



TEXAS STATE BOARD OF PHARMACY

COMPOUNDING ADVISORY GROUP MEETING

Held via Videoconference

Wednesday, January 13, 2021

MINUTES

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The meeting was called to order at 9:00 a.m.

Compounding Advisory Group members present via videoconference were Lisa Ashworth, R.Ph.; Jeff Carson, R.Ph.; Jim Hrcir, R.Ph.; Jobby John, Pharm.D., R.Ph.; Cole Knutson, R.Ph.; Jasper Lovoi, Pharm.D., R.Ph.; Pamella Ochoa, 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., Steve Hoffart, Pharm.D., R.Ph.; and Amanda Lawrence, 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; and Adrienne Bauer, Ph.T.R., Senior Compliance Inspector.

Ms. Benz advised that the group members had received drafted minutes from the November 18, 2020, meeting for their review and asked the group members to indicate if any changes were needed. No changes were requested.

Ms. Benz explained that at the Compound Advisory Group meeting on November 18, 2020, the group members requested board staff develop rule language suggestions based on the Compliance questions that did not have corresponding rules, to determine if a pharmacy is engaged in non-sterile compounding. Compliance staff drafted language to suggest changes in the non-sterile compounding rules, section 291.131 and these proposed changes were provided to the group members by email to review prior to this meeting.

Ms. Benz opened discussion concerning the suggested rule changes to §291.131.

During the discussion, suggestions were made to include language to clarify “preparation and handling of compounded non-sterile preparations” by removing reference to handling and update training.

Ms. Benz recessed the meeting at 10:21 a.m.

Ms. Benz reconvened the meeting at 10:30 a.m.

Discussion continued regarding the suggested updates to 291.131. It was suggested to include requirements outlining that initial training and outside validations testing of three compounding preparations occur within 6 months of hire.

After further discussion it was suggested the group focus on Class A and then review the other classes of pharmacy once changes for A have been implemented. It was also suggested to include Class E requirements at the same time as the Class A. Ms. Arnold explained the limitations on inspection of Class E pharmacies and what would require legislative change.

Next, Ms. Benz opened discussion concerning the suggested rule changes to §291.36. During the discussion it was suggested to modify the requirements for a Class A-N. Ms. Benz reminded the committee that we are not restricting a pharmacies ability to do non-sterile compounding, which is covered under existing rules, the committee is here to determine at which point there is a need for an additional license type which includes expanded rule requirements due to a potential for patient harm.

After further discussion, the group suggested to update the licensing requirement to include a pharmacy engaged in the compounding of non-sterile preparations that uses bulk API and/or bulk excipient or non-active pharmaceutical ingredient, or manipulation beyond commercially available products FDA approved dosage form.

Ms. Benz suggested the conversation with the group could be continued by email and that staff would email clarifications for review to which the group agreed. Ms. Benz also stated the correspondence would include language for the Class C pharmacies but not the Class Es. The group expressed concern and desire to include Class E pharmacies in these updates.

Ms. Benz informed the group staff would take their comments and suggestions and update the rules and send them back out by email for review and further comments to facilitate possible inclusion at the May Board meeting. A future meeting date after the May Board meeting would also be determined via email.

Ms. Benz adjourned the meeting at 1:05 p.m.