Minnesota Board of Pharmacy

EIGHT HUNDRED NINETY FIRST MEETING

At approximately 9:00 a.m. on September 30, 2020, the Minnesota Board of Pharmacy met in the Board’s conference room at the University Park Plaza Building, 2829 University Avenue Southeast, Minneapolis, Minnesota – and by WebEx and telephone - for the purpose of conducting a general business meeting. Mr. Stuart Williams, Board President, attended the meeting in the conference room, along with Dr. Cody Wiberg, Executive Director; Dr. Beth Ferguson, Deputy Director; and Tami Wier, Office Manager. Board members who attended by WebEx and/or telephone were: Dr. Stacey Jassey, Dr. Mary Phipps, Dr. Amy Paradis, Dr. Kendra Metz, Mr. Rabih Nahas, Dr. Andrew Behm, Ms. Samantha Schirmer, and Mr. James Bialke. Also, in attendance by WebEx and/or telephone were Mr. Hans Anderson, Assistant Attorney General; and Board staff members - Ms. Michele Mattila, Ms. Ame Carlson, Ms. Ame Carlson, Ms. Jill Phillips, Dr. Kelly Hadsall, Ms. Barbara Carter, Dr. Katrina Howard, and Ms. Shannon Whitman.

Due to the COVID-19 pandemic and the governor’s declaration of a peacetime emergency pursuant to Minn. Stats. §12.31 in Executive Order 20-01, the meeting was conducted by WebEx and telephone. Interested individuals were able to monitor the open session of the meeting remotely by WebEx or telephone at no charge.

President Williams called the meeting to order. A quorum was confirmed by roll call. The Board went into closed session to discuss disciplinary cases.

The Board returned to open session and Mr. Williams conducted a roll call and confirmed that a quorum was present.

The Board discussed the minutes of the August 19, 2020 business meeting. After discussion by the Board, President Williams declared the minutes approved as distributed with a correction on the first page, paragraph seven, to reflect that President Williams asked for discussion and a vote to approve the VPRC recommendation.

Next, the Board considered the Agenda for the meeting. President Williams requested to add a brief update of the PhRMA lawsuit that was filed against the Board. With no further discussion or additions, the Agenda was approved as distributed - with President William’s addition.

The Board then considered the Variance and Policy Review Committee (VPRC) Report. Since the meeting was conducted by WebEx and telephone, Board members were required to abstain from voting on the variance and policy requests that involved pharmacies owned by their employers. The VPRC report was included in the packet of meeting materials and contained details of the requests.

After consideration of the VPRC report by the Board members, President Williams conducted a vote to accept the recommendations of the VPRC for items not deferred to the Board, and to authorize the executive director to issue the appropriate orders. The recommendations from the VPRC were unanimously approved through roll call voting. Mr. Nahas abstained from voting on all variances and policy reviews concerning the Allina Health System. Dr. Paradis abstained from voting on all variances and policy reviews concerning Sterling Drug.
Next, the Board considered the variance request from the University of Minnesota, College of Pharmacy to allow first year pharmacy students to be eligible for internship registration after completing the first six weeks of the Doctor of Pharmacy program. Dr. Lynda Welage, Dean and Professor of the College of Pharmacy, Dr. Jeannine Conway, Associate Dean of Professional Education, and Dr. Andrew Traynor, Assistant Dean for Experiential Education were present to answer Board inquiries and concerns. Dr. Welage asked that the request be considered as a blanket request. After Board discussion, Dr. Welage agreed to defer the variance request to the November Board meeting so that the University could provide the additional information and data requested during the discussion.

The next variance and policy reviews were deferred to the Board for a discussion concerning the transition of Sterling Drug’s Spring Grove location into a telepharmacy with multiple secondary hubs (up to 11 locations) - taking into consideration the volume of prescriptions and the distance of the Spring Grove location to other pharmacies. Dr. Paradis recused herself from voting but was present during the Board discussion to answer any Board questions or concerns. After discussion, the Board consensus was to not favor a telepharmacy with multiple secondary hubs as presented. Since this was a discussion only, no other action was taken.

Next, the VPRC submitted a matter for Board discussion concerning Costco’s variance in relation to the use of a central services pharmacy arrangement that involves a pharmacy located outside of Minnesota. When approving past requests involving out-of-state central service pharmacies, the Board made approval of the necessary variances contingent upon having the pharmacy technicians that work at the out-of-state pharmacy registered by the Board. In this case, the technicians working at the facility are not employees of Costco – they are employees of McKesson. Speaking for Costco were Mr. Mike Bierly, and Mr. Todd Nova. During discussion, Ms. Sarah Brown from Fairview Health Services was allowed to comment on Fairview’s practice concerning contract employees. After additional discussion, the consensus of the Board was that using long-term contract technicians in a pharmacy would not prevent a variance request from being approved as long as there was appropriate and sufficient oversight of the contract technicians by the pharmacists on duty, and that the technicians were registered with the Minnesota Board of Pharmacy. Since this was for discussion only, no action was taken.

With no further variance and policy reviews, the Board moved to Rules, Statutes, and Guidances. The first item discussed involved a follow-up of the COVID-19 related request from Walgreens to allow pharmacists working in other states to be remotely involved in the dispensing process of Walgreens pharmacies located within Minnesota. Dr. Wiberg presented background information concerning the request. Ms. Nichole Cover, Director of Pharmacy Affairs for Walgreen’s and Mr. Steve Lincoln were present during the call to answer any Board questions. After review of the data and additional discussion, Mr. Bialke moved to continue the previous Board decision to use enforcement discretion to allow Walgreen’s to use their central fulfillment services in Arizona and Florida to provide dispensing support to Minnesota pharmacies on a rolling basis determined by COVID-related concerns, limited to the four temporary sites identified during the discussion and up to 15% of other Minnesota sites at any one time, until the next Board Meeting on November 18, 2020, at which time Walgreens will provide the Board with updates. Mr. Nahas seconded the motion. Using roll call voting, the motion passed unanimously.

Next, the Board heard presentations from the National Coalition for Drug Quality & Security (QAS) and AMICUS CGMP Consultants, LLC (“AMICUS”). QAS was seeking Board acceptance of their accreditation for drug wholesalers for whom an inspection may be required for licensure - when the facility does not have a current inspection from their home-state agency. AMICUS asked the Board to consider their organization as an authorized representative of the Board for compounding inspections. Ms. Denise
Frank from QAS spoke first, describing her organization’s mission and inspection program. Dr. Kristopher Le then provided a brief synopsis of AMICUS’ mission and program. After review and discussion of both programs, Mr. Bialke moved that the Board exercise enforcement discretion, through the duration of the declared peacetime emergency, to allow the submission of inspections conducted by QAS, which the Board’s Surveyors could review and either deny or approve on a case-by-case basis. Dr. Behm seconded the motion. Using roll call voting, the motion passed by divided vote, with Dr. Behm, Mr. Bialke, Dr. Metz, Mr. Nahas, Ms. Schirmer, and Dr. Phipps voting in favor and Dr. Jassey voting against. As President, Mr. Williams did not vote, and Dr. Paradis had to leave the meeting before this vote. The Board deferred AMICUS to the next Board meeting in November to allow AMICUS to provide additional information to the Board for review.

Next, Ms. Barbara Carter presented program updates from the Controlled Substance Reporting Section of the Board, including the annual report and related analysis for the Prescription Monitoring Program. Since this was informational only, no action was taken.

Dr. Wiberg briefed the Board on the current status of the Minnesota Insulin Safety Net Program. Since this was informational only, no action was taken.

Next, President Williams updated the Board on the PhRMA lawsuit. Since this was informational only, no action was taken.

Next, Dr. Wiberg mentioned the availability of the Continuing Education and Pharmacist Licensure Reports. The reports are informational only, no action was necessary.

At approximately 2:15 p.m., with no other business before the Board, President Williams declared the open session adjourned.