923rd Meeting of the Minnesota Board of Pharmacy
335 Randolph Avenue, First Floor Board Room
St. Paul, MN 55102
Wednesday, August 14, 2024

Public (Open) Session – 10:00 a.m.

President Ronda Marie Chakolis called the meeting to order at 10:02 am. This meeting was held in person and virtually. President Chakolis reviewed the mission of the Board.
A roll call of Board members was taken, and a quorum declared.

Board Members Present:

- Ronda Marie Chakolis
- Kendra Metz
- James Bialke
- Ben Maisenbach
- Michael Haag
- Amy Paradis
- Rabih Nahas
- John Zwier
- Barbara Dröher Kline

Surveyors Present:

- Ame Carlson
- Kelly
- Aaron
- Andrea Bistodeau
- Michele Mattila

Other Staff Present:

- Jill Phillips
- Katrina Howard
- Tawnie Langenfeld
- Patrick Sauer

Agenda Items:

1. Review and Approve Minutes – no discussion or corrections, approved with unanimous consent.

2. Review and Approve Agenda – no discussion or corrections, approved with unanimous consent.

3. Variances and Policy Reviews – Ame Carlson

    a. Thrifty White request for a telepharmacy to operate with a 1 telepharmacy to 1 hub pharmacist oversight OR to operate with a 2 telepharmacy (Baudette and Fertile) to 1 hub pharmacist oversight. ***This submission was reviewed at the June 5, 2024 VPRC meeting and the recommendation was deferred until the August 14, 2024 on condition that the Baudette and Fertile sites are inspected by board surveyors and the inspection findings are discussed at the August Board meeting.***
        a. President Chakolis invited the Board surveyors to review their inspection findings for the Board. An overview of findings, corrective actions that had been

implemented, and ongoing concerns were presented. At the conclusion of the surveyor remarks the floor was opened to the Board. Discussion was heard between Board members, surveyor staff, and representatives from Thrifty White who attended the meeting virtually. It was noted that any variance approved today would have an expiration date of Feb 8, 2025, to align with other variances, and further evaluation could be made at that time.

A motion to approve Thrifty White's variance to operate with a 2 telepharmacy (Baudette and Fertile) to 1 hub pharmacist oversight with an expiration date of Feb 8, 2025, was made by Kendra Metz and seconded by John Zwier.

Roll Call Vote:

- Ronda Marie Chakolis - abstain
- Kendra Metz - Y
- James Bialke - N
- Ben Maisenbach - Y
- Michael Haag - N
- Amy Paradis - Y
- Rabih Nahas - Y
- John Zwier - Y
- Barbara Dröher Kline - Y

b. Consideration of the Variances and Policy Review Committee (VPRC) Report. Pharmacist board members will abstain from voting on issues involving pharmacies owned by employer.

Motion to approve the remainder of the report as presented made by Michael Haag, seconded by John Zwier.

Roll Call Vote:

- Ronda Marie Chakolis - yes, abstaining from issues involving their employer.
- Kendra Metz - yes
- James Bialke - yes
- Ben Maisenbach - yes, abstaining from issues involving their employer.
- Michael Haag - yes
- Amy Paradis - yes
- Rabih Nahas - yes, abstaining from issues involving their employer.
- John Zwier - yes
- Barbara Dröher Kline - yes

4. NABP Pulse update – Andrew Funk

Mr. Funk provided an update on the Drug Supply Chain Security Act, reviewing milestones,

updates, and exemptions for small dispensers. He then described NABP Pulse, a digital directory to establish relationships throughout the drug supply chain. This will include product verification, tracing, authorized provider status, and contact information. Possible future Board steps were also discussed. The floor was opened for discussion, none heard. This presentation was informational, and no action was required of the Board at this time.

5. Legislative Presentation – Lindsey Franklin

   Legislative liaison, Lindsey Franklin, reviewed bill brought by a legislator that would require the Board to engage in rulemaking around labeling and instructions on medications. The Board must propose language and give authority to the Executive Director to notice it to the state legislature.

6. Proposed Rules Governing Prescription Labeling- Jill Phillips
   Executive Director Phillips presented the changes required to align with the aforementioned bill. Discussion was heard from the Board about the changes.

   A motion to approve was made by Kendra Metz, seconded by James Bialke.

   Roll Call Vote:
   - Ronda Marie Chakolis - yes
   - Kendra Metz - yes
   - James Bialke - yes
   - Ben Maisenbach - yes
   - Michael Haag - yes
   - Amy Paradis - yes
   - Rabih Nahas - yes
   - John Zwier - yes
   - Barbara Dröher Kline - yes

7. Draft FAQ Flavoring -Jill Phillips

   Executive Director Phillips introduced a draft guidance document aimed at Minnesota pharmacists regarding medication flavoring additives. Per USP, flavoring is considered to be non-sterile compounding. Minnesota does not have any codified exceptions or workarounds to this. The floor was opened for discussion and feedback from Board members was heard. A motion to approve the FAQ as written was made by Michael Haag, seconded by James Bialke. The draft as approved is attached to this document.

Roll Call Vote:

- Ronda Marie Chakolis - yes
- Kendra Metz - yes
- James Bialke - yes
- Ben Maisenbach - yes
- Michael Haag - yes
- Amy Paradis - yes
- Rabih Nahas - yes
- John Zwier - no
- Barbara Dröher Kline - yes

8. Staffing update – Licensure Supervisor (Patrick Sauer) – Jill Phillips

The new Board Licensure Supervisor, Patrick Sauer, was introduced and welcomed.

9. ALIMS update – Katrina Howard

Deputy Director Howard reviewed the fiscal year 2024 development of the Board's new records software system, ALIMS.

10. District V update – Ronda Marie Chakolis

Board members and staff who attended the District V meeting shared their experiences and highlights of the conference.

11. Miscellaneous
    a. CE Report
    b. Pharmacist Licensing Report
       These reports are informational, and no action is required by the Board.

12. Assistant Attorney General Hans Anderson introduced and welcomed new AAG Erin Farmer.

13. PhRMA vs. Williams – Sarah Krans
    A statement to the public was made by President Chakolis that the meeting would be closing as permitted by the attorney-client privilege under Minn. Stat. s. 13D.05, subd. 3(b) to discuss litigation strategy in Pharmaceutical Research and Manufacturers of America v. Bialke, District of Minnesota file number 0:20-cv-01497. The matter then moved to closed session.

At the conclusion of the closed session, President Chakolis reopened the meeting and adjourned at 12:30pm.

FAQ for Minnesota Board of Pharmacy Website

Question:

Is adding flavoring to a conventionally manufactured nonsterile product considered compounding?

Proposed Answer:

Yes. United States Pharmacopeia ("USP") has determined adding a component such as flavoring not stipulated in the labeling to a conventionally manufactured nonsterile product is compounding and has been within the scope of USP <795> since 2004. USP has reemphasized this in its November 1, 2022 guidance document entitled "<795>: Adding Flavor to Conventionally Manufactured Nonsterile Products."

Additionally, Minnesota Rule 6800.3300, subpart 1 sets forth the standards for nonsterile compounding. The rule states that if pharmacies engage in nonsterile compounding, they must follow USP <795> standards.

The Minnesota Board of Pharmacy ("Board") recognizes the importance of this service, particularly in the pediatric population. Furthermore, the Board is aware the majority of states, including those states who border with Minnesota and whose resident pharmacies may directly serve Minnesota patients, have either enacted rules or statutes creating exceptions for flavoring, or have indicated they may use enforcement discretion when applying USP 795 standards to its licensees who add flavoring.

Accordingly, at this time, if a licensed Minnesota pharmacy elects to add flavoring to a conventionally manufactured product for the purpose of improving palatability, the Board may exercise its enforcement discretion regarding the applicable USP <795> requirements with the exception of the following USP <795> requirements:

- Flavoring agents must still consist of inactive ingredients and must not exceed 10% variance from the labeled strength.
- If a pharmacy adds flavoring to a manufactured product it must still take into account the manufacturer's Beyond Use Date ("BUD") and the effect on stability caused by adding flavoring.
- The addition of flavoring including the flavor manufacturer or product, lot number, and expiration date must still be documented in the patient record notes for the prescription. This includes any relevant calculations and quantities/volumes of additives (e.g., water, flavoring agent(s), etc.). Such documentation must still be made available for inspection and copying upon the request of the Board or an agent of the Board.

The Board also expects its licensees to follow and adhere to all other applicable state and federal rules and laws while conducting pharmacy operations.