

**COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY**

**Pharmacy Advisory Committee
Meeting held via remote WebEx
Boston, Massachusetts, 02114
June 12, 2024**

Advisory Committee Members Present

David Sencabaugh chair designee by James Lavery)
Antoinette Lavino, RPh, BCOP (Expert in USP <797>)
John Walczyk, RPh, PharmD (Expert in USP <795>)
Sylvia B. Bartel, RPh (Expert in USP <797>)
David H. Farb, PhD (Expert in Clinical Pharmacology)
Karen B. Byers, MS, RBP, CBSP (Expert in Microbiology)
John P. Mistler, Pharm. D, RPh, MBA, BCSCP, CPH (Expert in cGMP)
Timothy D Fensky, RPh, DPh, FACA (Expert in USP <71>)

Board of Pharmacy Member Present

Sami Ahmed, PharmD, RPh, BCPS, BCSCP

Advisory Committee Members Not Present

Keith B. Thomasset, BS, PharmD, MBA, BCPS (Pharmacoeconomics)
Francis McAteer (Expert in Microbiology)
Michael J. Gonyeau, RPh, PharmD, Med, BCPS, FNAP, FCCP (Expert in Clinical Pharmacology)

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, Assistant Executive Director
Jacqueline Petrillo, PharmD, RPh, JD General Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh Quality Assurance Pharmacist
Nathan Van Allen, PharmD, RPh Pharmacy Investigator
Joanne Trifone, RPh, Director of Investigations
Gunjan Patel, Student MCPHS - Worcester

TOPIC I. Attendance by roll call:

Call to Order, by David Sencabaugh at 9:08am and announces that the meeting is being recorded.

Roll call attendance: John Mistler, Timothy Fensky, Antoinette Lavino, Sylvia Bartel, John Walczyk, David Fard, Karen Byers

Not Present: Michael Gonyeau, Francis McAteer, Keith Thomasset

TOPIC II. Approval of Agenda Time: 9:09am
Agenda: 06/12/24
Changes: 4/26/2023 meeting date

Agenda was approved by roll call vote with the noted change.

Roll call approval by all members present: John Mistler, Timothy Fensky, Antoinette Lavino, Sylvia Bartel, John Walczyk, David Farb, Karen Byers, David Sencabaugh

Topic III Approval of Board Minutes Time: 9:10am
1. Minutes
Draft 04/26/2023

Changes: No additional changes

Meeting minutes were approved by roll call vote with no changes.

Roll call approval by members present: John Mistler, Timothy Fensky, Antoinette Lavino, Sylvia Bartel, John Walczyk, David Farb, Karen Byers
Abstain – David Sencabaugh

Introduction of Sami Ahmed – President Elect of MA Board of Pharmacy

TOPIC IV: Recommendation Document 24-01 “Implantable Infusion Pump” Time: 9:12am
Recused: None
Presented: Sami Ahmed
Discussion: Provided general reason for discussion on behalf of Board of Pharmacy.

TOPIC V: Provide expert input and advisory opinion on the compounding of Implantable Infusion Pump by Board Licensees

Time: 9:18am
Recused: None
Presented: PAC Committee
Discussion:

W. Frisch – Provided background to discussion based on submitted letter by Pentec Health regarding

implantable infusion pumps. Specific points for discussion include revisiting restrictions implemented at the time of initial licensing and time at which administration begins.

M. Chan – Reviewed specific questions related to discussion regarding Pentec Health’s requirements of licensure.

A. Lavino – Inquired into additional resource accessibility for help in reviewing current consensus.

Members discussed elements of concern regarding time at which administration begins based on USP 797 standards, precipitation within devices, sterility, endotoxin, potency, time and temperature testing.

W. Frisch – Noted that direct testing has been conducted by Pharmacy on 13 drug combinations and noted that there may be relevant and reliable resources for other combinations.

Members inquired about number of drugs and drug combinations that the Pharmacy would be evaluating expansion of compounding services. Members noted that the Pharmacy would be compounding a combination of API and commercially available drugs, single and multi-drug combination.

Members inquired about other state BORP requirements for such procedures. None known of.

Members inquired about specific pump requirements and if another pump were to be used would the same restrictions for direct testing apply.

Members are concerned about limitations to patient access by implementing too many restrictions not currently described within the USP standard. Inquired if there is information related to how many pharmacies within the country are currently conducting such procedures and shipping into MA.

M. Chan – Inquired from members if specific requirements are only to be placed on Pentec Health or if a more general documents should be developed for all pharmacies who are/would be licensed in MA.

Members noted that a general guidance document would be beneficial.

W. Frisch – Noted that there are currently no reported serious adverse events by the Pharmacy.

M. Chan – Once non-resident regulations are finalized, the BORP will have a better understanding of compounds being shipped into MA.

Members noted that a Pharmacy should be conducting specific direct testing or utilizing reliable resources to evaluate the compounded and dispensed medication.

W. Frisch – Noted that DRAFT 247 CMR 17.00 previously included language for implantable pumps including BUD and dwell time. Language was removed upon recommendation by PAC and approval by BORP. Most current version of DRAFT 247 CMR 17.00 does not currently have any language describing implantable pumps.

W. Frisch – Noted that restriction of patient access is not the goal but rather safety for the preparation being compounded and instilled within an implantable pump device.

J. Walczyk – Recommended acquiring list of proposed medication to be compounded by Pentec Health for BORP review.

M. Chan – Reiterated BORP requirement of Pentec Health to conduct testing on specific combinations for the entire time within the pump. Asked members if this restriction is to be maintained.

Members noted that off label use typically includes a consenting process where the patient is made aware of the level supportive information available.

W. Frisch – Asked for final comments of PAC members.

D. Sencabaugh – Agreed to final discussion and developing an advisory opinion.

VI: Summarize Advisory Opinion and vote:

Time: 9:58am

Members noted that additional information is needed including what combinations are being proposed for compounding expansion, direct testing and/or relevant and reliable references. Additionally, a general guidance document could be developed to help with addressing future needs.

W. Frisch – Noted that a general reference document could be developed and could evolve over time.

Summary of Discussion/Motion:

W. Frisch – Motion to do further study and research on topic including working with Pentec Heath on experience out of state with drug combinations and review of published articles, focusing on FDA warning letter, and most current guidelines for practice.

Motion by T. Fensky and seconded by D. Sencabaugh and voted unanimously by those present to provide the above summary opinion to the BORP.

Roll call vote: John Mistler, Timothy Fensky, Antoinette Lavino, Sylvia Bartel, John Walczyk, David Farb, Karen Byers, David Sencabaugh

VII. Closing remarks and Adjournment of Meeting

Time: 10:11am

Comments:

Adjournment:

Motion by T. Fensky and seconded by A. Lavino and voted unanimously by those present to adjourn the meeting.

Roll call vote: John Mistler, Timothy Fensky, Antoinette Lavino, Sylvia Bartel, John Walczyk, David Farb, Karen Byers, David Sencabaugh
