COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

September 17, 2021

Webex Information

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

For video access click on the following link:

://statema.webex.com/statema/onstage/g.php?MTID=

To access the meeting by phone:

Call in Number: 1-203-607-0564 or toll free 1-866-692-3580

Access Code: 161 667 9914

Attendee: #

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator _ Phone: 617-937-9947 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.

Agenda

Time	#	Item	Page	Contact
8:00	Ι	CALL TO ORDER		J. Lanza
	II	APPROVAL OF AGENDA		
8:05	ш	 APPROVAL OF BOARD MINUTES Draft of August 20, 2021 Regular Session Minutes 		

		REPORTS		
8:10	TX 7	Applications approved pursuant to Licensure Policy 13-01Monthly report from probation		
	IV	 Board Delegated Review pursuant to Licensure Policy 14-02 Above Action Levels approved by Staff Action 16-04 		
		 PSUD Report-Policy 17-03 		
8:15	V	FLEX Pharmacy issues related to Covid-19 and the state of emergency NABP District 1 & 2 meeting report Introduction of new Board member		
		PTT LICENSE EXTENSION REQUESTS		
		PTT04848 Andrea Mclaughlin Issue Date: 04/24/2019 Expiration Date: 04/24/2020 15 hours		
8:30		PTT07815 Yasmin Arroyo Issue Date: 03/04/2020 Expiration Date:03/04/2021 150 hours		
		PTT09339 Damian Ortiz Issue Date: 09/17/2020 Expiration Date: 09/17/2021 Zero hours		
		PTT07043 Mikayla Hebert Issue Date: 12/09/2019 Expiration Date:12/09/2020 Zero hours		
		APPLICATIONS • East Bay Pharmacy – New Community Pharmacy		
8:45		 County Square Pharmacy; DS15805-Transfer of Ownership Jubilant DraxImage; NU0022 – Transfer of Ownership of a Nuclear 		
		Pharmacy		
		 Spectra Medical Devices; WD515-Transfer of Ownership CMV Wholesalers, LLC – Wholesale Distributor 		

		FILE REVIEW	
		1 CAS-2021-0451 SA-INV-17932 Marco Mares, PH2	26626
		2 CAS-2021-0420 PHA-2021-0031 Rite Aid #10166, I	DS3135
		3 CAS-2021-0516 PHA-2021-0036 Stop & Shop #787	, DS2308
		4 CAS-2021-0537 PHA-2021-0040 Walgreens #6295,	DS3045
9:30	VI	5 CAS-2021-0510 SA-INV-18028 CVS #209, DS359	7
		6 CAS-2021-0591 PHA-2021-0049 CVS #321, DS298	9
		7 CAS-2021-0536 PHA-2021-0038 CVS #859, DS361	8
		8 CAS-2021-0619 PHA-2021-0051 CVS #765, DS291	0
		9 CAS-2021-0620 PHA-2021-0052 CVS #153, DS265	5
		10 CAS-2021-0593 PHA-2021-0050 CVS #1866, DS29	56
10:15	VII	EXECUTIVE SESSION The Board will meet in Executive Session as authorized pursuar c. 30A, § 21(a)(1) for the purpose of discussing the reputation, c physical condition or mental health, rather than professional cor an individual, or to discuss the discipline or dismissal of, or con charges brought against, a public officer, employee, staff memb individual. Specifically, to evaluate the Good Moral Character a for registration for a pending applicant.	haracter, npetence, of plaints or er or CLOSED SESSION
10:45	VIII	M.G.L. c. 112, § 65C SESSION	CLOSED SESSION
11:30	IX	ADJOURNMENT	

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

MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting September 17, 2021

Board Members Present

Board Members Not Present

Sebastian Hamilton, Pharm D, MBA, RPh President-Elect Julie Lanza, CPhT, President Carly Jean-Francois, RN, NP Secretary Andrew Stein, PharmD (Leaves at 10:00 AM back at 10:59 AM) Timothy Fensky, RPh Susan Cornacchio, JD, RN Caryn Belisle, RPh, MBA John Rocchio, PharmD Jennifer Chin, RPh Dr. Richard Lopez, MD Dawn Perry, JD (leaves meeting at 11:00 AM) Katie Thornell, RPh, MBA (leaves meeting 10:00 AM back at 10:40 AM)

Board Staff Present

David Sencabaugh, RPh, Executive Director Heather Engman, 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 Joanne Trifone, RPh, Director of Investigation Gregory Melton, PharmD, JD, Investigator Cheryl Lathum, PharmD, Investigator Julienne Tran, PharmD, Investigator

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:03 AM

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

Roll call attendance: S. Hamilton, yes; C. Belisle, yes; A. Stein; C. Jean-Francois, yes; J. Rocchio, yes; J. Chin, yes; S. Cornacchio, yes; R. Lopez, yes; T. Fensky, yes; D. Perry, yes. K. Thornell, yes.

Topic II.

Approval of Agenda

TIME 8:06 AM

Agenda 09/17/21

DISCUSSION: Defer: Damian Ortiz and Spectra Medical Devices

ACTION:

Motion by A. Stein, seconded by J. Chin and voted unanimously by those present to approve the agenda with noted change by roll call vote.

Topic III

Approval of Board Minutes

TIME: 8:06 AM

Minutes

1. Draft 8/20/21

Change: Add September Board Meeting Dates to Flex discussion on September board meetings.

Action:

Motion by D. Perry seconded C. Belisle and voted unanimously to approve the regular session minutes of 8/20/21 with noted change by roll call vote. C. Jean-Francois and J. Rocchio abstain.

ΤΟΡΙϹ ΙV	REPORTS			
Applications approved pursuant to Li	censure Policy 13-01	Time: 8:08 AM		
Discussion : R. HARRIS reported there were fifty-one (51) Change of Manager applications and one (1)				
Business closure approved pursuant to	o Licensure Policy 13-01.			

So noted		
TOPIC IV	REPORTS	
Monthly Report from Pro	obation	Time: 8:08 AM
Discussion: R. HARRIS pro	ovided the July 29, 2021 – September 15	5, 2021, Pharmacy Board Probation

Discussion: R. HARRIS provided the July 29, 2021 – September 15, 2021, Pharmacy Board Probation Monthly Report, which noted that two (2) licensees successfully completed probation monitoring. There are currently 25 active cases.

So noted

TOPIC IVREPORTSMonthly Report from BDR pursuant to Policy 14-02

Time: 8:08 AM

Discussion: D. SENCABAUGH noted that there was two (2) Board Delegated Review case heard on August 19, 2021. Both are CE self-disclosures (SA-INV-18179 and SA-INV-18092) which were closed with discipline not warranted, remediation complete. SA-INV-18179 was attended by Sebastian Hamilton as the Board President-Elect, M. CHAN as QA Pharmacist, H. ENGMAN as Board Counsel, and Executive Director D. SENCABAUGH. SA-INV-18092 was attended by Sebastian Hamilton as the Board President-Elect, W. FRISCH Director of Pharmacy Compliance, H. ENGMAN as Board Counsel, and Executive Director D. SENCABAUGH.

So noted

TOPIC IV	REPORTS	
Above Action Levels Ap	pproved by Staff Action 16-04	Time: 8:09 AM
Discussion : N. ALEID no meeting pursuant to Lic	oted that there are zero (0) above action censure Policy 16-04.	level reports since the last Board
So noted		
TOPIC IV	REPORTS	
PSUD Report by Staff A	Action 17-03	Time: 8:09 AM
Discussion : E. TAGLIER active participants.	I noted that in August 2021, there were	two (2) new admissions and fifteen (15)
So noted		
ΤΟΡΙϹ V	Flex	
1. Pharmacy Issues Re	elated to Covid-19 and State of Emerge	ncy Time: 8:11

Presented by D. SENCABAUGH

- a. HHS has issued a 9th amendment to the PREP Act that now allows pharmacists, interns, and qualified pharmacy technicians to administer certain COVID-19 therapeutics. Board staff is working with other agencies to finalize a guidance document to assist licensees with the details. It will come before the Board when complete.
- b. Board staff is aware of the controversial issue of the use of ivermectin for COVID-19 and are working to put together some guidance for licensees. Board members can reach out to Board staff for any questions.

2. NABP District 1 & 2 Meeting Report

Time: 8:13

Presented by S. HAMILTON and T. FENSKY

S. HAMILTON attended the NABP District 1 & 2 meeting held on September 7-10, 2021, in Annapolis, MD as the Board's delegate along with Board member T. FENSKY. Sessions were held on Thursday and Friday (September and). The state of New Hampshire presented two resolutions: The first resolution focused on adverse event reporting associated with compounded preparations which passed and the second resolution, which dealt with 503b outsourcers dispensing compounded medications to pharmacies under common ownership, did not pass. Both Massachusetts resolutions ("Definition of pharmacist as a health care provider" and "Electronic prescribing functions in pharmacy practice") passed. Bradley Hamilton (Maine) was voted to represent District 1 for reappointment to the Executive Committee (EC) at next year's Annual Meeting. Board member T. FENSKY indicated that he will be serving as the Vice Chair for Rhode Islands' hosting of the NABP District 1 & 2 meeting in Newport RI next year and as the Chair for Massachusetts' hosting of the NABP District 1 & 2 meeting in 2024. The 2023 NABP District 1 & 2 meeting will be hosted by New Jersey. Districts 1 & 2 are looking to get students more involved by sponsoring attendance at both district and national meetings.

3. Introduction of New Board Member

Time: 8:09

Presented by D. SENCABAUGH

D. SENCABAUGH introduced and welcomed new Board member Mr. John Rocchio who replaces Leah Giambarresi in the chain pharmacy seat on the Board. Mr. Rocchio has been with the CVS Corporation for many years and has experience in different areas. Mr. Rocchio indicated that in his role in regulatory affairs at CVS, he has worked with the Board of Pharmacy in Massachusetts for several years, as well as with Boards across the country, and looks forward to serving with the Board.

TOPIC VI

PTT Applications Extensions

1. PTT04848 Andrea McLaughlin Time: 8:21AM Issue Date: 04/24/2019 Expiration Date: 04/24/2020 15 hours

Presented by S. HAMILTON

Andrea McLaughlin (PTT04848) appeared before the Board to request an extension of her Pharmacy Technician Trainee (PTT) license. The licensee indicated that she works at the CVS in Wrentham, MA, and hours were available to work in the pharmacy but when the COVID-19 pandemic hit, there were no hours available to work. The licensee indicates that there are now hours available to work in the pharmacy and is requesting an extension of her PTT license.

Action: Motion by T. FENSKY, seconded by C. BELISLE, and voted unanimously by roll call by all those present to approve the PTT license extension for a period of 1 year. Board members S. CORNACCHIO and J. ROCCHIO were recused from the matter.

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2. PTT07815 Yasmin Arroyo Issue Date: 03/04/2020 Expiration Date:03/04/2021 150 hours

Time: 8:25AM

Presented by S. HAMILTON

Yasmin Arroyo (PTT07815) appeared before the Board to request an extension of her Pharmacy Technician Trainee (PTT) license. The licensee indicated that she was working during the COVID-19 pandemic in March 2020 at the CVS in Charlestown, MA, and decided to pause her pharmacy technician career as to not place others she was living with at risk. The licensee indicates that now that the pandemic has eased, she is ready to resume her career as a pharmacy technician at the CVS Pharmacy in Natick, MA, and is requesting an extension of her PTT license.

Action: Motion by C. BELISLE, seconded by T. FENSKY, and voted unanimously by roll call by all those present to approve the PTT license extension for a period of 1 year. Board members S. CORNACCHIO and J. ROCCHIO were recused from the matter.

3. PTT07043 Mikayla Hebert Issue Date: 12/09/2019 Expiration Date:12/09/2020 Zero hours

Time: 8:32AM

Presented by S. HAMILTON

Mikayla Hebert (PTT07043) appeared before the Board to request an extension of her Pharmacy Technician Trainee (PTT) license. The licensee indicated that she was going to school to get a certificate and due to the school closing during the pandemic, was unable to obtain hours. The licensee indicated that when the school opened back up, she was unable to work due to the birth of her son. The licensee is waiting to start at UMass Memorial and is requesting an extension of her PTT license.

Action: Motion by T. FENSKY, seconded by C. JEAN-FRANCOIS, and voted unanimously by roll call by all those present to approve the PTT license extension for a period of 1 year.

ΤΟΡΙϹ VII	Applications	
1. East Bay Pharmacy	New Community Pharmacy	TIME
8:36am		
Represented by: Geoffrey Pete	erson, RPh and Ron Lanton, Esq	

Recusal: None

Discussion: G. PETERSON indicated that he sought approval from BORP to open a new community pharmacy. PETERSON described that EAST BAY PHARMACY planned to provide services for long term care facilities and assisted living facilities with minimal walk-in patients. BORP inquired whether EAST BAY PHARMACY would use a third-party courier for deliveries. PETERSON indicated that EAST BAY PHARMACY would employ his own delivery drivers to maintain maximum oversight. In addition, PETERSON confirmed that the blueprints for EAST BAY PHARMACY were modified. He

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indicated that the compounding area was moved closer to the handwash station on the opposite side of the pharmacy.

ACTION: A motion was made by T. Fensky to approve the transfer of ownership pending successful inspection; Seconded by A. Stein, then Board Members present voted unanimously by rollcall to approve motion.

County Square Pharmacy DS15805 Transfer of Ownership
 Represented by: Abram Agayby, RPh

TIME 8:49am

Recusal: None

Discussion: A. AGAYBY described that he sought BORP's approval for a transfer of ownership. He indicated that he entered into an agreement to purchase COUNTY SQUARE PHARMACY. AGAYBY described that his pharmacy background included stints as manager for several chain pharmacies. He explained that he grew up in the area in the Attleboro area where COUNTY SQUARE PHARMACY was located and wished to support his community by providing pharmacy care. He indicated that he underwent additional training to prepare for the transfer of ownership including certification in compounding non-sterile preparations. AGAYBY also planned to keep current staff at COUNTY SQUARE PHARMACY included a pharmacist with 28 years of non-sterile compounding experience and a pharmacy technician who he sent for compounding certification as part of his plan for transfer of ownership.

ACTION: A motion was made by A. Stein to approve the transfer of ownership pending successful inspection; Seconded by T. Fensky, then Board Members present voted unanimously by rollcall to approve motion.

3. Jubilant Draximage NU0022 Transfer Ownership of a Nuclear Pharmacy TIME 8:55am Represented by: Jeffrey Cone, RPh

Recusal: None

Discussion: J. CONE indicated that he sought approval of a transfer of ownership from BORP. He explained that an internal rearrangement/rebranding of corporate ownership occurred and the parent company for the pharmacy changed. CONE indicated that the ownership changes did not impact JUNILANT DRAXIMAGE's day to day practice.

ACTION: A motion was made by A. Stein to approve the transfer of ownership; Seconded by C. Belisle, then Board Members present voted unanimously by rollcall to approve motion.

4. Application: Spectra Medical Devices; WD515-Transfer of Ownership

Deferred:

5. CMV Wholesaler LLC Wholesale Distributer

Discussion: Carlos Velazquez presented for CMV Wholesaler LLC. The Board listened and discussed this application. This business already has a license with DCP as a wholesaler. It appears applicant may not need the Pharmacy Wholesale license in addition to the DCP license.

Action: A motion was made by T. Fensky and seconded by C. Belisle to take no action at this time. Board Members present voted unanimously by roll call vote to approve the motion.

ΤΟΡΙϹ VII	File Review	
Case #1/CAS-2021-0451		
SA-INV-17932	Marco Mares, PH26626	Time: 09:20 AM

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

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

- BORP was notified through NABP's clearinghouse that Pharmacist Mares entered into a disciplinary consent agreement for a \$1K fine with MI BOP effective February 10, 2021, for violations of recognized standards of pharmacy practice. According to the agreement, Pharmacist Mares failed to properly fill a prescription for doxycycline while practicing at a pharmacy located in MI and licensed by MI BOP.
- Specifically, Pharmacist Mares erroneously filled a prescription issued for doxycycline with the wrong drug, gabapentin 300mg, on January 3, 2020. The patient reported that they ingested approximately three doses of the wrong drug, gabapentin and became disorientated. They were then brought to an urgent care clinic by family members for treatment.
- Pharmacist Mares indicated that after discovering the error he immediately contacted the patient to notify them of the error, apologize, and provide the correct drug. He then proceeded to report the error to his supervisor and Rite Aid in accordance with corporate policy.
- Pharmacist Mares determined that the error occurred because his technician overrode scanning features in Rite Aid's workflow. He indicated that he was "committed to coaching my technicians at the importance of not overwriting the scan of stock bottles, unless it is completely necessary and, in those cases, they are putting the stock bottle in the basket along with the prescription vial." He also decluttered his work area and limits interruptions when verifying prescriptions. He also completed 4 hours of CE in patient safety on his own initiative in September 2020 after the error occurred to reeducate himself on best practices to reduce errors.

<u>ACTION</u>: Motion by C. BELISLE, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to CLOSE the matter (SA-INV-17932), No Discipline Warranted, Remediation Complete.

Case #2/CAS-2021-0420 PHA-2021-0031 Rite Aid #10166, DS3135

Time: 09:06 AM

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RECUSAL: NONE

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

- On April 12, 2021, Rite Aid 10166 belatedly submitted a DEA Form 106 which provided BORP with an initial notification of losses of CII & IV including a total of 123 tablets of four different benzodiazepines and 30 tablets of lisdexamfetamine 60mg discovered on February 27, 2021. Specifically, the belated initial notification of losses was not submitted within 7 days (approximately 37 days past due). Rite Aid 10166 then failed to submit any further information including a final report of loss and documentation for the losses until requested to do so as part of this complaint.
- Ultimately, Rite Aid submitted the required documents as requested. The documents clarified that the reason for the losses was unknown and confirmed the accuracy of drugs/quantities reported in the initial notification. Rite Aid 10166 noted that a change in regional pharmacy leader and a change in the process for reconciliation of CIII-V resulted in the delayed and discombobulated response to the losses.
- MOR reviewed procedures for the accurate handling, dispensing and accountability of controlled drugs with the associates and importance of following procedures for CS handling/storage. CII's will only be double counted by RPh. RPh are now required to initial prescription label & back count. Weekly control counts will be conducted to audit accuracy. MOR also reviewed proper reporting protocols to ensure timely reporting going forward including notifying her supervisor and loss prevention within 24 hours of initial identification of a discrepancy. In addition, MOR indicated that Schedule III-V controlled substances required "a triple count to be done by the verifying pharmacist after the techs double count."
- Lastly Rite Aid Region Pharmacy Leader Chibueze wrote, "I have worked with the PIC to identify and address operational lapses, enforce corrective action and institute new measures to prevent further discrepancies."

<u>ACTION</u>: Motion by T. FENSKY, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2021-0031), 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 a period of 1 year with special terms to include conducting an exact count CS inventory for all scheduled 3-5 medications within 30 days, and a monthly exact count of all benzodiazepine products for 12 months, staff retraining in the areas of inventory management, prescription production, and waiting bin management within 30 days and increased store visits from the Pharmacy Supervisor or Loss Prevention at least once every 30 days to validate said terms.

Case #3/CAS-2021-0516 PHA-2021-0036

Stop and Shop #787, DS2308

Time: 09:12 AM

<u>RECUSAL</u>: K. THORNELL exited the meeting and was not present for the discussion or vote in this matter.

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

• OPP received notification that Stop & Shop #787 had a loss of #99 oxycodone/apap 10/325mg tablets discovered on April 8, 2021. The reason for the loss was unknown.

- Stop & Shop #787 reported that Pharmacist Krupczak discovered the loss when performing a back count while dispensing a prescription on 04/08/21. It was alleged that Pharmacist Krupczak believes he may have discarded the open bottle of 99 tablets in error. He was the one that filled the script on 4/5/21.
- MOR Nathman noted that video footage was reviewed back to the date of the previous product dispensing but the cause for the loss was not able to be definitively determined during that review.
- MOR Nathman indicated to prevent similar events from occurring that they updated dispensing procedures and now when a narcotic is dispensed the pharmacist is to immediately return any product to the safe after dispensing. A successful back count is done to make sure we have the correct inventory and only the pharmacist handles/dispenses any CII products.
- A retail compliance inspection (ISP-15842) was conducted on April 29, 2021, which was deemed satisfactory.

<u>ACTION</u>: Motion by C. BELISLE, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to refer the matter (PHA-2021-0036), 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 #4/CAS-2021-0537		
PHA-2021-0040	Walgreens #6295, DS3045	Time: 09:16 AM

RECUSAL: NONE

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

- OPP received notification that the Pharmacy had an unknown loss of #100 oxycodone 5mg tablets as a result of the drug allegedly being thrown into the trash.
- MOR Huseland indicated that the loss was discovered on May 8, 2021, while performing the perpetual inventory reconciliation. The records submitted documented the reconciliation being performed on May 9, 2021.
- MOR Huseland noted that the video footage was reviewed. The security cameras provided a view of the rear of the pharmacy showing that two pharmacists receiving a CII order on May 6, 2021 and disposing of the package inserts and it is suspected that a 100-count bottle was mistakenly thrown out during this time. Walgreens was unable to provide video footage to support this statement.
- MOR Huseland noted that package inserts will no longer be discarded upon receipt of orders to avoid this occurring again. Additionally, it was indicated that the bottles should be brought directly from the tote to the safe after scanning them in.

<u>ACTION</u>: Motion by C. BELISLE, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2021-0040), 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 REPRIMAND.

Case #5/CAS-2021-0510 SA-INV-18028 CVS #209, DS3597

Time: 09:23 AM

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

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

- OPP received a veterinarian complaint indicating that on or about May 20, 2021, the veterinarian returned a phone call from the Pharmacy regarding a feline's new prescription for prednisolone. This veterinarian was covering for his colleague and spoke with a pharmacist regarding the missing DEA number on the prescription. The pharmacist responded that the prescription would not be filled without a DEA number.
- MOR Santoro indicated that PT Letourneau data-entered the prescription but could not find the prescriber in the database. PTT Letourneau asked MOR Santoro for help who also could not find it. MOR Santoro asked PT Letourneau to call the veterinary hospital to obtain licensing information on the prescriber.
- During the call back, the MOR noted that the gentleman she spoke with refused to provide any information and refused to allow MOR Santoro to speak to the prescribing veterinarian. The gentleman was reportedly upset with the inquiry for a DEA number, used profanity, called MOR Santoro an inappropriate name and was threatening to file a complaint on the pharmacy.
- The MOR indicated that at that point it became an unsafe call and she hung up as she was not comfortable at that point filling the prescription. MOR Santoro indicated that she politely explained to the ultimate patient that we would not be able to fill the prescription.
- MOR Santoro stated, "Since this incident, my District Leader has advised me of the proper steps to take when presented with a prescription authorized by a veterinarian".

<u>ACTION</u>: Motion by C. JEAN-FRANCOIS, seconded by A. STEIN, and voted unanimously by those present, to CLOSE the matter (SA-INV-18028), No Discipline Warranted, Remediation Complete.

Case #6/CAS-2021-0591		
PHA-2021-0049	CVS #321, DS2989	Time: 09:25 AM

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

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

- Untimely RLCS for unknown loss of #674 alprazolam 2mg tablets identified on 02/16/2021 via controlled substance monitoring. Cycle counts, biennial inventories, staffing schedules and inventory reports were reviewed. Security footage was inconclusive. Once the variance was discovered, pharmacists performed cycle counts and interviews of staff were conducted.
- MOR Guzzino stated the loss is suspected to have occurred between a change of MOR inventory in 11/2020 and the annual CIII-CV inventory in May 2021. MOR Guzzino contended, "At this time, we suspect internal theft and have interviewed all colleagues that we feel could have been involved, a mixture of both part time and full-time technicians. We do have several technicians that have since left CVS Pharmacy #321 or who have gone on a leave of absence, and since the investigation we have not seen any variances in this NDC". A reconciliation for all NDCs of alprazolam 2 mg tablets stocked from 04/30/2020 to 05/21/2021 showed a discrepancy of -973 tablets in totality. On 8/12/21, an amended DEA 106 was submitted reporting the total loss of 973 tablets for all NDCs.

• According to the final reports submitted on 06/11/2021, "All loss prevention policy and procedures will be reviewed with the Pharmacy Team to prevent future losses. This includes diligent inventory management and dispensing standards". A copy was provided of CVS policy CCIG-0025 "Adherence to Compliance & Integrity Program and Code of Conduct" signed and dated by all Pharmacy staff attesting review.

<u>ACTION</u>: Motion by T. FENSKY, seconded by C. BELISLE, and voted unanimously by those present, to refer the matter (PHA-2021-0049), to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for STAYED PROBATION for a period of one year, with special terms to include conducting an exact count CS inventory for all scheduled 3-5 medications within 30 days, and a monthly exact count of all benzodiazepine products for 12 months, staff retraining in the areas of inventory management, prescription production, and waiting bin management within 30 days and increased store visits from the Pharmacy Supervisor or Loss Prevention at least once every 30 days to validate and sign off on the BOH report cover page.

Case #7/CAS-2021-0536					
PHA-2021-0038	CVS #859, DS3618	Time: 09:30 AM			

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

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

- Untimely RLCS for an unknown loss of #60 oxycodone 30mg reported as discovered on 3/19/21 during the weekly state counts. Former MOR Forbes stated that an over-dispensing was suspected noting that 4 prescriptions were in question. He claimed the four patients were contacted and all denied an over-dispensing. Video was not reviewed since the 30-day retention window had passed.
- Responses contradictory to the final reports were provided. Although neither were working during the time of the loss, both Former MOR Forbes and Current MOR Williams provided verbatim statements attesting the loss occurred during the filling of a prescription on 3/19/2021 by Pharmacist Gobeille and was due to not back counting the medication. No prescriptions were filled on that date per the perpetual inventory. Pharmacist Gobeille stated, "If I, as the dispensing pharmacist, would have manually back counted the remaining tablets in the bottle and confirmed it with the perpetual count, I feel the dispensing error could have been prevented".
- Interim MOR Graffam discovered the discrepancy while filling a prescription on 3/16/21. Interim MOR Graffam printed a dispensing report "...and could only see one possible source of error" despite 4 prescriptions being filled since the last reconciliation on 3/6/21. She contacted only the one patient who denied an over-dispensing. Both Pharmacist Ahmed and Pharmacist Budz stated they double-counted and back-counted the prescriptions filled on 3/8/21 and 3/14/21, respectively which they said they documented. The perpetual inventory did not reflect the medication was back counted.
- Former MOR Forbes reviewed how to count Schedule II drugs going forward with Pharmacist Gobeille to include double-counting and back-counting with documentation in the computer. Former MOR Forbes, Current MOR Williams, and Pharmacist Gobeille provided statements confirming CVS Pharmacy Employee Loss Prevention/Drug Diversion policy had been reviewed.

<u>ACTION</u>: Motion by J. CHIN, seconded by C. BELISLE, and voted unanimously by those present, to refer the matter (PHA-2021-0038), 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 #8/CAS-2021-0619		
PHA-2021-0051	CVS #765, DS2910	Time: 09:34 AM

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

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

- During a retail compliance inspection (ISP-16277) conducted on 6/17/2021, unstaffed, unsecured "vaccination booths" set up in the front store with unlabeled, pre-drawn syringes, sharps containers, epinephrine auto-injectors, syringes, and what appeared to be unsecured HIPAA information was observed.
- MOR Merk acknowledged at there were no locks on the doors of these booths on 6/17/2021 which were continuously staffed, aside from bathroom breaks, etc. At the start of the shift, the immunizer retrieves the rolling cart containing supplies for administering vaccines from the Pharmacy, rolls it to the vaccination booth, then returns it when done for the day to the Pharmacy where is it stored.
- Pharmacist Rubin responded, "The only time I would have left the immunization booth would have been to use the rest room". He confirmed the door to the booth did not have a lock and the prescription items were not secured. Pharmacist Rubin stated, "The pre-drawn syringes were not labeled since per the CDC you can keep the vaccine with the appropriate vaccine vials. I always kept the vaccine vials next to the syringes. All patient information that I used was on a handheld device, which was accessed with a password. Without scanning the password, no one would have access to it".
- Only staff pharmacists are currently immunizing. For a scheduled vaccine appointment, the vaccines and syringes are brought into the booth for administration. The carts are brought into the booths at the first vaccination appointment and returned to the Pharmacy after the last appointment of the day. Locks were installed and the doors are locked and secured when the vaccination booth is not in use.
 MOR Merk, Pharmacist Sandy and Pharmacist Wellspeak reviewed all policies and procedures specific to the set-up and use of the COVID-19 vaccination booths, the COVID-19 immunizer programs, and the storage and handling of COVID-19 vaccines. Pharmacist Rubin completed 1 CE in the topic of COVID-19 and 1 CE in the topic of HIPAA privacy.

<u>ACTION</u>: Motion by C. BELISLE, seconded by K. THORNELL, and voted unanimously by those present, to DISMISS the matter (PHA-2021-0051), No Discipline Warranted, Remediation Complete, and include in the closing letter a recommendation to label pre-drawn syringes going forward.

Case #9/CAS-2021-0620 PHA-2021-0052

CVS #153, DS2655

Time: 09:45AM

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

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

- Inspectional deficiencies on 6/22/2021 when 2 vaccination rooms with unsecured doors set up in the front store were observed with epinephrine auto-injectors inside each. The last documented use of the rooms was on 6/5/21 and the epinephrine auto-injectors and Sharps[®] containers were removed during the inspection.
- MOR Mooney stated the vaccination rooms were constructed for large-scale COVID-19 immunizations on 04/11/2021 and were considered an extension of the Pharmacy. The set-up of the rooms included stocking them with emergency supplies needed for potential anaphylactic reactions which included epinephrine auto-injectors. CVS guidance for end of day activities did not include the removal of them. MOR Mooney stated the key for the vaccination rooms was a "Front-Store key" and not a Pharmacy key which was held by the front store.
- Vaccine clinics using the vaccination rooms were held daily 4/21/21-6/5/21. The rooms were used intermittently 6/6/21-7/2/21 and use of the rooms discontinued on 7/3/21. There is no visibility from one room into the other for supervision of a pharmacy technician by a pharmacist. On 3 days, a pharmacy technician immunizer worked alone.
- Responses were provided by Pharmacist Harmon, CPhT Malek, PT Chavis and PT Alsamarraie. Pharmacist Harmon stated she followed the CVS end of day guidance which did not include removing epinephrine auto-injectors and locking the doors. The 3 technicians also stated they followed the CVS end of day guidance which did not include removing epinephrine auto-injectors.
- All current immunizers for the Pharmacy were counseled to carry supplies to and from the Pharmacy when immunizing including epinephrine and Sharps[®] containers. The vaccination rooms were locked and closed on 7/3/2021 and a notice was posted that vaccines are to be administered in the usual designated Pharmacy vaccination location. If a future need for large vaccine clinics is determined by CVS, proper on-going compliance protocol is in place to ensure the security at all times of prescription medications such as epinephrine. MOR Mooney related, "In addition, a message went out to all pharmacy teams from Corporate to as a reminder to not store any supplies within the vaccine room when not in use and to remove any items brought into the room upon exiting each time".

<u>ACTION</u>: Motion by C. BELISLE, seconded by T. FENSKY, and voted unanimously by those present, to DISMISS the matter (PHA-2021-0052), No Discipline Warranted, Remediation Complete.

Case #10/CAS-2021-0593		
PHA-2021-0050	CVS #1866, DS2956	Time: 09:54 AM

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

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

• RLCS for an untimely, unknown loss of #60 amphetamine salts 20 mg tablets reported as discovered on 5/8/21 for a prescription that could not be found in the bin on 5/6/21. MOR Owens reviewed controlled substance recordkeeping, the bins were searched, and security footage was viewed but was inconclusive.

- MOR Owens recounted and dispensed the prescription for the patient thinking it would be found in the wrong bin. MOR Owens informed the overnight pharmacist the count would be short 60 tablets and asked him to tell the morning pharmacist if found. MOR Owens clarified the security cameras only cover a section of the waiting bins and the footage is not clear. According to MOR Owens, CVS required that filled CIIs be placed in the waiting bins along with the regular prescriptions. She speculated the filled prescription bag, which was in a pile of completed prescriptions waiting to be filed, fell into the trash and was not noticed when emptied.
- Pharmacist Igo filled the prescription on 5/5/21 indicating there were many unfiled bags after the overnight shift as she began filling prescriptions. That created a pile of bags right next to where the trash was previously located. She believed this caused the bag to fall into the trash when there was no longer room up top.
- MOR Owens indicated that the trash bin was moved, and the Pharmacy staff do not allow a build-up of filled prescriptions on the counter. Filled CII prescriptions are placed in separate bins located behind the pharmacist in clear view of the security camera. Staff pharmacists provided a signed and dated statement confirming review of the CVS Pharmacy Employee Loss Prevention/Drug Diversion policy.

<u>ACTION</u>: Motion by C. BELISLE, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2021-0050), 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.

Andrew Stein leaves meeting at 9:59 AM Katie Thornell leaves meeting at 9:59 AM			
Topic IX: By: S. Ham	Executive Session Call to Order: nilton	Time: 9:59AM	
ACTION: Motion to enter execution	a by, C. Jean-Francois, seconded by T. Fensky, all voted affinite session.	rmatively by those present	
	ce: S. Hamilton, yes; C. Belisle, yes; C. Jean-Francois, yes; J. nacchio, yes; R. Lopez, yes; T. Fensky, yes; D. Perry, yes.	Rocchio, yes;	
Topic X:	65C Sessions MGL c. 112 section 65C	Time: 10:48 AM	
DISCUSSION: None	e t elect S. Hamilton request a motion to enter 65C.		

At 10:48 AM T. Fensky, seconded by J. Chin and voted unanimously by all those present to enter 65C by roll call vote.

Topic XI

ADJOURMENT OF MEETING

TIME: 12:11 PM

ACTION: Motion by S. Hamilton seconded by K. Thornell 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 9/17/21 General Session
- 2. Draft Minutes of the 8/20/21 Meeting
- 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 Above Action Levels approved by Staff Action 16-04
- 7. Report on PSUD 17-03
- 8. PTT License Extension: PTT04848 Andrea McLaughlin
- 9. PTT License Extension: PTT07815 Yasmin Arroyo
- 10. PTT License Extension: PTT09339 Damian Ortiz
- 11. PTT License Extension: PTT07043 Mikayla Hebert
- 12. Application: East Bay Pharmacy New Community Pharmacy
- 13. Application: County Square Pharmacy; DS15805-Transfer of Ownership
- 14. Application: Jubilant DraxImage; NU0022 Transfer of Ownership of a Nuclear Pharmacy
- 15. Application: Spectra Medical Devices; WD515-Transfer of Ownership
- 16. Application: CMV Wholesalers, LLC Wholesale Distributor
- 17. CAS-2021-0451 SA-INV-17932 Marco Mares, PH26626
- 18. CAS-2021-0420 PHA-2021-0031 Rite Aid #10166, DS3135
- 19. CAS-2021-0516 PHA-2021-0036 Stop & Shop #787, DS2308
- 20. CAS-2021-0537 PHA-2021-0040 Walgreens #6295, DS3045
- 21. CAS-2021-0510 SA-INV-18028 CVS #209, DS3597
- 22. CAS-2021-0591 PHA-2021-0049 CVS #321, DS2989
- 23. CAS-2021-0536 PHA-2021-0038 CVS #859, DS3618
- 24. CAS-2021-0619 PHA-2021-0051 CVS #765, DS2910
- 25. CAS-2021-0620 PHA-2021-0052 CVS #153, DS2655
- 26. CAS-2021-0593 PHA-2021-0050 CVS #1866, DS2956

Respectfully Submitted, Carly Jean-Francois, NP, Secretary