## **COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy**

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

## April 6, 2023

## **Webex Information**

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

## For video access click on the following link:

https://eohhs.webex.com/eohhs/onstage/g.php?MTID=e60479a9f7c82e21e5cf1779d42de592b

To access the meeting by phone:

Call in Number: 1-650-479-3208

Access Code: 2531 420 0196

Attendee: #

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Erin Bartlett, <u>erin.bartlett2@mass.gov</u> or 857-262-7431 in advance of the meeting. While the Board will do its best to accommodate you, certain accommodations may require distinctive requests or the hiring of outside contractors and may not be available if requested immediately before the meeting.

Time	#	Item	Page		
8:00	Ι	CALL TO ORDER		C. Belisle	
8:02	II	APPROVAL OF AGENDA			
8:05	III	<ul> <li>APPROVAL OF BOARD MINUTES</li> <li>Draft of March 2, 2023 Regular Session Minutes</li> </ul>			

## Agenda

8:10	IV	<ul> <li>REPORTS</li> <li>Applications approved pursuant to Licensure Policy 13-01</li> <li>Monthly report from Probation</li> <li>Board Delegated Review pursuant to Licensure Policy 14-02</li> <li>PSUD Report-Policy 17-03</li> <li>Plan of correction reports</li> <li>Research Drug Study report pursuant to Staff Action Policy 18-02</li> <li>Pharmacy Technician Licensing Examinations and Training Programs report pursuant to Staff Action Policy 17-02</li> </ul>	D.
8:15	V	<ul> <li>FLEX</li> <li>Pharmacy issues related to COVID-19</li> <li>Update of the March 22<sup>nd</sup> Pharmacy Advisory Committee Mtg</li> <li>Pharmacy Advisory Committee Meeting, April 26, 2023 <ul> <li>Recommendation document 23-03 for Advisory Committee meeting</li> </ul> </li> </ul>	D. Sencabaugh S. Ahmed W. Frisch
9:00	VI	<ul> <li>APPLICATION</li> <li>•UMass-Memorial Specialty; DS89822 – Renovations</li> <li>• Vital Care Pharmacy; DS90363 – Renovations</li> <li>•Koala Pharmacy; DS90386 -Renovation</li> <li>•Westminster Pharmacy; DS1710 -Transfer of Ownership</li> <li>•Marlboro Pharmacy and Wellness-New Pharmacy</li> <li>•East Boston Health Care Center-DS90332- Renovation</li> </ul>	
10:00	VII	REGULATIONS         • 247 CMR 2.00: Definitions	
10:30	VIII	<ul> <li>POLICIES</li> <li>Policy 2023-01: Compliance Packaging and Reusable Dose Planners</li> <li>Policy 2023-04: Continuity of Care</li> </ul>	

		FILE	E REVIEW			
		1	CAS-2022-0665	SA-INV-20260	CAPS Pharmacy, DS3312	
		2	CAS-2022-0868	SA-INV-20914	CAPS Pharmacy, DS3312	
		3	CAS-2022-1384	SA-INV-21085	Ngoc Bich Tran, PH235829	
		4	CAS-2022-1266	PHA-2022- 0199	Bravo Pharmacy, DS89981	
		5	CAS-2022-1234	SA-INV-20885	Thoa Pham, PH238708	
		6	CAS-2022-0813	SA-INV-20827	Bonifice Ochigbo, PH239914	
		7	CAS-2022-1540	PHA-2022- 0219	Rite Aid #10092, DS2886	
		8	CAS-2023-0038	SA-INV-21385	Pharmacy Amanecer, DS90354	
		9	CAS-2023-0046	SA-INV-21386	Letourneaus Pharmacy, DS2777	
IX	10:45	10	CAS-2023-0040	PHA-2023- 0021	Walgreens #6072, DS3004	
		11	CAS-2023-0045	PHA-2023- 0025	Joseph Ciampa, PH24402	
		12	CAS-2022-1074	SA-INV-20825	CVS #17727, DS90243	
		13	CAS-2022-1074	PHA-2023- 0041	Irene Rigas, PH23188	
		14	CAS-2022-1074	PHA-2023- 0042	Angelique Rigas, PTT05467	
		15	CAS-2022-1381	PHA-2022- 0210	CVS #281, DS2727	
		16	CAS-2023-0121	PHA-2023- 0029	CVS #119, DS89835	
		17	CAS-2023-0127	PHA-2023- 0032	CVS #915, DS3395	
		18	CAS-2022-1606	SA-INV-21324	CVS #2128, DS2720	
		19	CAS-2022-1336	SA-INV-20941	CVS #2476, DS2904	

12:00		LUNCH BREAK	
12:30	х	<b>EXECUTIVE SESSION</b> 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, or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, 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.	
1:30	XI	M.G.L. c. 112, § 65C SESSION	
4:00	XII	ADJOURNMENT	

#### COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

#### MINUTES OF THE GENERAL SESSION April 6, 2023

#### **Board Members Present**

Caryn Belisle, RPh, MBA, President Katie Thornell, RPh, MBA President Elect Sebastian Hamilton, Pharm D, MBA, RPh John Rocchio, RPh, PharmD Sami Ahmed, PharmD., RPh, BCPS, BCSCP Rita Morelli, PharmD, BCACP, RPh Delilah Barnes, RPh Johanna Lopez, MS (arrives 12:30 PM) Julie Lanza, CPhT Carly Jean-Francois, RN, NP (leaves 2 PM) Dawn Perry, JD (leaves 10-11 AM)

## Jennifer Chin, RPh Secretary Dr. Richard Lopez, MD

**Board Members Not Present** 

#### **Board Staff Present**

David Sencabaugh, RPh, Executive Director Monica Botto, Associate Executive Director Michael Egan, JD, Board Counsel William Frisch, RPh Director of Pharmacy Compliance Michelle Chan, RPh, Quality Assurance Pharmacist Ed Taglieri, MSM, NHA, RPh PSUD Supervisor Richard Harris, Program Analyst Joanna Chow, Office Support Specialist Taylor Lee, Office Support Specialist Joanne Trifone, RPh, Director of Investigations Gregory Melton, JD, PharmD, BCPS, Investigator Julienne Tran, RPh PharmD, Investigator Christina Mogni, RPh, Investigator Nancy Aleid, Compliance Officer

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

#### CALL TO ORDER 8:02 AM

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

Roll call attendance: J. Lanza, yes; S. Hamilton, yes; C. Belisle, yes; D. Barnes; J. Rocchio, yes; S. Ahmed, yes; R. Morelli, yes; D. Perry, yes; D. Barnes, yes; C. Jean-Francois joins meeting 8:03 AM; J. Lopez joins meeting 12:30 PM. **Approval of Agenda** 

Topic II.

Agenda 4/6/23

#### DISCUSSION:

Defer: **Application: Westminster Pharmacy** Application: East Boston Health Center

#### **ACTION:**

Motion by J. Lanzo, seconded by D. Barnes and voted unanimously by those present to approve the agenda with no noted change by roll call vote.

#### **Topic III**

Approval of Board Minutes

**TIME: 8:02 AM** 

#### Minutes

1. Draft 3/2/23

Change: no changes

#### Action:

Motion by S. Ahmed seconded S. Hamilton and voted unanimously to approve the regular session minutes of 3/2/23 with no noted changes by roll call vote.

#### **TOIC IV** Reports Applications approved pursuant to Licensure Policy 13-01 **TIME: 8:03 AM** PRESENTED BY: M. BOTTO DISCUSSION: M. Botto reported 39 Change of Manager applications and 2 facility closures that have been approved via Staff Action since the March 2<sup>nd</sup> Board meeting. So noted. **Topic IV.** REPORTS **TIME: 8:03 AM**

## **Monthly Report from Probation**

PRESENTED BY: M. BOTTO DISCUSSION: M. Botto indicated 21 active probation cases, 3 which have successfully completed probation monitoring since the March 2<sup>nd</sup> Board meeting. So noted.

Topic IV.	REPORTS			
Monthly Report from BDCR pursuant to Policy 14-02 TIME: 8:03 AN				
PRESENTED BY: M. BOTTO				
DISCUSSION: M. Botto reported 12 CE discrepancies, all of which were closed with no discipline				
warranted. 3 petitions for waiver renewals were received from Genoa, all of which have been approved.				
	Page <b>2</b> of <b>23</b>			

So noted.

successful completion of t So noted. <b>Topic IV.</b> <b>Plan of Correction Report</b> <u>PRESENTED BY</u> : N. ALEID <u>DISCUSSION:</u> N. Aleid report completed in 2022, an incorrestrictions while the number <b>DISCUSSION:</b> N. Aleid report <b>DISCUSSION:</b> N. <b>DISCUSSION:</b> N. <b>D</b>	RI ported a total of 8 active members in the PSUD prog the program since the March 2 <sup>nd</sup> Board meeting. REPORTS s ported 2,240 retail compliance inspections and 218 sit	TIME: 8:04 AM
DISCUSSION: E. Taglieri re successful completion of t So noted. Topic IV. Plan of Correction Report PRESENTED BY: N. ALEID DISCUSSION: N. Aleid report completed in 2022, an inc restrictions while the num	ported a total of 8 active members in the PSUD prog the program since the March 2 <sup>nd</sup> Board meeting. REPORTS s ported 2,240 retail compliance inspections and 218 sit	TIME: 8:04 AM
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DISCUSSION: N. Aleid report completed in 2022, an inc restrictions while the num	· · ·	
completed in 2022, an inc restrictions while the num	· · ·	o visits that word
451 inspections were appr Equipment facility and dru cited in 2022. Despite the pharmacists were cited fo So noted.	rease in 8% from 2021. Inspections occurred during on ober of investigators conducting work in the field was OCs) were issued, an increase in 192 POCs from 2021 roved, 21 were requested reinspection, and 24 cases ag storage was the most cited category, with immuni increase of POCs, both chain and non-chain had ider r similar deficiencies across both years.	continued COVID-19 s reduced by 1. A total of 1. s were referred to Triage. ization being the least
Topic IV.	REPORTS	
	ort pursuant to Staff Action Policy 18-02	TIME: 8:07 AM
PRESENTED BY: M. CHAN		
	orted 5 retail pharmacies participating in drug studie e investigational drug studies. 1 new study has been a	
Topic IV.	REPORTS	
-	s and Training Report pursuant to Staff Action Polic	ty 17-02 TIME: 8:07 AM
PRESENTED BY: M. CHAN		
·	orted a total of 13 entities with approved technician	
-	ing exams were approved with 1 program approved	for the 2023 calendar
year.		
So noted.		

TOPIC V

Flex

### 1. Pharmacy issues related to COVID-19

Presented by: D. SENCABAUGH / M. CHAN

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**Discussion:** The open meeting law exemption has been extended to March 31, 2025, so Board meetings will continue to be held virtually.

With the end of the federal Public Health Emergency ending on May 11, several document changes and updates are in the works and will be presented next month. Two coming changes of note are the allowance for technician immunization to continue, and the perpetual inventory requirement change to every 15 days.

#### 2. March 22, 2023, Pharmacy Advisory Committee Meeting Update Time: 8:09 AM

Presented by: S. AHMED / W. FRISCH

**Discussion:** The Pharmacy Advisory Committee made several recommendations and clarifications to the draft of 247 CMR 2.00 Definitions and Severability.

#### 3. April 26, 2023, Pharmacy Advisory Committee Meeting

Time: 8:11 AM

Presented by: W. FRISCH

**Discussion:** The Pharmacy Advisory Committee's input and advisory opinion are sought on the safety and necessity of compounding of ketamine nasal spray. Last year, the FDA issued an alert regarding potential risks associated with compounded ketamine nasal spray. The alert references Spravato<sup>®</sup> (esketamine), a commercially available product, that is subject to strict safety controls of dispensing and administration under a REMS program. The REMS program requires Spravato<sup>®</sup> to be dispensed and administered in health care settings that are certified in the REMS and not dispensed directly to the patient. In the alert, FDA cited concerns about the increased potential risk of adverse events, misuse, and abuse associated with compounded ketamine nasal spray.

**Action:** Motion by K. THORNELL, seconded by S. HAMILTON, and voted unanimously by roll call of those present, to appoint S. AHMED with J. LANZA as an alternate to present the Pharmacy Advisory Recommendation request (23-03) to the Pharmacy Advisory Committee on April 26, 2023, and then provide an update to the Board at the May 4, 2023, meeting.

#### TOPIC VI

Applications

#### 1.Umass-Memorial Specialty DS89822 Renovation

TIME: 8:15 AM

Represented by: Harshvina Patel, David Mangan, Christopher Conboy

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#### Recusal: D. Barnes Discussion:

D. Mangan indicates that they are requesting a non-contiguous space authorization as a specialty pharmacy in the ambulatory care services. They offer a mail order service, and they need additional space to continue serving patients. They do have unutilized space one floor below the current pharmacy that they can use for their packaging and shipping operations which would allow them to increase their patient volume and continuing their services. D. Mangan notes that Health Care Quality has been notified of their plans and have not responded yet, but they do not expect to receive any pushback. C. Conboy states that they serviced over 80,000 patients this year and they primarily serve Medicare and Medicaid patients. H. Patel goes on to describe the transportation process of the medications including controlled temperature medications. C. Belisle if this space was already approved for storage and if the ask was to also allow a staffing and distribution component. B. Frisch responds that it was adjacent to a space that was already approved and D. Mangan responds that this information is correct. B. Frisch indicates that they do not have any objections to the request but ask the board to make the approval contingent upon Healthcare Quality approval and a successful inspection.

Motion to approve the application as submitted pending successful inspection and approval from Health Care Quality made by S. Hamilton; Seconded by J. Lanza, then Board Members presented voted unanimously by rollcall to approve motion.

2.Vital Care Pharmacy DS90363 Renovation

TIME: 8:25 AM

Represented by: Hadee Alkhandak, Nicholas,

Recusal: none Discussion:

H. Alkhandak indicates that he is coming before the board to request approval for renovations to add a cleanroom in the pharmacy in their unlicensed space to accommodate sterile compounding. He also notes that they are adding a changing and storage room to that area. Nicholas indicates that he is the sterile compounding expert and will be using the cleanroom for the non-hazardous compounding and will be having an ISO 7 buffer room and an ISO ante room and everything is enclosed for circulation purposes. They will only be compounding category 2 or medium risk and will not engage in high-risk compounding in the facility. D. Barnes inquired about the fingertip testing. H. Alkhandak indicates that all individuals engaging in compounding will be fingertip tested. B. Frisch indicates that H. Alkhandak (MOR) will be completing all the compounding initially and was asked to describe his experiences. H. Alkhandak described his experiences with compounding and noted that he will initially be focusing on compounding antibiotics until they hire highly experienced compounding pharmacists and technicians.

# Motion to approve the renovation application pending successful inspection by D. Barnes; Seconded by S. Ahmed, then Board Members presented voted unanimously by rollcall to approve motion.

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TIME: 8:39 AM

#### 3. Koala Pharmacy DS90386 Renovation

#### Represented by: Benjamin Nadeau

# Recusal: none Discussion:

B. Nadeau indicates that Koala Pharmacy is a mail-order veterinary pharmacy focusing on companion animals and are growing their operations and have acquired the space on the floor below the area that they are currently licensed in. They plan on utilizing the new area for their fulfilment operations and utilizing the current space for their administrative staff, PV1, and data entry. C. Belisle inquires if the space is in the basement and B. Nadeau responds that the space is slightly underground and has some windows that have been glossed over so that individuals are not able to see inside the facility. B. Nadeau indicates that they do not anticipate the risks of leaks, water damages, moisture, etc. D. Barnes inquires if the area will be secured to which B. Nadeau responds that it will be. S. Ahmed inquires if there will be a pharmacy in both spaces and B. Nadeau responds that the majority of the fulfillment will be completed in the new space and the upstairs portion of the pharmacy will be performing data entry. C. Belisle inquired if they complete any compounding and B. Nadeau responds that they do not. R. Morelli inquires if they are primarily mail-order, and B. Nadeau indicates that they are, but they can also have individuals drop off scripts based on their license type.

Motion to approve the renovation application pending successful inspection by J. Rocchio; Seconded by D. Barnes, then Board Members presented voted unanimously by rollcall to approve motion

4. Westminster Pharmacy Transfer of Ownership

Deferred

#### 5. Marlboro Pharmacy and Wellness New Pharmacy

TIME: 8:47 AM

Represented by: Vivane Nogarotto

Recusal: D. Sencabaugh Discussion:

V. Nogarotto indicates that the pharmacy will be a traditional retail pharmacy. She plans on having a wellness center component in the front with high-end vitamins and supplements and plans on having some clinical work including chronic disease testing and point of care testing. In the retail space she will have a traditional pharmacy, packaging, and delivery services. V. Nogarotto indicates that she is Brazilian and speaks Portuguese and Spanish which is why she decided to open a pharmacy in Marlborough. D. Barnes inquiries about the contingency plan and the delivery services. V. Nogarotto indicates that she expects to have her own vehicle and driver and if the patient is not home the medication will return to the pharmacy and be stored appropriately. C. Belisle inquires if the pharmacy plans on engaging in compounding to which V. Nogarotto responds that they will engage in

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simple non-sterile compounding and that she has experience with compounding and will be the manager of record. R. Morelli inquires if V. Nogarotto will be the only pharmacist at the pharmacy and what the hours will be. V. Nogarotto responds that she will be the only pharmacist at the moment but does have a per diem pharmacist that is on call in case of emergency. She indicates that the hours will be 9-6 Monday-Friday and Saturday 9-2 and will be closed on Sunday. The contingency plan when the pharmacy is closed on Sunday is a message for the patient to fill the medication at an open pharmacy if they are not able to wait until Monday. S. Hamilton inquires if the pharmacy will be administering any immunizations and V. Nogarotto indicates that she plans on administering vaccinations. Board members asked some further questions and V. Nogarotto responded to these questions accordingly.

Motion to approve the application for a new community pharmacy pending successful inspection by S. Hamilton; Seconded by D. Barnes, then Board Members presented voted unanimously by rollcall to approve motion

6.East Boston Health Center

Deferred

**TOPIC VII** 

Regulations

247 CMR 2.00 Definitions and Severability

Time: 9:00 AM

Presented by: W. FRISCH and M. CHAN

**Discussion:** This section of draft regulations was previously brought before the Board and approved on March 5, 2020, to be sent for administrative review and a public hearing. But due to other draft regulatory sections being in flux, primarily draft sections 247 CMR 13, 17, and 18, the definitions section was not moved forward. Now that draft sections 13, 17, and 18 have been approved by the Board to move forward, the plan is to include 247 CMR 2.00 *Definitions and Severability* in that group of draft regulations for administrative review and a public hearing. The Pharmacy Advisory Committee has provided great input and suggestions and many changes have been incorporated.

Action: Motion by S. HAMILTON, seconded by S. AHMED, and voted unanimously by roll call of those present, to forward the document for administrative review and approval to hold a public hearing.

TOPIC VIII

Policies

1. Policy 2023-01: Compliance Packaging and Reusable Dose Planners Time: 9:04 AM

Presented by: M. CHAN

**Discussion:** Language from the draft regulations at 247 CMR 9.00 that speaks to reusable dose planners was added to this policy due to some confusion as to the practice differences between reusable dose planners and other compliance packaging. This policy replaces Policy 2022-08.

**Action:** Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by roll call of those present, to approve this policy.

#### 2. Policy 2023-04: Continuity of Care

Time: 9:05 AM

#### Presented by: M. CHAN

**Discussion:** In addition to the existing language on how to handle scripts after a prescriber ceases to practice, language was added to the Discontinuation of a Prescriber's Practice policy to allow the dispensing of a small supply or smallest available package of a Schedule VI with no refills when the pharmacist is unable to obtain prescriber authorization in a timely manner. This is only for Schedule VI drugs EXCEPT gabapentin. This policy replaces Policy 2020-06.

The draft regulations at 247 CMR 9.00 will only allow a 14-day supply, but J. ROCCHIO suggested we change the policy to allow a 30-day supply to reduce copays in the interim. Legal counsel will explore whether the draft regulations can be changed to 30 days upon final promulgation.

**Action:** Motion by J. ROCCHIO, seconded by K. THORNELL, and voted unanimously by roll call of those present, to approve this policy with a change to the days' supply allowance to 30 days.

ΤΟΡΙϹ ΙΧ	File Review	
Case #1/CAS-2022-0665 SA-INV-20260	CAPS, DS3312	Time: 09:32 AM

<u>RECUSAL</u>: C. BELISLE and D. BARNES recused and were not present for the vote or discussion in this matter.

- Licensee disclosed notice of an ISO 5 Above Action Level (AAL) in their facility on or about 05/27/2022 and failed to properly remediate in accordance with Board Policy 2019-08: Sterile Compounding Pharmacy Response to Above Action Level Environmental Monitoring Results.
- Pharmacy had 3 above action level events: 05/27/2022 (2 CFU micrococcus in ISO 5 Hood; 06/29/2022 (1 CFU gram negative Moraxella and 1 CFU mold) and 07/07/2022 (1 CFU moraxella, positive ISO 7, air sample). Initial EM, repeat EM and microbiology reports from the AALs were properly remediated.
- A USP 797 inspection (ISP-18545) was conducted on 5/11/2022 with deficiencies noted in the area of cleaning and disinfecting. Investigator Van Allen observed white crystallized contamination on the rear of the APEX compounders and weighing station in addition to the diffuser screen on multiple vertical flow PECs.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by D.PERRY, and voted unanimously by those present, to CLOSE the matter (SA-INV-20260), No Discipline Warranted, Remediation Complete.

Case #2/CAS-2022-0868		
SA-INV-20914	CAPS, DS3312	Time: 09:34 AM

<u>RECUSAL</u>: C. BELISLE and D. BARNES recused and were not present for the vote or discussion in this matter.

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

- In July 2022, CAPS Pharmacy submitted two Disclosures of Above Action Level Environmental Monitoring (EM) Results to the BORP eight days apart for EM sampling that took place on two separate dates in June 2022. These were the second and third disclosures in a series of three dating back to May 2022. In the disclosures the AAL samples were from air samples taken in ISO 7 and ISO 8 spaces. Separately, documentation of remediation per Board Policy 2019-08 for both events was requested for OPP investigator review.
- In both instances, CAPS Pharmacy provided documentation of remediation actions taken. Based on that documentation submitted, it was determined that CAPS Pharmacy did not remediate the AAL events per Board Policy 2019-08 because they did not re-sample every site, both air and surface, in the affected ISO classified areas according to their Environmental Sampling plan as required. All other aspects of the policy were adhered to.
- CAPS Pharmacy was notified about the opening of SA-INV-20914 for failure to remediate two AAL events because every site in the affected ISO classified areas according to their Environmental Sampling plan was not resampled after the AAL sample dates. In response, CAPS Pharmacy provided additional EM sampling documentation that was not initially included in their original responses to both events when those events occurred. This additional documentation showed that CAPS Pharmacy did indeed perform EM sampling at every site in the affected classified areas according to their EM Sampling plan for both AAL events. Based on this new information provided, CAPS Pharmacy did remediate both AAL events in question per Board Policy 2019-08.

<u>ACTION</u>: Motion by S. AHMED, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to CLOSE the matter (SA-INV-20914), No Discipline Warranted, Remediation Complete.

Case #3/CAS-2022-12384		
SA-INV-21085	Ngoc Bich Tran, PH235829	Time: 09:38 AM

#### RECUSAL: NONE

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

• PH Tran reported that when she completed her CEs in 2021, there were 2 CE courses that she believed were on Law topics, but she did not double check the ACPE topic number at the time. She only realized while she was preparing for renewal in 2022 that the CEs in question were not considered to be in the area of Pharmacy Law. Because of this oversight, the licensee only completed 0.5 hours of Law CE in 2021, resulting in a deficiency of 1.5 hours of CE in this area. She has apologized for her oversight and

stated that she will monitor her CE's quarterly in the future and check the ACPE numbers to prevent further issues.

• After reviewing the licensee's CPE monitor, it was determined that RPH Tran remediated the Law CE deficiency from 2021 in the year 2022 by completing a total of 4.25 hours of CE in the area of Pharmacy Law which is 2.25 hours above the yearly requirement.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by K. THORNELL, and voted unanimously by those present, to CLOSE the matter (SA-INV-21085), No Discipline Warranted, Remediation Complete.

Case #4/CAS-2022-1266 PHA-2022-0199 Bravo Pharmacy, DS89981 Time: 09:40 AM

#### RECUSAL: NONE

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

- BORP learned that Bravo entered into as settlement agreement with the Office of the Attorney General to resolve charges of unlawfully billing MassHealth for automatically refilled prescriptions, for a costly prescription multivitamin that was not provided to patients, and other prescriptions that were not authorized by a physician.
- Bravo agreed to pay \$800,000.00 in restitution and hire at its own expense an Independent Compliance Monitor to establish and implement a compliance program... and annual independent site and record audits" for a three-year period. The compliance program was required to include updated policy and procedures, annual training, a process for investigation of noncompliance and corrective action, and periodic auditing of billing and refilling practices.
- In addition, the Independent Compliance Monitor was required to conduct yearly on-site audits and submit a report of those audits to the Office of Attorney General during the three-year period. Lastly, Bravo was required to submit a plan of correction for any deficiency uncovered during the three-year period of monitoring within 30 days and pay additional restitution for any overpayments.
- Bravo underscored that "the settlement agreement between Bravo and the Office of the
- Attorney General expressly and intentionally did not contain any admission of wrongdoing by Bravo." Bravo then denied the allegations by the Office of the Attorney General.
- CA: Bravo indicated that the pharmacy "[took] extraordinarily seriously the importance of ensuring that policies, procedures, and practices are in place to ensure that neither these nor any other violations occur at Bravo." Bravo then described the corrective action required to be implemented by the settlement agreement including new, updated, or revised SOPs and training. In addition, Bravo indicated that the Independent Compliance Monitor "[had] not identified any issues of non-compliance with the settlement, nor the need for any corrective actions" over the past year.

<u>ACTION</u>: Motion by D.BARNES, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to refer the matter (PHA-2022-0199), 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 a PROBATION for a period of 1 year to align with the AGO settlement timeline.

Case #5/CAS-2022-1234 SA-INV-20885

Thoa Pham, PH238708

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#### RECUSAL: NONE

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

- Pharmacist Pham was cited by CA BOP after an inspection and subsequent investigation at Paseo Oaks Pharmacy during 2020. Pharmacist Pham was PIC at Paseo from July 18, 2018, to January 10, 2019. During that period, Paseo dispensed multiple compounded drug preparations which were copies of commercially available drug products without documentation of a shortage or specific medical need. Pharmacist Pham was initially fined \$3,500.00 but the fine was reduced to \$1,500.00 after she appealed.
- Pharmacist Pham described that she was hired as a PIC at Paseo as a new graduate. However, she only worked one or two days a week. Pharmacist Pham explained that "[she] did not feel comfortable working there so [she] left, and [her] last date of employment was on around November 15th, 2018. Paseo's owner indicated that he would hire a replacement, but he failed to do so. Ultimately, Pharmacist Pham notified CA BOP that she was no longer PIC at Paseo on January 10, 2019.
- Pharmacist Pham described that she was not physically present in the pharmacy on fourteen occasions when prescriptions were purportedly approved by her. According to Pharmacist Pham, she conveyed this to CA BOP during a phone conference in October 2020. As a result, CA BOP reduced her fine to \$1,500.00.
- CA: Corrective action "include[d] notifying/emailing the Board of Pharmacy immediately on my last date of employment as PIC so that my name/license is not abused and forged with prescriptions. I have also read over the laws and regulations more carefully under the Board's website so I can be knowledgeable about the laws and to not take any Pharmacist in Charge/Manager of Record positions until I am fully comfortable, and I have more oversight physically at the pharmacy."

<u>ACTION</u>: Motion by C. BELISLE, seconded by K. THORNELL, and voted unanimously by those present, to ELEVATE the matter (SA-INV-20885), to a complaint.

Case #6/CAS-2022-0813		
SA-INV-20827	Bonifice Ochigbo, PH239914	Time: 09:50 AM

RECUSAL: NONE

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

- BORP opened a complaint (PHA-2022-0145) against WAG 6349 after Investigator Rick Geaney discovered during a retail compliance inspection on July 5, 2022, that the pharmacy failed to notify BORP about a change in manager of record appointing Pharmacist Ochigbo as MOR.
- Pharmacist Ochigbo's CE records were evaluated after he failed to indicate whether he completed annual CE requirements in his change in MOR application. The evaluation revealed that Pharmacist Ochigbo failed to complete two contact hours of CE in pharmacy law during 2020. Triage was notified about Pharmacist Ochigbo's 2020 CE deficiency and opened this staff-assignment investigation.
- Triage further reviewed records and discovered additional deficiencies during 2021. Specifically, Pharmacist Ochigbo completed 11.5 hours of CE on December 28, 2021, of which only 8 hours of CE counted towards 2021 annual requirements. Thus, Pharmacist Ochigbo completed only 17 of 20 total

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Draft Minutes General Session: 4/6/23 BOP Approved: 5/4/23 contact hours of CE required annually in 2021. Investigator Melton then discovered a deficiency of one contact hour of CE in pharmacy law during 2022 while confirming whether remediation for 2020 and 2021 was completed.

- In response, Pharmacist Ochigbo asserted that CE completed in excess of annual requirements should satisfy deficiencies in other years. In turn, Pharmacist Ochigbo was provided a copy of 247 CMR 4.00: Personal Registration Renewal; Continuing Education Requirement and BORP Policy 2021-04: Continuing Education (CE) for Requirements for reference. Pharmacist Ochigbo later indicated that he completed one contact hour of pharmacy law to remediate his 2022 deficiency.
- CA: Ultimately, Pharmacist Ochigbo remediated his 2020, 2021, and 2022 CE deficiencies.

<u>ACTION</u>: Motion by S. AHMED, seconded by S. HAMILTON, and voted unanimously by those present, to CLOSE the matter (SA-INV-20827), No Discipline Warranted, Remediation Complete.

Case #7/CAS-2022-1540 PHA-2022-0219

Rite Aid #10092, DS2886

Time: 09:54 AM

#### RECUSAL: NONE

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

- Rite Aid 10092 was issued a POC based in part for storing epinephrine autoinjectors and an open Sharps disposal container outside the licensed space of the pharmacy during an RC inspection on 12/05/2022.
- CA/POC: Rite Aid indicated that epinephrine autoinjectors were stored in the bottom drawer of the pharmacy's immunization cart according to Rite Aid immunization policy and the cart would be kept in the pharmacy's licensed space unless required for an emergency going forward. Rite Aid also indicated that the Sharps disposal container would be stored with the cap closed inside the pharmacy's licensed space when not in use and immunizers would "carry the container back and forth" when required for immunizations going forward.

<u>ACTION</u>: Motion by K. THORNELL, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2022-0219), 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 a REPRIMAND.

Case #8/CAS-2023-0038		
SA-INV-21385	Pharmacy Amanecer, DS90354	Time: 09:56 AM

#### RECUSAL: NONE

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

 Complex non-sterile compounding of gabapentin 10%/naproxen 5% multiphasic emulsion from BioPhysics components was observed during an inspection on 12/22/2022. The MFR was incomplete. None of the bases or APIs had expiration dates or open dates on the containers. Expiration dates for components were listed on a component expiration dates sheet provided by BioPhysics. Additionally, the compounding records were incomplete and no SDSs were available. The POC indicated SDSs were obtained, and the Pharmacy voluntarily ceased complex compounding on 12/23/22.

- MOR Szarek alleged BioPhysics consulted MOR Beckman at Custom Medicine who told him this was simple compounding, so he had no training in complex-NSC. The MFR was referenced off of an incomplete BioPhysics formulation and when compared, significant discrepancies were identified including mixing speeds and times and containers for the final preparation. A 120 BUD was assigned based on a potency test conducted on a 2021 sample failed at day 150. Although physical changes were noticed on day 60 of the 1/31/22 report and day 30 of the 10/10/22 report for BioPhysics analysis of samples, MOR Szarek contended the lab found no level of degradation. All appropriate PPE in the SDSs was not used.
- Four prescriptions were compounded from 9/21/22 to 12/2/22 and were all issued by Dr. Crowley on pre-printed prescriptions. The prescriptions stated they could only be filled at pharmacies licensed to use the proprietary base and the Pharmacy was specified. MOR Szarek indicated the Pharmacy had no contract or license with BioPhysics.
- MOR Szarek did not complete complex-NSC CEs since he thought this preparation was simple compounding. All P&Ps were obtained from NPSC. He provided a statement dated 8/15/22 indicating he had completed the NPSC compounding training module.
- MOR Szarek stated he would obtain BORP approval prior to resuming complex-NSC and he would engage a compounding consultant. He indicated the Pharmacy would compound requests for simple or moderate compounds. MOR Szarek provided a signed and dated statement confirming review of the Pharmacy's policies and procedures for non-sterile compounding.

<u>ACTION</u>: Motion by D. BARNES, seconded by R. MORELLI, and voted unanimously by those present, to ELEVATE the matter (SA-INV-21385), to a complaint.

#### D. Perry leaves meeting 10:00 AM to 11:00 AM

Case #9/CAS-2023-0046 SA-INV-21386

Letourneaus Pharmacy, DS2777

Time: 10:01 AM

#### RECUSAL: NONE

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

- MOR Picard contacted the BORP on 12/23/22 for further guidance for compounding acetaminophen on prescription due to the shortage. MOR Picard was notified oral acetaminophen products were not on the FDA shortage list and may not be compounded. MOR Picard agreed to cease compounding acetaminophen on 12/23/22 and the remaining compounded acetaminophen was discarded with the Pharmacy's hazardous waste company.
- The week of 12/19/22, the Pharmacy had received calls from prescribers and patients for liquid acetaminophen that was on back-order. MOR Picard compounded 5 prescriptions for acetaminophen

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160mg/5mL suspension from 12/21/22-12/23/22. All parents were aware it was compounded, and no adverse reactions were reported as of 1/23/23.

- MOR Picard compounded 2 batches (1,000mL each) of "Acetaminophen Spectrum Formula 160mg/5mL" based off a formula for acetaminophen 65mg/mL found on spectrumrx.com. She documented on the first batch it contained 32mg/mL and did not properly calculate the conversation to 160mg using this formula (160mg/2.46mL). The formula did not identify the dosage form, complete instructions, physical description of the final preparation, all labeling requirements, and all QC procedures. A 90-day BUD was assigned for room temperature and refrigerated storage. A copy of a Medisca formula was obtained by this investigator with a 14 BUD, refrigerated. MOR Picard did not test and adjust the pH of the compound.
- Going forward, MOR Picard will always check the FDA shortage list prior to compounding a commercially available product. MOR Picard discussed the Pharmacy's related policy for "Procedure: Determining the Availability of a Commercial Drug" with the Pharmacy staff with a signed and dated copy submitted confirming review.

<u>ACTION</u>: Motion by K. THORNELL, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to ELEVATE the matter (SA-INV-21386), to a complaint.

Case #10/CAS-2023-0040		
PHA-2023-0021	Walgreens #6072, DS3004	Time: 10:06 AM

RECUSAL: NONE

- Repeat inspectional deficiency on 12/27/22 for failure to submit a change of MOR application and failure to implement the POC from an inspection on 1/3/22. Former MOR Tranter had continued to be the MOR on file with the BORP as cited in PHA-2022-0004 which is pending a reprimand.
- Current MOR Gallo stated when he became MOR, he knew he had to complete a CS inventory but was unaware an application for a change of MOR needed to be submitted. Once the deficiency was cited, he worked with leadership to implement the POC, but the paperwork was sent to the incorrect e-mail address at the corporate office causing a delay. He ensured the application and fee was sent directly to the BORP with tracking.
- A copy of the application showed the change of MOR occurred on 9/29/22. MLO showed no notifications were received for an interim MOR at the Pharmacy. CS inventories were provided which showed change of MOR inventories were completed on 8/29/2021 with no name/signature, on 2/1/22 for incoming Former MOR Mahmoud, and on 09/29/22 for Current MOR Gallo. A copy of the unnamed SOP provided indicated the Walgreens DM is responsible for ensuring compliance for a change of MOR.
- The POC for the 12/27/22 inspection indicated the Incoming MOR will ensure the application is completed and received by the BORP within 7 days of a change. In the 02/24/2023 response, Walgreens DM Krunal Patel stated, "Going forward the field will send any change of MOR paperwork along with the corresponding fee directly to the Board of Pharmacy to ensure that we comply in a timely manner and notify of those changes so our records are up to date, rather than sending it to our corporate office first".

<u>ACTION</u>: Motion by D. BARNES, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2023-0040), 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 a PROBATION for a period of 1 year.

Case #11/CAS-2023-0045 PHA-2023-0025 Joseph Ciampa, PH24402 TIME: 10:10 AM

<u>RECUSAL</u>: R. MORELLI recused and was not present for the vote or discussion in this matter.

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

- During a retail compliance inspection conducted on 1/4/23 at Home Care Pharmacy, it was noted that MOR Ciampa was practicing with an expired license. Pharmacist Ciampa renewed his pharmacist license during the inspection.
- Pharmacist Ciampa related that the reason he overlooked his license renewal was because he did not receive a reminder notice in the mail.
- Pharmacist Ciampa claimed the Pharmacy was closed on 1/1/23 and he performed limited pharmacist duties on 1/2/23 to 1/4/23. Pharmacist Ciampa indicated on the few days in question, no CII had been ordered and no immunizations were administered. Contrary to his statement, documentation provided showed that Pharmacist Ciampa's name was associated with 4 vaccines and 143 additional prescriptions during the time period of 01/01/23 to 01/04/23.
- To resolve this issue going forward Pharmacist Ciampa has entered a recurring task in his daily calendar to remind him of the renewal of his pharmacist license.

<u>ACTION</u>: Motion by S. AHMED, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2023-0025), 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 a REPRIMAND.

Case #12/CAS-2022-1074		
SA-INV-20825	CVS #17727, DS90243	Time: 10:13 AM

<u>RECUSAL</u>: J. ROCCHIO recused and was not present for the vote or discussion in this matter. D. PERRY had exited the meeting and was not present for the vote or discussion in this matter.

- Allegation by PT Gilman that the Pharmacy did not have a MOR for 5 months and a floater pharmacist, identified as Former MOR Rigas, brought her unlicensed daughter, PTT Rigas, into work at the Pharmacy on multiple occasions. PTT Rigas' license expired on 6/26/20.
- During a site visit on 9/8/22, it was noted Former MOR Rigas became MOR on 07/1/22. The Pharmacy was cluttered, needed organization, and expired CIIs were not reconciled. Investigator Van Allen discussed the allegations with DL Ekbatani who "acknowledged the unlicensed individual in the pharmacy and noted that corrective action had been conducted". On 10/7/22, Sr. Analyst Furtado

stated Former MOR Rigas was no longer employed by CVS and a potential new MOR was hired. The POC stated HR was investigating the specific instance of PTT Rigas working in the Pharmacy.

- Former MOR Rigas responded her last day was on 10/6/22. Until April 2022, she had worked as a floater then was assigned to the Pharmacy. After Former MOR Rasla gave her notice, she agreed under duress to temporarily become the MOR temporarily until August. She completed CS inventories on 7/17/22, worked 7/19/22 then was off until 8/9/22. She alleged she had minimal to no help in the Pharmacy, so she asked PTT Rigas to come in as a last resort. She claimed PTT Rigas worked one day in May as a cashier only (when Former MOR Rigas was a staff pharmacist). CVS HR had no record of PTT Rigas working after 9/2/21 but worked unlicensed for 137 hours total at 2 other locations from 7/16/20-9/2/21.
- A response could not be obtained by CVS from PT Gilman. DL Ekbatani confirmed Former MOR Rigas agreed to become MOR temporarily and the potential MOR hired for August didn't occur. Current MOR Amin assumed the role on 10/18/22. After the fact, PTT Rigas was found working without punching in against CVS policies.
- The matter of SA-INV-208205 was heard at the 2/2/23 Board meeting and deferred with complaints opened against Former MOR Rigas and PTT Rigas. MOR Rigas indicated she did not wish to provide additional information. PTT Rigas provided a copy of an application for a license extension dated 6/28/21 that was not granted. She indicated she was hired in 2019 at CVS #363 and only worked one day in May 2022 as a cashier to help her mom. She no longer works in pharmacy and has no intention to return.
- According to the POC, having non-CVS and unlicensed employees in the pharmacy is strictly against policy and is addressed during training which DL Ekbatani reviewed with her pharmacy team. DL Ekbatani and Current MOR Amin will ensure compliance is met. DL Ekbatani will double check all MOR change paperwork for accuracy prior to submitting to avoid future delays. Current MOR Amin and Staff pharmacist signed copies of BORP Policy 2022-02: Extended Absence of a Manager of Record and CVS policies Pharmacists in Charge and Powers of Attorney at CVS Health Professional Standards confirming review.

<u>ACTION</u>: Motion by C. JEAN-FRANCOIS, seconded by K. THORNELL, and voted unanimously by those present, to CLOSE the matter (SA-INV-20825), No Discipline Warranted, Remediation Complete.

Case #13/CAS-2022-1074		
PHA-2023-0041	Irene Rigas, PH23188	Time: 10:20 AM

<u>RECUSAL</u>: J. ROCCHIO recused and was not present for the vote or discussion in this matter. D. PERRY had exited the meeting and was not present for the vote or discussion in this matter.

- Allegation by PT Gilman that the Pharmacy did not have a MOR for 5 months and a floater pharmacist, identified as Former MOR Rigas, brought her unlicensed daughter, PTT Rigas, into work at the Pharmacy on multiple occasions. PTT Rigas' license expired on 6/26/20.
- During a site visit on 9/8/22, it was noted Former MOR Rigas became MOR on 07/1/22. The Pharmacy was cluttered, needed organization, and expired CIIs were not reconciled. Investigator Van Allen discussed the allegations with DL Ekbatani who "acknowledged the unlicensed individual in the pharmacy and noted that corrective action had been conducted". On 10/7/22, Sr. Analyst Furtado

stated Former MOR Rigas was no longer employed by CVS and a potential new MOR was hired. The POC stated HR was investigating the specific instance of PTT Rigas working in the Pharmacy.

- Former MOR Rigas responded her last day was on 10/6/22. Until April 2022, she had worked as a floater then was assigned to the Pharmacy. After Former MOR Rasla gave her notice, she agreed under duress to temporarily become the MOR temporarily until August. She completed CS inventories on 7/17/22, worked 7/19/22 then was off until 8/9/22. She alleged she had minimal to no help in the Pharmacy, so she asked PTT Rigas to come in as a last resort. She claimed PTT Rigas worked one day in May as a cashier only (when Former MOR Rigas was a staff pharmacist). CVS HR had no record of PTT Rigas working after 9/2/21 but worked unlicensed for 137 hours total at 2 other locations from 7/16/20-9/2/21.
- A response could not be obtained by CVS from PT Gilman. DL Ekbatani confirmed Former MOR Rigas agreed to become MOR temporarily and the potential MOR hired for August didn't occur. Current MOR Amin assumed the role on 10/18/22. After the fact, PTT Rigas was found working without punching in against CVS policies.
- The matter of SA-INV-208205 was heard at the 2/2/23 Board meeting and deferred with complaints opened against Former MOR Rigas and PTT Rigas. MOR Rigas indicated she did not wish to provide additional information. PTT Rigas provided a copy of an application for a license extension dated 6/28/21 that was not granted. She indicated she was hired in 2019 at CVS #363 and only worked one day in May 2022 as a cashier to help her mom. She no longer works in pharmacy and has no intention to return.
- According to the POC, having non-CVS and unlicensed employees in the pharmacy is strictly against policy and is addressed during training which DL Ekbatani reviewed with her pharmacy team. DL Ekbatani and Current MOR Amin will ensure compliance is met. DL Ekbatani will double check all MOR change paperwork for accuracy prior to submitting to avoid future delays. Current MOR Amin and Staff pharmacist signed copies of BORP Policy 2022-02: Extended Absence of a Manager of Record and CVS policies Pharmacists in Charge and Powers of Attorney at CVS Health Professional Standards confirming review.

<u>ACTION</u>: Motion by S. AHMED, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2023-0041), 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 a REPRIMAND.

Case #14/CAS-2022-1074		
PHA-2023-0042	Angelique Rigas, PTT05467	Time: 10:21 AM

<u>RECUSAL</u>: J. ROCCHIO recused and was not present for the vote or discussion in this matter. D. PERRY had exited the meeting and was not present for the vote or discussion in this matter.

- Allegation by PT Gilman that the Pharmacy did not have a MOR for 5 months and a floater pharmacist, identified as Former MOR Rigas, brought her unlicensed daughter, PTT Rigas, into work at the Pharmacy on multiple occasions. PTT Rigas' license expired on 6/26/20.
- During a site visit on 9/8/22, it was noted Former MOR Rigas became MOR on 07/1/22. The Pharmacy was cluttered, needed organization, and expired CIIs were not reconciled. Investigator Van Allen discussed the allegations with DL Ekbatani who "acknowledged the unlicensed individual in the

pharmacy and noted that corrective action had been conducted". On 10/7/22, Sr. Analyst Furtado stated Former MOR Rigas was no longer employed by CVS and a potential new MOR was hired. The POC stated HR was investigating the specific instance of PTT Rigas working in the Pharmacy.

- Former MOR Rigas responded her last day was on 10/6/22. Until April 2022, she had worked as a floater then was assigned to the Pharmacy. After Former MOR Rasla gave her notice, she agreed under duress to temporarily become the MOR temporarily until August. She completed CS inventories on 7/17/22, worked 7/19/22 then was off until 8/9/22. She alleged she had minimal to no help in the Pharmacy, so she asked PTT Rigas to come in as a last resort. She claimed PTT Rigas worked one day in May as a cashier only (when Former MOR Rigas was a staff pharmacist). CVS HR had no record of PTT Rigas working after 9/2/21 but worked unlicensed for 137 hours total at 2 other locations from 7/16/20-9/2/21.
- A response could not be obtained by CVS from PT Gilman. DL Ekbatani confirmed Former MOR Rigas agreed to become MOR temporarily and the potential MOR hired for August didn't occur. Current MOR Amin assumed the role on 10/18/22. After the fact, PTT Rigas was found working without punching in against CVS policies.
- The matter of SA-INV-208205 was heard at the 2/2/23 Board meeting and deferred with complaints opened against Former MOR Rigas and PTT Rigas. MOR Rigas indicated she did not wish to provide additional information. PTT Rigas provided a copy of an application for a license extension dated 6/28/21 that was not granted. She indicated she was hired in 2019 at CVS #363 and only worked one day in May 2022 as a cashier to help her mom. She no longer works in pharmacy and has no intention to return.
- According to the POC, having non-CVS and unlicensed employees in the pharmacy is strictly against policy and is addressed during training which DL Ekbatani reviewed with her pharmacy team. DL Ekbatani and Current MOR Amin will ensure compliance is met. DL Ekbatani will double check all MOR change paperwork for accuracy prior to submitting to avoid future delays. Current MOR Amin and Staff pharmacist signed copies of BORP Policy 2022-02: Extended Absence of a Manager of Record and CVS policies Pharmacists in Charge and Powers of Attorney at CVS Health Professional Standards confirming review.

<u>ACTION</u>: Motion by JD. BARNES, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2023-0042), 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 a REPRIMAND.

Case #15/CAS-2022-1381		
PHA-2022-0210	CVS #281, DS2727	TIME: 10:22 AM

<u>RECUSAL</u>: J. ROCCHIO recused and was not present for the vote or discussion in this matter. D. PERRY had exited the meeting and was not present for the vote or discussion in this matter.

- Unknown loss of #551 alprazolam 0.5mg tablets on or about 10/13/2022.
- On 10/13/2022, MOR Callahan reported the loss was identified from corporate controlled substance monitoring as a variance.
- On 2/13/2023, additional information was submitted. A DEA 106 form was subsequently filed on 11/3/2022 to close this matter. Further investigation after the submission of the 106-form concluded there was no significant loss of controlled substances at this pharmacy on this date.

- RASA Pacia indicated that the bottle was supposed to be delivered on 9/1/2022. The employee who checked in the order had a training opportunity in a new paperless invoice process. As a result, the items were put on the shelves, and no one was aware we had not received the bottle since it had inadvertently been checked in.
- Cardinal submitted a copy of the manifest dated 9/1/2022 indicating that the Pharmacy accepted the order which included the #500 count bottle of alprazolam 0.5mg tablets (NDC#00228-2029-50)
- On 03/06/2023, Cardinal Health confirmed a good will credit was issued to the Pharmacy for the missing bottle of #500 alprazolam 0.5mg tablets.

<u>ACTION</u>: Motion by R. MORELLI, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to DISMISS the matter (PHA-2022-0210), No Discipline Warranted, Remediation Complete.

Case #16/CAS-2023-0121		
PHA-2023-0032	CVS #119. DS89835	TIME: 10:24 AM

<u>RECUSAL</u>: J. ROCCHIO recused and was not present for the vote or discussion in this matter. D. PERRY had exited the meeting and was not present for the vote or discussion in this matter.

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

- During a retail compliance inspection (ISP-20515) conducted on 01/20/2023, it was observed that there was epinephrine and antihistamines stored in the vaccination room which is unlicensed space.
- MOR Hom indicated that he had an emergency response kit residing in the room which contained epinephrine auto-injectors, OTC cetirizine and diphenhydramine. On the same day of the inspection, he removed the epinephrine and antihistamines from the unlicensed space.
- The MOR indicated that the entire team has been made aware of the new location of the kit in case of an emergency and are now compliant with the regulations.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2023-0029), 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 a REPRIMAND.

Case #17/CAS-2023-0127		
PHA-2023-0032	CVS #915, DS3395	TIME: 10:26 AM

<u>RECUSAL</u>: J. ROCCHIO recused and was not present for the vote or discussion in this matter. D. PERRY had exited the meeting and was not present for the vote or discussion in this matter.

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

- RLCS- unknown loss of #60 dextroamphetamine salts 7.5mg tablets on or about 12/22/2022.
- The loss was identified during an inventory count on 12/22/2022.
- On 2/15/2023, Pharmacy Regulatory Affairs Senior Analyst (RASA) Lauren Pacia submitted an updated response indicating that there was no loss as the medication was discovered on 12/22/2022.
- The medication was found in the waiting bin while staff were pulling prescriptions older than 14 days. A prescription for 10mg dextroamphetamine salts was incorrectly filled as 7.5 mg tablets. The medication error was discovered prior to the prescription being dispensed.

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<u>ACTION</u>: Motion by D. BARNES, seconded by K. THORNELL, and voted unanimously by those present, to DISMISS the matter (PHA-2023-0032), No Discipline Warranted, Remediation Complete.

Case #18/CAS-2022-1606		
SA-INV-21324	CVS #2128, DS2720	TIME: 10:28 AM

<u>RECUSAL</u>: J. ROCCHIO recused and was not present for the vote or discussion in this matter. D. PERRY had exited the meeting and was not present for the vote or discussion in this matter.

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

- During December 2022, BORP received a report from a Massachusetts veterinarian authorized to prescribe federally controlled and non-federally controlled substances. According to the veterinarian, a veterinary technician was tasked to phone in a prescription issued for methylprednisolone 4mg tablets, a non-federally controlled substance, for a feline at CVS 2128 on December 19, 2022. Pharmacist Manisha Patel refused to fill the prescription without the veterinarian's DEA Registration Number which was not required for a non-federally controlled substance.
- Current MOR Khalid explained that Pharmacist Patel was unable to locate the veterinarian in the pharmacy's prescription software system. Pharmacist Patel requested the DEA Registration Number to facilitate locating the veterinarian in the system. The veterinarian refused to provide the number. Current MOR Khalid further explained that locating providers in the pharmacy's prescription software system without the provider's DEA Registration Number was cumbersome at times.
- Current MOR Khalid next indicated that patient's owner contacted the veterinarian's office and obtained the veterinarian's DEA Registration Number. The patient's owner then provided the DEA Registration Number to Pharmacist Patel. In turn, Pharmacist Patel was able to fill and dispense the methylprednisolone to the patient's owner "within an hour."
- CA: Kimberly Gonsalves, Senior Analyst, CVS Health Pharmacy Regulatory Affairs, indicated that staff at CVS 2128 were "provided with guidance on how to search for veterinarians in the system" as part of corrective action to mitigate recurrence of a similar incident. In addition, Alicia Palombo, PharmD, Senior Advisor, CVS Health Pharmacy Regulatory Affairs indicated that the pharmacy was trained on "searching for Veterinarian Prescriber records and walked... through the options of searching for a record without the DEA number from the provider."

<u>ACTION</u>: Motion by S. AHMED, seconded by K. THORNELL, and voted unanimously by those present, to CLOSE the matter (SA-INV-23124), No Discipline Warranted, Remediation Complete.

Case #19/CAS-2022-1336 SA-INV-20941 CVS #2476, DS2904

TIME: 10:31 AM

<u>RECUSAL</u>: J. ROCCHIO and D. PERRY recused and were not present for the vote or discussion in this matter.

- On or about October 25, 2022, CVS 2476 refused to fill an electronic prescription for a Schedule II narcotic because the provider, a dentist licensed in Rhode Island, was not licensed in Massachusetts. According to the dentist, the pharmacist on duty at CVS 2476 asserted that "only doctors and pa's from surrounding states could prescribe and that dentists were not permitted the same courtesy."
- Director Frisch then contacted CVS 2476 and spoke to MOR Sonsini, regarding Dr. Asaro's prescription. MOR Sonsini acknowledged that she refused to fill the prescription. MOR Sonsini explained that CVS 2476's prescription processing software did not permit filling of prescriptions issued by out-of-state dentists for Schedule II narcotics.
- Director Frisch informed MOR Sonsini about a change in law on January 1, 2021, which permitted Massachusetts pharmacies to fill prescriptions for Schedule II narcotics issued by any out-of-state practitioner, in states contiguous to Massachusetts, and Maine.
- Director Frisch next contacted CVS Pharmacy Regulatory Affairs and notified them about the change in law. CVS corporate indicated that "pharmacy operations made the effective changes needed for prescriptions of this nature to be filled within CVS systems."
- In addition, MOR Sonsini responded to this complaint and reiterated the events as described by Director Frisch and Dr. Asaro. She explained that she promptly contacted CVS Health's helpdesk and her manager to notify them about the improper hard stop. MOR Sonsini indicated that "this issue has since been corrected. Going forward, we will be able to fill these types of prescriptions..."

<u>ACTION</u>: Motion by C. JEAN-FRANCOIS, seconded by R. MORELLI, and voted unanimously by those present, to CLOSE the matter (SA-INV-20941), No Discipline Warranted, Remediation Complete.

Topic X: Executive Session Call to Order: Time: 10:36 AM

By: Caryn Belisle reads the executive session language and requests a motion to enter executive session.

Action: A motion was made by J. Lanza to enter Executive Session; Seconded by C. Jean-Francois and Board Members present voted unanimously by roll call to approve motion. Roll call attendance: J. Lanza, yes; S. Hamilton, yes; C. Belisle, yes; D. Barnes; J. Rocchio, yes; S. Ahmed, yes; R. Morelli, yes; D. Perry, yes; D. Barnes, yes; C. Jean-Francois, yes; J. Lopez joins meeting 12:30 PM.

Topic XI:

65C Sessions MGL c. 112 section 65C

Time: 10:40 AM

<u>DISCUSSION</u>: None <u>ACTION</u>: President Caryn Belisle request a motion to enter 65C.

At 10:40 AM J. Lanza, seconded by S. Hamilton and voted unanimously by all those present to enter 65C by roll call vote.

#### Lunch 12:00 PM to 12:30 PM

#### J. Lopez joins meeting 12:30 PM C. Jean-Francois Leaves meeting 2 PM

#### Topic XII

#### ADJOURMENT OF MEETING

#### TIME: 11:59 PM

ACTION: Motion by D. Perry seconded by J. Lopez and voted unanimously by those present, to adjourn from General Session by roll call vote.

#### EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

- 1. Draft Agenda of the 4/6/23 General Session
- 2. Draft Minutes of the 3/2/23Meeting
- 3. Report on Applications approved pursuant to Licensure Policy 13-01
- 4. Report on probation
- 5. Report on Board Delegated Complaint Review to licensure policy 14-02
- 6. Report on PSUD 17-03
- 7. Report: Plan of Correction
- 8. Report: Research Drug Study pursuant to Staff Action Policy 18-02
- 9. Report: Pharmacy Technician Licensing Examinations and Training Programs report pursuant to Staff Action Policy 17-02
- 10. Application: UMass-Memorial Specialty; DS89822 Renovations
- 11. Application: Vital Care Pharmacy; DS90363 Renovations
- 12. Application: Koala Pharmacy; DS90386 -Renovation
- 13. Application: Westminster Pharmacy -Transfer of Ownership
- 14. Application: Marlboro Pharmacy and Wellness-New Pharmacy
- 15. Application: East Boston Health Center
- 16. Regulation: 247 CMR 2.00: Definitions
- 17. Policy: Policy 2023-01: Compliance Packaging and Reusable Dose Planners
- 18. Policy: Policy 2023-04: Continuity of Care

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19. CAS-2022-0665	SA-INV-20260	CAPS Pharmacy, DS3312
20. CAS-2022-0868	SA-INV-20914	CAPS Pharmacy, DS3312
21. CAS-2022-1384	SA-INV-21085	Ngoc Bich Tran, PH235829
22. CAS-2022-1266	PHA-2022-0199	Bravo Pharmacy, DS89981
23. CAS-2022-1234	SA-INV-20885	Thoa Pham, PH238708
24. CAS-2022-0813	SA-INV-20827	Bonifice Ochigbo, PH239914
25. CAS-2022-1540	PHA-2022-0219	Rite Aid #10092, DS2886
26. CAS-2023-0038	SA-INV-21385	Pharmacy Amanecer, DS90354
27. CAS-2023-0046	SA-INV-21386	Letourneaus Pharmacy, DS2777
28. CAS-2023-0040	PHA-2023-0021	Walgreens #6072, DS3004
29. CAS-2023-0045	PHA-2023-0025	Joseph Ciampa, PH24402

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30. CAS-2022-1074	SA-INV-20825 CVS #17727, DS90243
31. CAS-2022-1074	PHA-2023-0041 Irene Rigas, PH23188
32. CAS-2022-1074	PHA-2023-0042 Angelique Rigas, PTT05467
33. CAS-2022-1381	PHA-2022-0210 CVS #281, DS2727
34. CAS-2023-0121	PHA-2023-0029 CVS #119, DS89835
35. CAS-2023-0127	PHA-2023-0032 CVS #915, DS3395
36. CAS-2022-1606	SA-INV-21324 CVS #2128, DS2720
37. CAS-2022-1336	SA-INV-20941 CVS #2476, DS2904

Respectfully Submitted, Jennifer Chin, RPh, Secretary