

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

**Pharmacy Advisory Committee  
Meeting held via remote WebEx  
Boston, Massachusetts, 02114  
April 26, 2023**

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**Advisory Committee Members Present**

Ed Taglieri, MSM, NHA, RPh (chair designee by James Lavery)  
Antoinette Lavino, RPh, BCOP (Expert in USP<797>)  
Sylvia B. Bartel, RPh (Expert in USP<797>)  
David H. Farb, PhD (Expert in Clinical Pharmacology)  
John P. Mistler, Pharm. D, RPh, MBA, BCSCP, CPH (Expert in cGMP)  
Patrick Gannon, RPh, MSM, FABC additional expert member  
Timothy D Fensky, RPh, DPh, FACA (Expert in USP<71>)  
Michael J. Gonyeau, RPh, PharmD, Med, BCPS, FNAP, FCCP (Expert in Clinical Pharmacology)  
Keith B. Thomasset, BS, PharmD, MBA, BCPS (Pharmacoeconomics) (leaves at 11:00 AM)

**Board of Pharmacy Member Present**

Sami Ahmed, PharmD, RPh, BCPS, BCSCP

**Advisory Committee Members Not Present**

Judith Barr, MEd, ScD, FASHAP (Expert in Pharmacoeconomics)  
John Walczyk, RPh, PharmD (Expert in USP<795>)  
Francis McAteer (Expert in Microbiology)  
Karen B. Byers, MS, RBP, CBSP (Expert in Microbiology)

**Board Staff Present**

David Sencabaugh, RPh, Executive Director  
Monica Botto, Assistant Executive Director  
Jacqueline Petrillo, PharmD, RPh, JD General Counsel  
Michael Egan, JD, Board Counsel  
William Frisch, RPh Director of Pharmacy Compliance  
Michelle Chan, RPh Quality Assurance Pharmacist  
Sam Penta, RPh Senior Investigator  
Nathan Van Allen, PharmD, RPh Pharmacy Investigator  
Joanne Trifone, RPh, Director of Investigations

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**TOPIC I.** Attendance by roll call:

Call to Order, by Ed Taglieri at 10:03am and announces that the meeting is being recorded.

Roll call attendance: S. Bartell, J. Mistler, P. Gannon, T. Fensky, K. Thomasset, M. Gonyeau, E. Taglieri, A. Lavino joined the meeting at 10:04am, D. Farb joined the meeting at 10:08am.

Not Present: J. Barr, J. Walczyk, F. McAteer, K. Byers, J. Lavery (E. Taglieri appointed chair by J. Lavery for this meeting)

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<b>TOPIC II.</b>	<b>Approval of Agenda</b>	<b>Time: 10:03am</b>
<b>Agenda: 4/26/23</b>		
<b>Changes:</b>	<b>None</b>	

Motion by T. Fensky and seconded by M. Gonyeau and voted unanimously by those present to approve the agenda with no noted changes by roll call vote.

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<b>Topic III</b>	<b>Approval of Board Minutes</b>	
<b>1. Minutes</b>		<b>Time: 10:04am</b>
<b>Draft 3/22/23</b>		
<b>Changes:</b>	<b>None</b>	

No discussion

Motion by P. Gannon and seconded by T. Fensky and voted unanimously by those present to approve the minutes from the 3/22/2023 meeting with no noted changes by roll call vote.

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**TOPIC IV:** Presentation of Recommendation Document 23-03, "Compounding Ketamine Nasal Spray"

**Time: 10:06am**

**S. Ahmed:** Requests Pharmacy Advisory Committee members to review the safety and necessity of compounded ketamine nasal spray by board licensees with consideration on both the needs of the patients and public safety. There are many issues of concern from diversion to the opioid epidemic.

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**TOPIC V:** Provide expert input and advisory opinion on the compounding of Ketamine Nasal Spray by Board Licensees

**Time: 10:07am**

**Presented: PAC Committee**

**E. Taglieri:** Read committee the summary statement of the discussion topic. Recommendations will be presented to the Board of Registration in Pharmacy (BORP). Concerns with safety, REMS programs, prescribing scopes of practice.

**J. Petrillo:** Contacted counsel at Board of Registration in Medicine (BORIM). BORIM traditionally allows a licensed physician to prescribe medications to a patient without direct concern for scope of practice as long as the prescriber is licensed, in good standing, and prescribing within the standard of care.

**P. Gannon:** Noted concern with prescribing outside the scope of practice with an example of anesthesiologists prescribing for patients being treated for psychiatric and treatment resistant depressive disorders. Patient provider relation may not be present in such circumstances.

**J. Petrillo:** Clarified that issue for discussion does not include the physician-patient relationship or compounding of the preparation. The topic for discussion is should a board licensed pharmacist be able to compound ketamine nasal spray with or without restrictions comparative to esketamine REMS requirements for dispensing. Board staff and members are looking for opinion from committee on these points.

**E. Taglieri:** Noted this is the Pharmacists corresponding responsibility for the care of the patient. Is the pharmacist comfortable with its prescribing and within scope of practice?

**T. Fensky:** Described that the medication is not only being used for pain or depression. Drug has been used for a long time either compounded topically, or for nasal use. Off label use is an allowable circumstance and questions why this situation is any different.

**K. Thomasset:** Noted that this is an opportunity to focus on the safety elements as the primary point.

**J. Petrillo:** Noted that multiple dosage forms exist that are not subject to REMS requirements. Dosage forms include oral troches, injection, topicals.

**E. Taglieri:** Posed question to group regarding development of safeguards when assessing prescriptions for compounded ketamine nasal spray.

**S. Bartell:** Noted that esketamine is typically not the agent used in the institutional facilities. Other dosage forms exist.

**T. Fensky:** Expressed that additional safeguards for the compounding of the ketamine nasal spray are not necessary and that current USP 795, if followed, should manage the risk.

**K. Thomasset:** Noted that additional safeguards would be in place for the patient.

**J. Petrillo:** Request is to provide recommendations to bring forward to the BORP.

**T. Fensky:** Recommended searching other states limiting compounding of ketamine nasal spray and suggested NABPLAW may be a good starting point?

**E. Taglieri:** Noted that safety concerns have been identified by the FDA and that is the reason for REMS. The compounded preparation does not have to adhere to the same restrictions of esketamine.

**S. Bartell:** Noted that ISMP recommends not compounding preparations when a commercial alternative exists.

**J. Petrillo:** Clarified that FDA is clear that ketamine and esketamine are not the same drug. If committee determines that certain safeguards should be considered, recommendations can be made.

**E. Taglieri:** Recommended the committee make a motion to move to next step regarding allowance of pharmacies to compound ketamine nasal spray.

Motion by T. Fensky, and seconded by S. Bartell, and voted on in the affirmative by members present to allow compounding pharmacies to continue compounding ketamine nasal spray.

**Vote Conducted:**

**Approve:** A. Lavino, S. Bartell, D. Farb, T. Fensky, M. Gonyeau, E. Taglieri

**Abstain:** J. Mistler, P. Gannon

**E. Taglieri:** Motion passed.

**E. Taglieri:** Recommended the committee continue with next motion for compounding with or without restrictions.

Motion by S. Bartell, seconded by A. Lavino, and voted on in the affirmative by members present to allow compounding with restrictions.

**Vote Conducted:**

**Approve:** A. Lavino, S. Bartell, D. Farb, P. Gannon, K. Thomasset, M. Gonyeau, E. Taglieri

**Abstain:** J. Mistler

**Nay:** T. Fensky

**E. Taglieri:** Motion passed

**E. Taglieri:** Described the elements of the REMS program to the committee.

**J. Petrillo:** Noted that monitoring requirements included observation period after administration. is after administration.

**Members:** Noted that additional steps that regularly occur in the course of pharmacy practice do not need to be included in the safeguards.

**T. Fensky:** Noted that patient access would suffer due to logistics issues with dispensing and monitoring requirements.

**M. Gonyeau:** Concerned with both access and safety and two-tiered system for the patient and providers.

**P. Gannon:** Agree with safety concerns of other members. Interested while under REMS program evaluation, how much data was captured to determine need for REMS.

**K. Thomasset:** Abuse potential is equally important in this decision procedure.

**J. Mistler:** Added cost considerations with brand versus compounded preparations, telehealth, and out of state pharmacies compounding.

**T. Fensky:** Noted that licensure issues will push compounds out of state with less restrictions and oversight.

**A. Lavino:** Noted the need for more information to determine quality recommendations.

**S. Bartell:** Noted importance to determine extent of events adverse events.

**J. Petrillo:** Noted that the committee can recommend a more general approach to safety versus more specific restrictions.

**K. Thomasset** left meeting at 11:00 am.

**A. Lavino** left meeting at 11:00 am.

**E. Taglieri:** Described some instances where reasonable actions taken by Pharmacist would be appropriate to ensure patient safety. Requested committee to provide a suggestion for a general safety restriction.

**T. Fensky:** Reiterated the need of the RPh to appropriately counsel the patient and to be able to determine when extra counseling is necessary.

**P. Gannon:** Noted that self-administration could present safety considerations and recommended another person for observation.

**M. Gonyeau:** Asked if BORIM could make recommendations to prescribers to have the conversation with patient during the evaluation.

**E. Taglieri:** Maybe a joint policy with BORIM be developed.

**J. Petrillo:** Noted that a final decision is not required at this time.

**D. Farb:** Noted that the counseling is part of normal RPh practice.

**E. Taglieri: Next steps.**

- Is another meeting necessary or in committee comfortable in providing initial recommendation?
- BORIM consider issuing guidance to prescribers.

**J. Petrillo:** Noted that this topic is planned to be discussed at the next Board meeting.

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#### **VI: Summarize Advisory Opinion and vote:**

**Time: 11:20am**

Motion by P. Gannon, seconded by M. Gonyeau, and voted on in the affirmative by members present to allow compounding of ketamine nasal spray by board licensees with some restrictions to continue (not defined at this time), refer matter to BORIM for input from prescribers, Pharmacy Advisory Committee willing to meet again, review data from NABPLAW, ADR, PMP as requested by BOP.

**Vote: S. Bartell, D. Farb, M. Gonyeau, P. Gannon, T. Fensky, E. Taglieri**

**Abstain: J. Mistler**

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#### **VII. Closing remarks and Adjournment of Meeting**

**Time: 11:24am**

##### **Comments:**

Motion by P. Gannon, seconded by T. Fensky, and voted unanimously by members present to adjourn the meeting by roll call vote.