Association, and PCCA;
- Lemrey “Al” Carter, Executive Director/Secretary, National Association of Boards of Pharmacy;
- Kasra Amirdelfan, M.D.; Ramsin Benyamin, M.D.; Anjum Bux, M.D.; Michael Fishman, M.D.; Salim M. Hayek, M.D., Ph.D.; Sean Li, M.D.; Yeshvant Navalgund, M.D.; Ali Nairizi, M.D, M.S., D.ABA; Anish S. Patel, M.D., M.B.A., F.A.S.A.; Jason E. Pope, M.D.; DABPM, FIPP; Dawood Sayed, M.D.; Peter S. Staats, M.D., MBA, FIPP, ABIPP; and Ricardo Vallejo, M.D.; and
- Charles R. Bell, Jr., President and Founder, Bond Pharmacy dba AIS Healthcare.

The group members heard public comments from:

- David Pore, Legislative and Regulatory Counsel, Alliance for Pharmacy Compounding, who spoke in support of requesting that FDA delay enforcement of the MOU for two years;
- Carmen Catzione, Founding Partner, CLM Pharmacy Advisors, who spoke in support of executing the MOU;
- Charles R. Bell, Jr., President and Founder, Bond Pharmacy dba AIS Healthcare, who spoke in support of executing the MOU; and
- John Finley, Chief Legal Officer, Bond Pharmacy dba AIS Healthcare, who spoke in support of executing the MOU.

Ms. Ashworth left the meeting at 9:59 a.m.

Ms. Benz recessed the meeting at 10:13 a.m.
Ms. Benz reconvened the meeting at 10:31 a.m.

The group members heard additional comments from Neal Watson, Senior Manager, Member Relations and Government Affairs, and Melissa Madigan, Associate Executive Director, Professional Affairs, National Association of Boards of Pharmacy (NABP), who provided information about the system being implemented by NABP to assist boards of

pharmacy in complying with the MOU.

Ms. Ashworth rejoined the meeting at 11:00 a.m.

Following discussion, a motion was made by Mr. Ray to recommend that the MOU not be executed, the concerns identified by Board staff be communicated to FDA, and to request a two-year extension from FDA for enforcement of the MOU. The motion was seconded by Dr. John and passed unanimously.

V. Discussion Concerning Virtual Training for Individuals Performing Sterile Compounding

Ms. Benz explained that at the February 2, 2021 Board meeting, there was a comment regarding virtual training for individuals performing sterile compounding and the Board wanted input from the Compounding Advisory Group. Ms. Benz directed the group's attention to §291.133 concerning required training for sterile compounding. Ms. Benz explained that there was concern with some training providers allowing for the required experiential training to be conducted virtually. Ms. Benz clarified that currently the Board requires that the training courses be ACPE-approved or through an ACPE-approved provider.

Following discussion, a motion was made by Dr. Schexnayder to recommend that virtual training for individuals performing sterile compounding not be accepted for the experiential training requirement. The motion was seconded by Mr. Knutson and passed unanimously.

VI. Discussion and Recommendations Concerning Proposed Changes of Non-Sterile Compounding Rules

Ms. Holloway explained that after receiving input and comments from the group members, there were items identified that needed discussion to resolve. Ms. Holloway directed the group's attention to the suggested rule changes to §291.131, which included annotated comments from the group members.

Ms. Holloway opened discussion regarding which pharmacists should be included in the special requirements and explained that Mr. Ray had suggested removing pharmacists "handling" non-sterile preparations from the list. Following discussion, the group member consensus was to only include pharmacists involved in the preparation and mixing of compounded non-sterile preparations.

Ms. Benz recessed the meeting at 12:07 p.m.
Ms. Benz reconvened the meeting at 1:02 p.m.

Ms. Holloway opened discussion concerning testing of preparations for accuracy of correct identities and amounts of ingredients. Discussion included adding the testing requirement to pharmacy technicians, how many preparations should be tested, and the timeline for completing and re-evaluating the testing. Following discussion, the group members determined that the suggested changes for additional requirements, including

the testing requirements, should only apply to pharmacies required to be licensed under the suggested new non-sterile designations and Ms. Holloway explained that §291.131 can be updated to separate out the requirements for all pharmacies compounding non-sterile preparations and the requirements for pharmacies required to comply with additional requirements.

Ms. Holloway explained that Ms. Ashworth had recommended that "hands-on" be added to the initial experiential training and opened discussion concerning this recommendation. Following discussion, the group member consensus was to add "hands-on, in person" to the experiential training requirements.

Ms. Holloway opened discussion concerning the suggested changes for the environment requirements and explained that Ms. Lawrence had commented that the requirements for a designated space for non-sterile compounding and the cleaning and sanitizing requirements may require a remodel. Following discussion, the group members recommended no changes to the environment requirements.

Ms. Holloway opened discussion concerning the calibration of balances and explained that Ms. Ashworth recommended defining "routine basis" for the calibration and verification requirement. Following discussion, the group recommended separating the requirement that the balance be inspected and calibrated by a qualified independent individual and that the balance be calibrated and verified on a routine basis as defined by the pharmacy's SOPs.

Ms. Holloway opened discussion concerning the requirement for compounding activities performed in a closed system processing device and explained that Ms. Lawrence had provided comments regarding the added expense to lower volume compounding sites and indicating she did not feel the requirement was necessary. Ms. Holloway also presented Mr. Knutson's suggested new language for the requirement, which Mr. Knutson indicated was to clearly identify that the requirement was for a closed system processing device. Following discussion, the group recommended keeping the requirements for a closed system processing device and using Mr. Knutson's suggested changes with updates to keep the list format.

VII. Discussion and Recommendations Concerning Proposed Changes for New Classes of Pharmacy

Ms. Holloway reviewed the suggested rule changes for Class A, Class C and Class E pharmacies that would establish licensing requirements for the "N" designation for pharmacies compounding non-sterile preparations and the "SN" designation for pharmacies compounding sterile and non-sterile preparations.

Mr. Knutson asked if the added requirement for the pharmacies to be inspected prior to renewal would cause issues for the Board. Ms. Grant indicated that it would not be a problem and the inspections could be worked into the inspectors' scheduling process.

Mr. Carson suggested updating the language for which pharmacies require the new non-sterile designations. Following discussion, the group members recommended

updating the language to include pharmacies engaged in compounding of non-sterile preparations that “use bulk API or excipients or manipulation beyond the FDA labeling of a commercial product (e.g., crushing a tablet or opening a capsule).” Ms. Holloway clarified that this language would be updated throughout all the suggested rule changes.

VIII. Items for Next Meeting

Ms. Benz asked for recommendations for discussion items for the next meeting and when to schedule the next meeting and indicated that there have been comments about reviewing sterile compounding or nuclear rules.

Mr. Carson suggested reviewing the possibility of incorporating a peer review process at the next meeting, which would include a resource for the board for expert witnesses at hearings.

Mr. Knutson suggested reviewing the requirement for signature on cleaning logs to possibly include initials. Ms. Grant clarified that the inspectors accept initials and suggested a key be documented for initials and names.

Ms. Benz indicated that proposed dates for the next meeting either in October or November would be sent to the group and recommended continuing to meet on Zoom.

Ms. Benz adjourned the meeting at 3:03 p.m.