



TEXAS STATE BOARD OF PHARMACY

COMPOUNDING ADVISORY GROUP MEETING

Held via Videoconference

Wednesday, November 18, 2020

MINUTES

Wednesday, November 18, 2020

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.; Steve Hoffart, Pharm.D., R.Ph.; Jim Hrcir, R.Ph.; Jobby John, Pharm.D., R.Ph.; Cole Knutson, R.Ph.; Amanda Lawrence, Pharm.D., 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.; and Board Member Liaison Donna Montemayor, R.Ph. Pamela Ochoa, Pharm.D., R.Ph., was 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; Tera McConnell, Pharm.D., R.Ph., Compliance Program Officer; and Adrienne Bauer, Ph.T.R., Senior Compliance Inspector.

Ms. Benz advised that the group members had received drafted minutes from the September 16, 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 September 16, 2020, the group members had requested questions for compliance officers to ask to determine if a pharmacy is engaged in non-sterile compounding and to determine if a pharmacy is safely compounding non-sterile preparations. Ms. Benz informed the group that their question recommendations were provided to compliance staff for review and compliance staff used the recommendations to develop a list of useful questions for them, which were provided to the group members by email.

Ms. Benz opened discussion concerning the questions.

During the discussion, Ms. Benz asked for suggestions from the group regarding rules requiring the pharmacy to have the balances/scales checked by an outside vendor and the frequency the checks would need to occur. Following discussion, the group recommended that rule language be added to require certification of balances/scales by an outside vendor at least annually or following the manufacturer specifications and requiring documentation of any calibrations, including those completed in-house and by an outside vendor.

Ms. Benz directed the group's attention to the revised questions from compliance staff to be used to determine if a pharmacy is engaged in non-sterile compounding and asked for feedback from the group. The group made suggestions to modify the order the questions should be asked and to clarify the question regarding ingredients used in the compounding process.

Ms. Benz recessed the meeting at 10:11 a.m.
Ms. Benz reconvened the meeting at 10:26 a.m.

Ms. Benz directed the group's attention to the revised questions from compliance staff to be used to determine if a pharmacy is safely compounding non-sterile preparations and asked for feedback from the group. Ms. Burrows explained that to incorporate some of the initial question recommendations from the group for use during the inspection process, the rules would need to be amended. Ms. Benz suggested that if the group agreed on the necessity for the suggested questions which did not have existing rules, then board staff can develop new rule language suggestions based on those questions.

Following a question from Mr. Carson regarding developing a new class of pharmacy for pharmacies engaged in non-sterile compounding, Ms. Benz polled the group and all were in agreement to recommend that a new class of pharmacy for non-sterile compounding pharmacies be proposed to the board.

The group continued discussion regarding the questions to determine if a pharmacy is safely compounding non-sterile preparations. The group made suggestions for rule changes including language to incorporate the highlighted questions in the question list that did not have corresponding rules.

Ms. Benz explained that the earliest any rule language could be proposed to the board would be at the May 2021 board meeting and suggested the group meet again on January 13, 2021, to review the suggested rule changes.

Ms. Benz adjourned the meeting at 11:53 a.m.