REVISED 8/29/3035

COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

NOTICE OF THE REGULARLY SCHEDULED MEETING OF THE BOARD OF REGISTRATION IN PHARMACY

September 4, 2025

The regular session is open to the public by video or phone.

Join link:

https://eohhs.webex.com/eohhs/j.php?MTID=mae7577a778450e41838e8ff2961ea82e

Webinar number: 2536 811 0093 Webinar password: Bop456 Join by phone:

+1-617-315-0704 United States Toll (Boston) +1-650-479-3208 United States Toll

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Stacy Hart, Stacy. Hart@mass.gov or 857-274-1120 in advance of the meeting. While the Board will do its best to accommodate you, certain accommodation may require distinctive requests or the hiring of outside contractors and may not be available if requested immediately before the meeting.

Agenda

8:00		CALL TO ORDER	S.
			Ahmed
8:05	II	APPROVAL OF AGENDA	
8:10	Ш	APPROVAL OF BOARD MINUTES	
		Draft of August 7, 2025, Regular Session Minutes	
		PEROPEC	
8:15	IV	REPORTS	
		Applications approved pursuant to Licensure Policy 13-01	
		Monthly report from Probation	
		Board Delegated Review pursuant to Licensure Policy 14-02	

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		TE VISED 0/2	710000
8:45	V	FLEX PAC Recommendation Document 25-02 meeting on 10/16/25 NABP Resolution Election of delegate and alternate to NABP district meeting Notice of Opportunity Response for Board approved inspector: Accreditation Commission for Health Care (ACHC) Proposed 2026 Board meetings Thursday, January 8 Thursday, February 5 Thursday, March 5 Thursday, March 26 Thursday, May 7 Thursday, June 4 July – No meeting Thursday, August 6 Thursday, September 3 Thursday, November 5 Thursday, November 5	
9:15	VI	POLICY • Policy 2021-04: Continuing Education (CE) Requirements for Pharmacists • Policy 2023-02: Vaccine Administration	

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9:20		• CarePartners; DS1000008 – Drug Schedule Amendment							
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		Rutland Family Pharmacy DENIE 1000280							
		o Retail Pharmacy DSNE1000389							
		O Complex Non-Sterile; DSNE46255NS							
		Nantucket Pharmacy DSNE10000324—Petition for waiver 247 CMR 0.10 (2) Proposition area is at least 225 as ft.							
		o 247 CMR 9.19 (2) Prescription area is at least 325sq ft							
		 CVS CarePlus/CVS2516; DS2873 Renovation DSRN10140 							
	VII		_	odel Change					
				C	Non-Sterile Compounding -				
		•	NDSNE62038NS	i-Resident Complex	Non-sterne Compounding -				
		•	Jungle Jim's Pharm	nacy					
		· ·	_	ent Retail Pharmacy	NDSNE31822				
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		 Non-Resident Complex Non-Sterile Compounding NDSNE62086NS 							
		Non-Resident Sterile Compounding – NDSNE97456SC							
		o from Resident Sterine Compositioning (1951/2)/ 1868							
	VIII	FILE REVIEW							
		1 (CASE-2025-1279	PHA-2025-0051	Walgreens #5075, DS2928				
		2 (CASE-2025-0881	INV17494	Walgreens #3062, DS2337				
10:30		3 0	CASE-2025-1991	PHA-2025-0061	Vivo Health Pharmacy at Home, NDS31272				
10.50		4 (CASE-2025-1830	PHA-2025-0062	Nehal Patil, PH233631				
		5 (CASE-2025-0983	INV17782	Christopher Ryan, PH22331				
		6 (CASE-2025-0808	PHA-2025-0035	Walgreens #10427, DS3611				
			IVE SESSION	iva Sassion as outho	orized pursuant to M.G.L. a. 2014				
		The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition,							
11.00	IV	or mental health, rather than professional competence, of an individual, or to discuss							
11:00	IX			or complaints or charges brought against, a public					
		officer, employee, staff member or individual. Specifically, to evaluate the Good							
		Moral Character as required for registration for a pending applicant.							
11:30	X	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)							
11:45				LUNCH					
12:15	XI	M.G.L. c. 112, § 65C SESSION							
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4:00	XII	ADJOURNMENT			
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COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting September 4, 2025

Board Members Present

Sami Ahmed, PharmD., RPh, BCPS, BCSCP, President
Saad Dinno, RPh, FACP/FACA, President-Elect
Mark Sciaraffa, CPhT, Secretary
Katie Thornell, RPh, MBA
Caryn Belisle, RPh, MBA
John Rocchio, RPh, PharmD
Delilah Barnes, RPh
Rita Morelli, PharmD, BCACP, RPh
Julie Dorgan, RN
Timothy Fensky, RPh
Stephanie Patel, MD, MBA, FFHPM, HMDC

Board Staff Present

Michael Godek, Executive Director
Monica Botto, Associate Executive Director
Jacqueline Petrillo, PharmD, RPh, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh, Quality Assurance Pharmacist
Richard Harris, Program Analyst
Joanna Chow, Program Analyst
Taylor Lee, Office Support Specialist
Joanne Trifone, RPh, Director of Investigations
Julienne Tran, PharmD, Investigator
Gregory Melton, JD, PharmD, BCPS, Investigator
Cheryl Lathum, RPh, PharmD, BCPS, Senior Investigator
Keith Johnstone, Compliance Officer
David Sencabaugh
Gayatri Ramasubramanian, Pharmacy Intern

Board Members Not Present

Frank Lombardo

TOPIC I. Attendance by roll call:

Madhurima Chowdhury, Pharmacy Intern

CALL TO ORDER 8:01 AM

A quorum of the Board was present, established by roll call. President Sami Ahmed chaired the meeting and explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: S. Dinno, yes; M. Sciaraffa, yes; D. Barnes, yes; C. Belisle, yes; R. Morelli, yes; J. Rocchio, yes; K. Thornell, yes; S. Patel; yes; S. Ahmed, yes.

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Draft Minutes General Session: 09/04/25

Topic II. Approval of Agenda TIME 8:03 AM

Agenda: 09/04/25

DISCUSSION: Revised agenda.

<u>ACTION:</u> Motion by D. BARNES, seconded by M. SCIARAFFA and voted unanimously by those present to approve the agenda with the noted change by roll call vote.

Topic III Approval of Board Minutes TIME: 8:06 AM

Minutes

1. Draft 08/07/25

Change: None

<u>ACTION:</u> Motion by K. THORNELL seconded J. DORGAN and voted unanimously by those present to approve the regular session minutes of 7/10/2. C. Belisle, S. Ahmed and D. Barnes abstained.

Topic IV. REPORTS

Applications approved pursuant to Licensure Policy 13-01

PRESENTED BY: R. Harris

<u>DISCUSSION:</u> R. HARRIS reported that the 13-01 report is in the Board packet and these are staff action files that have been approved since the last meeting.

TIME: 8:04 AM

TIME: 8:04 AM

So noted.

Topic IV. REPORTS

Monthly Report from Probation

PRESENTED BY: R. Harris

<u>DISCUSSION:</u> Discussion: R. HARRIS indicated that the probation report is also in the bord packet and that there is one licensee that was given the opportunity to cure.

So noted.

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Draft Minutes General Session: 09/04/25

Topic IV. REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

PRESENTED BY: R. Harris

<u>DISCUSSION:</u> R. HARRIS noted that the board delegated review was sent out separately.

So noted.

Topic V. FLEX

PAC Recommendation Document 25-02 meeting on 10/16/25
 TIME: 8:05 AM

TIME: 8:04 AM

PRESENTED BY: W. Frisch

RECUSAL: NONE

<u>DISCUSSION</u>: W. FRISCH mentioned that the board would like to meet with the Advisory Committee to collect expert input on lyophilization to guide the Board on how to best regulate the practice of lyophilization by sterile compounding pharmacies to safeguard the public. A meeting has been tentatively scheduled for 10/16/25.

S.Patel re-enters the meeting at 8:07 AM

<u>ACTION:</u> A motion was made by M. SCIARAFFA, seconded by K. THORNELL, voted unanimously by those present for the recommendation documents to move forward with the meeting as well as a board member identified who can take the topic forward to the advisory committee and report back to the board at the November meeting.

Draft Minutes General Session: 09/04/25

• NABP resolutions TIME: 8:09 AM

PRESENTED BY: M. Chan

RECUSAL: NONE

<u>DISCUSSION</u>: M. CHAN announced, now that the Board is licensing non-resident pharmacies, it has been noticed that some 503A pharmacies utilize specialized sterile compounding practices such as lyophilization that have traditionally been used in c-GMP drug manufacturing facilities. These practices are not addressed in USP <797> and therefore create a gap to properly regulate these practices.

Board staff has drafted a resolution titled "Specialized Sterile Compounding Practices" that requests NABP develop guidance or model act language for Boards of Pharmacy to regulate these specialized sterile compounding pharmacy practices to safeguard the public.

<u>ACTION:</u> A motion was made by C. BELISLE, seconded by J. ROCCHIO, voted unanimously by those present to approve the proposed resolution to bring to the district meeting.

Topic V. FLEX

Election of delegate and alternate to NABP district meeting
 TIME: 8:12 AM

PRESENTED BY: M. GODEK

RECUSAL: NONE

<u>DISCUSSION</u>: M. GODEK discusses that keeping with the theme of district meeting that's coming up on October 15th until the 17th in Philadelphia, if there is anyone going, we would need a delegate and an alternate delegate. Tim Fensky and John N Rocchio are attending the district meeting, J. Rocchio as delegate and T. Fensky as alternate.

<u>ACTION:</u> A motion was made by S. AHMED, seconded by S. DINNO, voted unanimously by those present to have J. ROCCHIO as delegate and T. Fensky as the alternate delegate for NABP district meeting.

Topic V. FLEX

• Notice of Opportunity Response for Board approved inspector: TIME: 08:14 AM Accreditation Commission for Health Care (ACHC)

PRESENTED BY: W. FRISCH

RECUSAL: NONE

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<u>DISCUSSION:</u> ACHC which now owns PCAB, has applied to become a Board approved inspector for sterile and complex non-sterile compounding pharmacies. Board staff have reviewed their submission documents and recommend approval of ACHC and their inspection tools. W. FRISCH believes that there was a supplemental distribution of all the materials for the application and all the related documentation that has been received and, after thorough review, would recommend approval.

<u>ACTION:</u> A motion was made by C. BELISLE, seconded by M. CHAN, voted unanimously by those present to add ACHC to the list of Board approved inspectors with their inspection tools

TIME: 8:19 AM

Topic V. FLEX

- 2026 Board meetings
 - Thursday, January 8
 - Thursday, February 5
 - Thursday, March 5
 - Thursday, March 26
 - Thursday, May 7
 - Thursday, June 4
 - July No meeting
 - Thursday, August 6
 - Thursday, September 3
 - Thursday, October 1
 - Thursday, November 5
 - Thursday, December 3

PRESENTED BY: R. Harris

RECUSAL: NONE

<u>DISCUSSION:</u> R. HARRIS announces that the proposed 2026 Board meetings are listed on the agenda, taking into consideration civil and religious holidays, July has been given off and the meetings continue to be on the first Thursdays of the month.

<u>ACTION:</u> A motion was made by M. SCIARAFFA, seconded by D. BARNES, voted unanimously by those present to approve the 2026 Board meeting dates decided.

Draft Minutes General Session: 09/04/25

TOPIC VI ADVISORIES

Failed HEPA Filters in ISO-Classified Environments

PRESENTED BY: M. CHAN

<u>DISCUSSION:</u> Updates guidance for compounding during remediation of failed HEPA filters, including

TIME: 8:10 AM

TIME: 8:25 AM

updated BUD assignments in accordance with USP <797>.

ACTION: Motion by R. MORELLI, seconded by C. BELISLE, and voted unanimously by roll call of those

present, to approve edits to the advisory.

Policy 2023-02: Vaccine Administration

PRESENTED BY: M. CHAN

<u>DISCUSSION</u>: To clarify confusion with the new federal COVID vaccine recommendations, a change was made to allow administration of all vaccines in accordance with DPH guidance instead of the CDC. A

statewide standing order for COVID vaccines has already been issued by DPH, and further guidance is to

come.

Along with these changes, a list of requirements for standing orders was added as well as clarification that

pharmacists, using their professional judgement, may dispense a vaccine to a patient, caregiver, or healthcare provider who is authorized to administer the vaccine. Such dispensing may be pursuant to

either a standing order or patient-specific prescription.

Qualified pharmacy personnel may now administer COVID vaccines to eligible persons at this time. J.

PETRILLO stated that "all" persons are eligible in accordance with the statewide standing order.

ACTION: Motion by T. FENSKY, seconded by S. DINNO, and voted unanimously by roll call of those present,

to approve the updates to the policy.

Topic VII. APPLICATIONS

1. CarePartners; DS1000008 – Drug Schedule Amendment TIME: 8:34 AM

REPRESENTED BY: Matthew Moy

RECUSAL:

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<u>DISCUSSION</u>: The applicant was issued a resident retail license on August 4th of this year for Sch VI medications only. The applicant has expressed that there are a number of vendors, networks and wholesalers who require a DEA registration and permit from the BORP to cover federally controlled medications.

The intentions of the applicant are to dispense the full range of medications but erred in completing the application and only selecting Schedule VI.

Questions:

- The Board does not issue shelf licenses for pharmacies, so if an investigator knows where to inspect your facility will they find you carry controlled substances?
 - Yes, most likely, we order on an as needed basis so when we do have orders for it, we will order for the medication and ship it to the patient.
- Currently you said that you will order as needed. Have you had situations where a patient has come in and tried to order a controlled substance?
 - No, this is a proactive move. In my previous roles, we've had orders of IV lorazepam along with IVIG. We have seen that some patients in Chicago, where our main branch is, do utilize IV pre-med
- Have you seen anything that is sch2 in the past?
 - We have seen IV morphine sulfate before, but it is not very common. We are more likely to see IV lorazepam

<u>ACTION:</u> D. Barnes made a motion to approve the Drug Schedule amendment for the controlled substances schedule II-V; Seconded by C. Belisle and voted unanimously by roll call of members present.

TIME: 8:44 AM

2. Rutland Family Pharmacy - Retail Pharmacy DSNE1000389 - Complex Non-Sterile; DSNE46255NS

REPRESENTED BY: David Beck

RECUSAL:

<u>DISCUSSION</u>: Currently I co-own Westminster Pharmacy and have formed a new partnership with my current partners called Rutland Family Pharmacy. The applicant is currently renovating the space with the hope of opening a community pharmacy. There are no waivers requested, and the proposed Manager of Record has had a reprimand on their license in 2003 due to CE violations.

Questions:

- You are currently the owner of Westminster Pharmacy; will this be separate from Ruland Pharmacy? Will they be at the same location?
 - o Yes, they are two different entities
- Could you explain this business relationship?
- o Ruland Pharmacy is a new pharmacy at a new location and will have the same owners as Westminster Pharmacy
- Is this building freestanding or a part of a plaza?

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- o It is a free-standing pharmacy, and has apartments on the 2nd floor, but the first floor is entirely pharmacy
- Between the upstairs and downstairs, is the ceiling wooden or concrete? I'm asking to understand if there is anything preventing upstairs from accessing the pharmacy space
 - o It is a wood frame building; we have an alarm system installed to detect a break-in.
- I see you are doing nonsterile compounding with no hazardous and will have positive [air] pressure. What are you planning on compounding?
- o Yes, we do a food deal of group home and hospice dispensing and both require compounding. And we have also found that there is a demand for it in the area as independent pharmacies have closed in the area.
- Was this the location of the previous Rutland pharmacy?
 - o Yes, it is.

<u>ACTION:</u> T. Fensky made a motion to approve the retail pharmacy application pursuant to a satisfactory inspection; Seconded by C. Belisle and voted unanimously by roll call of those present to approve the motion.

T. Fensky made a motion to approve the Complex Non-sterile application pursuant to a satisfactory inspection; Seconded by J. Dorgan and voted unanimously by roll call of those present to approve the motion.

TIME: 8:54 AM

3. Nantucket Pharmacy DSNE10000324- Petition for waiver 247 CMR 9.19 (2) Prescription area is at least 325sq ft

PRESENTED BY: Laurie Abreu

RECUSAL:

<u>DISCUSSION</u>: The applicant has submitted a petition for waiver 247CMR9.19(2) regarding the size of the prescription area. The Pharmacy was approved at the previous board meeting, but the prescription area of the pharmacy is less than the required 325 square feet. Applicant has stated they are the only pharmacy in the historic downtown Nantucket area, and the historic nature of the building makes it impossible to renovate or find more space.

Questions:

Is the reasoning why you cannot expand the Pharmacy structural? Or because it is a historical building? Yes, it is a historical building, and Nantucket has a historic district commission, which would need to approve any renovation to the building. However, there is nowhere in which we can expand. There is some historic charm to the building that is an important piece of the community and has been operating as a pharmacy in this space for many years.

Would there be an opportunity to decrease the retail space and expand the pharmacy space? We would need to work with the historic commission and that would take months, it would also be a major renovation to reduce the retail space. We don't see how it would be possible to do that considering the historical nature of the building. the building.

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<u>ACTION:</u> T. Fensky made a motion to approve the waiver of 247CMR9.19(2); seconded by D. Barnes and voted unanimously by roll call of those present to approve the motion.

TIME: 9:01 AM

4. CVS CarePlus/CVS2516; DS2873 - Renovation DSRN10140 - Business Model Change

PRESENTED BY: Grace Sesi, Jennifer DiMauro, Sihyun Park

RECUSAL: J. Rocchio

<u>DISCUSSION</u>: The Pharmacy plans to add a manager's office, a conference and training room, and a larger employee breakroom, as well as additional technical building updates. CVS also plans to significantly reduce the number of drugs on site and increase the staff count to 35, in the very near future

- So, you are decreasing drug and increasing staff, so will this be more of a shared services area rather than dispensing?
 - With regard to decrease in drug volume, that is only for what is being kept on site. In terms of the services we are providing to patients that will not change. With the increase in staff size, we want to have the option to increase staff, however we are not planning to increase staff immediately.
- Your application says that most of the work will be done from 5pm to midnight by contractors, will you have any security measures?
 - We do have a large medicine cabinet where medications will be stored, and we plan to have a pharmacist on site during all construction hours.
- Will all personnel working in the licensed space be licensed staff?
 - Yes, they will be certified, and we will be complaint with ratios as well
- Can you explain the increase of the call center? Will this be for supporting other site?
 - We are expecting to serve a larger volume of specialty patients, and this increase would help to support that expansion in patient volume.
- Will your business model be changing?
 - No, it will remain the same.

<u>ACTION</u>: T. Fensky made a motion to approve the Renovation application pursuant to a satisfactory inspection; seconded by J. Dorgan and voted unanimously by those present to approve the motion.

TIME: 9:17 AM

5. Get Relief RX-Non-Resident Complex Non-Sterile Compounding - NDSNE62038NS

<u>PRESENTED BY:</u> Dennis Rudolph, Kendra Johnson, Saeed Sadri <u>RECUSAL:</u>

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<u>DISCUSSION</u>: Board staff provided a summary of the application, noting that the applicant was found to have been making copies of certain commercially approved medications in a previous inspection.

Questions:

- Since they were here last year, the difference is that Get Relief provided us with information about the essential copies, is that right?
 - Correct
- And has the applicant addressed all of the Plan of correction items that were issued?
 - Correct
- One issue in the inspection is that it does not appear that the orders received are legitimate prescriptions, can you please elaborate on that and where the patient/provider relationship is?
 - We have an actual prescription that comes into the pharmacy, and we are also registered with Surescripts.
 - We verify all physicians, and we compound based on the evaluation of the licensed clinicians through prescriptions we receive. If a prescription comes in and has all of the basic components to do our reviews (DUR, Patient info, clinician info), we have it available in our prescription screen.
- You only compound two medications? The sublingual Semaglutide and the combination cetirizine famotidine medication?
 - Yes, that is correct
 - I will add that our formulary stands at 21 products, and we are evaluating the expansion of that formulary based on physician and patient need.
- With regard to the famotidine and cetirizine compound, did the physicians that prescribe this combination provide you with literature to support the compounds efficacy?
 - No, we have supporting documentation as to why it is done and written in prescription form that is in the specific concentrations.
- If a prescriber sends a prescription for any compound that they feel works, how would you determine what to compound?
 - We did our due diligence and found documentation as to why this concentration of the 8 and 22mg seems to be effective and it is outside the 10% range of what is commercially available.
- What testing do you do on your nonsterile compounded products to ensure potency?
 - We do initial ARL testing, and we resubmit annually to make sure that everything is staying in potency
- DO you test every batch that you make?
 - We do a visual test to make sure it is visually appropriate, but we don't send every batch to ARL for testing.
- Are you batching that for anticipator prescriptions?
 - No, we don't compound in advance, our batches are very small. As much as 14 bottles for prescriptions coming in.
- You mentioned prescriptions coming in, do you have an active prescription in hand or prescriptions that you understand to be coming in?
 - No, we only compound the medication when the prescription is in our system. The batches are small and adhere to strict guidelines that we have
- I'm a bit confused; it sounds like you are doing anticipatory compounding, can you please elaborate?

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- We prepare the compounds in batches of 7 bottles of 30 capsules each time we make a batch. But we have prescriptions coming in for those. There would be a certain amount of anticipatory compounding because we can't make one batch of 30.
- So, this was the original question, you keep saying coming in and it sounds like you are batching ahead of time
 - If a doctor prescribes a product, they usually put refills on it and based on the refill history of the patient we supply 30 at a time
- Before the patient requests the refill?
 - Yes
- So that is in anticipation of the patient requesting the refill
 - It's not just going and compounding in advance for prescriptions that we receive. Since
 the batches are small and they are gone after a few days, then we'll begin planning for
 the next batch once they're gone
- DO the patients know there is a cheaper version of this product over the counter?
 - We have not had a specific dialog with patients unless they question. And we've had
 patients ask why they couldn't just pick up the medication over the counter. In those
 cases, we refer back to the documentation as to why this specific concentration has
 better results than commercially available products.
- What documentation and evidence do you have for this?
 - We have provided a file which specifically talks about the clinical evidence that has been provided to us.
 - As for compounding OTC products, we do not do this. The only product that would be close is the famotidine cetirizine product, but these products do not contain otc.
- Last time you were here this medication was indicated for IBS, and now it is indicated for IBS and covid 19 so I don't feel comfortable with this.
- Last time you were here you explained that the physicians who prescribed the medication were providing the research. Are those the same physicians for the study regarding COVID-19?
 - Yes they are part of the clinicians, though we also have other physicians prescribing too
- You said last time that the other physicians prescribing it doing so based off the core group of physicians, are these core group of physicians the same?
 - Yes, GI associates.
- What is the BUD you are giving for this compound?
 - 180 days
- Do you do any other testing besides the annual potency tests?
 - No
- Are you treating pediatric patients with this compound?
 - \circ No
- I reviewed the study and there are limitations to this study, and it is not saying it is approving the therapy.
 - According to our understanding, FDA guidelines allow the compounding of medication that are 10% different and this is 20% different. And we are doing this based on the due diligence and clinical evidence we have found.
 - We are doing our best in our due diligence, and we have gone extensively in covering those aspects
- When looking at the study with COVID 19, the dosing used was famotidine 20mg, and cetirizine 10mg po, and that is the commercially available dosing.

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- We are compounding currently at 8mg and famotidine at 22mg, and that is based on the recommendation
- This dosing comes at the requirement and prescription of the physicians
- Where is the evidence to support that dosing?
 - We have a white paper that we have thoroughly reviewed and there are 10 clinical references in that white paper that just recently came out.
- Is Board staff satisfied with the correction measures taken during the last inspection that had a lot of issues?
 - The applicant has indicated it is resolved
- I'm concerned about the Semaglutide compounding, and I see the documentation you provided, but how do you explain that against the FDA's current guidelines?
 - We are making a suspension product, and the absorption is all mucosal so we can get around the needle phobia and the Rubleses issue. Doing the suspension also helps with absorption
- Where are the numbers which support this, I don't see it in the evidence provided?
 - From the consultations we do see that the patients are losing weight with this formulation, and that is the evidence
- When you do this oral compound does it come with specific instructions?
 - Yes, very specific that we provide to the patients and there is a phone number they can call if they have any questions

TIME: 10:07 AM

<u>ACTION:</u> T. Fensky made a motion to deny the application for Non-Resident Complex Non-Sterile Compounding, seconded by C. Belisle and voted unanimously by roll call to deny the application.

6. Jungle Jim's Pharmacy
Non-Resident Retail Pharmacy NDSNE31822
Non-Resident Complex Non-Sterile Compounding NDSNE62086NS
Non-Resident Sterile Compounding – NDSNE97456SC

<u>PRESENTED BY:</u> Courtney Sullivan, Jordan Phelps, Eric Smith, Connor Elliot RECUSAL:

<u>DISCUSSION</u>: The applicant came in front of the board in April and addressed questions regarding previous discipline in Ohio and questions regarding USP797 violations. At that time, the vote was deferred to allow for the applicant to provide more information to the Board.

Questions:

- Are there any restrictions now with the board of Ohio?
 - We are in good standing
- Do you stock commercially available Semaglutide?
 - o No, we don't
- What would you do in the case that a patient needs it?
 - We could offer it to them at the cash price, but we do not currently accept insurance.

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- Have you received a prescription for the commercially available dose and contacted the prescriber to get the indication?
 - Yes, we have called that doctor in the past and we will also call the patient to make sure they are aware of what is happening
- It sounds like you limit what is on your shelf, the expectation is that pharmacy should be able to fill the prescription of a patient if they were to walk in and ask for the prescription to be filled
 - We have ways to get prescription filled next day; we also can offer a local pharmacy nearby that they can have that prescription filled as well.
- Are you doing hazardous compounding?
 - o All our compounding at this moment is non-hazardous
- What business do you plan to do in the Commonwealth of Massachusetts?
 - We offer a fair number of products such as nonsterile compounded capsules, creams, sprays and ointments.
- There have been some questions about the HVAC documentation regarding engineering and pressurization.
 - Our Compliance officer has that documentation available and will be reaching out to Board staff to provide that
- You mentioned that you compound GLP-1s with methylcobalamin, is that true for each compound?
 - We use Cyanocobalamin and we do individual doses based on the need of the patient for B-12 supplementation
- Can you explain the testing you do for your initial and ongoing testing of your products?
 - For initial testing we do potency, sterility, and endotoxin for all injectables and we do category 3 for Semaglutide, in accordance with USP 791. We then send them out to be tested at two labs
 - We also use 10% of our annual product for sterility testing.
- How often do you do competencies for your compounding?
 - About every 3 months.
- For non-sterile products what is your testing?
 - We do quarterly testing, with 10 random products for potency and 3 products for additional testing. We also don't use the same person twice when selecting products to send to be tested
- Could you discuss the smoke studies?
 - We do a smoke study bi-annually, under dynamic conditions.

<u>ACTION:</u> S. Dinno made a motion to approve the Non-resident Retail Pharmacy Application pending any documentation Board staff may need; seconded by J. Dorgan and voted unanimously by roll call to approve the motion

- D. Barnes made a motion to approve the Non-resident complex nonsterile compounding application pending any documentation board staff may need; seconded by S. Dinno and voted unanimously by roll call to approve the motion.
- S. Dinno made a motion to approve the non-resident sterile compounding application pending any documentation board staff may need; seconded by D. Barnes and voted by roll call to approve the motion with a vote of 10 ayes and 1 nay (S. Ahmed, S. Dinno. M. Sciaraffa, K. Thornell, J. Rocchio, D.

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Barnes, R. Morelli, J. Dorgan, T. Fensky, S. Patel all voted Ay; C. Belisle voted Nay; F. Lombardo was not present)

TOPIC X: FILE REVIEW

Case #1/CASE-2025-1279

PHA-2025-0051 Walgreens #5075, DS2928 Time: 11:01 AM

RECUSAL: NONE

<u>DISCUSSION</u>: C. LATHUM presented and summarized the investigative report that pertained to this matter.

- On 04/19/2025, Walgreens Pharmacy #5075 submitted a final RLCS confirming 2 losses totaling #200 methylphenidate 20 mg tablets.
- MOR Dinh stated that Pharmacist Shepherd overfilled a prescription with #100 methylphenidate 20mg tablets on 02/28/2025. MOR Dinh stated a back count was not conducted.
- The patient was called multiple times but did not respond. The prescriber was informed.
- MOR Dinh stated that the second loss of #100 methylphenidate 20 mg tablets is an unknown loss. MOR Dinh may have accidentally thrown a bottle of #100 into the trash while putting away an order on 03/25/2025. However, there is no video confirmation that this occurred.
- All staff attested to reviewing all policies for the proper storage and handling of controlled substances.
- MOR Dinh reminded all pharmacists to double count a Schedule II prescription and to back count the remaining stock medication.
- Pharmacist Shepherd stated that she will "complete the task at hand before addressing other situations"
- Pharmacist Shepherd attested to having reviewed 247 CMR 15: Continuous Quality Improvement Program in its entirety.
- MOR Dinh and Pharmacist Shepherd completed 2 CEs in an area related to patient safety and attested that these CEs are over and above the minimum yearly requirement for 2025.

<u>ACTION</u>: Motion by R. MORELLI, seconded by D. BARNES, and voted unanimously by those present, except for T. FENSKY who abstained, to refer the matter (PHA-2025-0051), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #2/CASE-2025-0881

INV17494 Walgreens #3062, DS2337 Time: 11:04 AM

RECUSAL: NONE

<u>DISCUSSION</u>: G. MELTON presented and summarized the investigative report that pertained to this matter.

• On 03/24/2025, OPP Investigator Murray discovered that 1 amphetamine mixed salts ER 5mg capsule, 1 amphetamine mixed salts ER 30mg capsule, and 1 methylphenidate LA 20mg capsule included in the

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- perpetual inventory were damaged and/or empty. In turn, Investigator Murray issued a POC for deficiencies related to the management of controlled substances. In addition, BORP opened this staff assignment investigation.
- MOR Ngo indicated that she was not familiar with DSCSA reporting requirements when Investigator
 Murray brought the damaged capsules to her attention. She explained that the damaged capsules
 were quarantined in a safe waiting for hazardous waste disposal. MOR Ngo reported the incident to
 Walgreens Corporate after the inspection. Walgreens determined that the loss was not significant so
 was not required to be reported.
- MOR Ngo described that the "pharmacy team now has a greater understanding to the detail of reporting loss or damaged schedule II that follows the Walgreens DSCSA reporting process. Some steps include calling the manufacturer if we notice empty or damaged capsules inside a sealed stock bottle, Walgreens STARS reporting event if miscount, and notifying proper management about the loss."

<u>ACTION</u>: Motion by J. ROCCHIO, seconded by S. DINNO, and voted unanimously by those present, to CLOSE the matter (INV17494), No Discipline Warranted, Remediation Complete.

Case #3/CASE-2025-1991

PHA-2025-0061 Vivo Health Pharmacy at Home, NDS31272 Time: 11:07 AM

RECUSAL: NONE

<u>DISCUSSION</u>: G. MELTON presented and summarized the investigative report that pertained to this matter.

- On 06/13/2025, BORP was notified by the National Association of Boards of Pharmacy's Clearinghouse that Vivo was disciplined by NC BOP. Upon review, Vivo entered into a final consent order with NC BOP effective 05/20/2025 to resolve charges that the pharmacy shipped prescription drugs into NC without a proper out-of-state pharmacy permit following a business restructuring which invalidated said permit. NC BOP granted a new permit to Vivo then indefinitely suspended that permit. NC NOP next stayed the suspension for 10 years. Vivo then failed to notify BORP about the order within 14 days.
- MOR Petkanas asserted that Vivo properly notified BORP about the consent order with NC BOP by email on 05/29/2025. MOR Petkanas also provided a copy of an email which included an attachment entitled, "MA E.Petkanas 5.28.2025 VivoMO 14 (1).pdf," sent to BORP on 05/29/2025.
- MOR Petkanas explained in the attachment that Vivo underwent a business restructuring which NC BOP misinterpreted as a change in ownership. NC BOP asserted that the change in ownership invalidated the pharmacy's permit and the shipment of prescriptions into North Carolina after the date of the change in ownership was not permitted. MOR Petkanas then indicated that Vivo entered into a consent order with NC BOP so the pharmacy was able to continue to serve patients in North Carolina.

<u>ACTION</u>: Motion by D. BARNES, seconded by J. DORGAN, and voted unanimously by those present, to DISMISS the matter (PHA-2025-0061), No violation.

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Case #4/CASE-2025-1830

PHA-2025-0062 Nehal Patil, PH233631 Time: 11:11 AM

RECUSAL: NONE

<u>DISCUSSION</u>: G. MELTON presented and summarized the investigative report that pertained to this matter.

- On 06/05/2025, BORP learned that Pharmacist Patil was fine \$500.00 in a summary order issued on 05/01/2025 by KS BOP after she failed to submit reports to KS BOP's Rx monitoring program from 12/31/2024 to 05/01/2025 while serving as PIC at West 35th Apothecary LLC.
- Pharmacist Patil acknowledged that she failed to notify BORP within 14 days about the summary order issued by KS BOP. She stated, "The delay was due to a misunderstanding that disciplinary actions are to be reported upon renewal."
- Pharmacist Patil pledged that she "has taken steps to prevent similar incidents from recurring" as corrective action. In addition, Pharmacist Patil asserted that she notified "all state boards of the Kansas action."

<u>ACTION</u>: Motion by R. MORELLI, seconded by J. DORGAN, and voted unanimously by those present, to DISMISS the matter (PHA-2025-0062), No Discipline Warranted, Remediation Complete.

Case #5/ CASE-2025-0983

INV17782 Christopher Ryan, PH22331 Time: 11:12 AM

RECUSAL: NONE

<u>DISCUSSION</u>: G. MELTON presented and summarized the investigative report that pertained to this matter.

- Pharmacist Ryan entered into a settlement agreement for disciplinary action with CT COP in which he
 was issued a letter of reprimand and fined \$5,000.00 to resolve violations observed during inspection
 at a CT pharmacy while he was MOR. The violations included making false, misleading statements to a
 CT DCA, recordkeeping violations involving CII perpetual inventory log, and expired OTC drugs in front
 store.
- Pharmacist Ryan emphasized that he did not make false, misleading statement to the CT DCA. He was not aware that a technician/part owner of the pharmacy was forging his name and signature on DEA 222s because the other owner did not want to drive to the pharmacy in New Haven, CT from New Britain, CT. However, the agent did not believe him.
- Pharmacist Ryan also admitted that OTC drugs in the front were expired. He described that he had
 just relocated and prioritized operation of the pharmacy proper and had not yet vetted the front store
 OTC drugs.

<u>ACTION</u>: Motion by T. FENSKY, seconded by D. BARNES, and voted unanimously by those present, to elevate the matter (INV17782), to a complaint.

Case #6/CASE-2025-0808

PHA-2025-0035 Walgreens #10427, DS3611 Time: 11:16 AM

RECUSAL: NONE

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DISCUSSION: J. TRAN presented and summarized the investigative report that pertained to this matter.

- Loss of #598 acetaminophen/codeine 300mg/30mg attributed to an unknown loss (on or about 01/31/2025, 02/14/2025-03/07/2025) and failure to submit a final report within 21 days.
- The loss of the acetaminophen/codeine 300mg/30mg was discovered on 01/31/2025 during a corporate reconciliation.
- The footage was not conclusive and did not reveal any wrongdoing with the pharmacy team. The onhand inventories, receiving and claims were reviewed, and the medication was counted daily over 75 days with no losses reported.
- The MOR noted that there was an opportunity for retraining on inventory processes with the Inventory Specialist. They recounted all controls in the pharmacy and during the perpetual inventory. They audit random drugs to ensure counts are accurate and accounted for.

<u>ACTION</u>: Motion by T. FENSKY, seconded by S. DINNO, and voted unanimously by those present, to refer the matter (PHA-2025-0035), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for PROBATION for 1 year, with special terms to include the CS Loss Protocol for all acetaminophen with codeine containing products.

Topic IX: Executive Session Call to Order: TIME: 11:20 AM

By: President S. Ahmed reads the executive session language and requests a motion to enter executive session.

<u>ACTION</u>: Motion by J. DORGAN seconded by K. THORNELL, voted unanimously by roll call to enter executive session #1.

Topic X: Adjudicatory Session TIME: 11:54 AM

DISCUSSION: None

ACTION: President S. Ahmed request a motion to enter Adjudicatory Session.

At 11:54 AM K. THORNELL seconded by J. DORGAN and voted unanimously by all those present to enter the Adjudicatory Session by roll call vote.

Topic XI: 65C Sessions MGL c. 112 section 65C TIME: 12:06 PM

DISCUSSION: None

ACTION: President S. Ahmed request a motion to enter M.G.L 65 c Session.

At 12:06 PM J. ROCCHIO seconded by J. DORGAN and voted unanimously by all those present to enter M.G.L. chapter 65 C Session by roll call vote. J. Dorgan was not present for the vote.

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Topic XII: ADJOURMENT OF MEETING TIME: 03:29 PM

<u>ACTION:</u> Motion by J. DORGAN seconded by T. FENSKY and voted unanimously by those present, to adjourn the meeting by roll call vote.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

- 1. September 4, 2025, Agenda
- 2. August 7, 2025, Board Minutes
- 3. Licensure Policy 13-01 Report
- 4. Monthly Probation Report
- 5. BDR Licensure Report pursuant Policy 14-02
- 6. PAC Recommendation Document 25-02
- 7. NABP Resolution
- 8. Notice of Opportunity Response for Board approved inspector: Accreditation Commission for Health Care (ACHC)
- 9. Policy 2021-04: Continuing education (CE) Requirements for Pharmacists
- 10. CarePartners application: DS1000008
- 11. Rutland Family Pharmacy applications; DSNE100389, DSNE46255NS
- 12. Nantucket Pharmacy application DSNE10000324
- 13. CVS CarePlus application DSRN10140
- 14. Get Relief RX application NDSNE62038NS
- Jungle Jim's Pharmacy applications: NDSNE31822, NDSNE62086NS, NDSNE97456SC
- 16. Vital Care of Cambridge- New Retail Pharmacy
- 17. BET Pharm, LLC: Non-Resident Retail Pharmacy
- 18. Empower Pharmacy: Non-Resident Sterile Compounding
- 19. Get Relief: Non-Resident Complex Non-Sterile Compounding
- Jungle Jim's Pharmacy: Non-Resident Retail Pharmacy, Complex Non-Sterile Compounding, Sterile Compounding.

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 Walgreens 5075, DS2928

 22.
 INV17494
 Walgreens 3062, DS2337
- 23. PHA-2025-0061 Vivo Health Pharmacy at Home, NDS31272
- PHA-2025-0062 Nehal Patil, PH233631
 INV17782 Christopher Ryan, PH22331
 PHA-2025-0035 Walgrens 10427, DS3611

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