

COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy

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

February 3, 2022

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=edf95992eb3f831a036f901131fb2ba33>

To access the meeting by phone:

Call in Number: 1-650-479-3208

Access Code: 2530 379 1442

Attendee: #

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator [Yulanda Kiner](#), Phone: 617-624-5848 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	I	CALL TO ORDER		S. Hamilton
8:02	II	APPROVAL OF AGENDA		
8:05	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">Draft of January 6, 2022 Regular Session Minutes		

8:07	IV	REPORTS <ul style="list-style-type: none"> • Applications approved pursuant to Licensure Policy 13-01 • Monthly report from probation • Board Delegated Review pursuant to Licensure Policy 14-02 • PSUD Report-Policy 17-03 • Research Drug Study Report 		
8:10	V	FLEX <ul style="list-style-type: none"> • Pharmacy issues related to Covid-19 and the state of emergency • Delegate to NABP Annual Meeting, May 19-21, 2022 in Phoenix, AZ 		
8:15	VI	APPLICATIONS <ul style="list-style-type: none"> • Wellforce Pharmacy; DS90377 – Waiver • Greater Boston Long Term Care;DS3306 – Relocation • Healthcare Pharmacy; DS1585 – Transfer of Ownership • Signature Healthcare Pharmacy – New Community Pharmacy • Walmart Pharmacies - Waiver 		
8:45	VII	POLICIES <ul style="list-style-type: none"> • Staff action policy 13-01: Licensure Applications and Notices • Staff action policy 14-01: Individual Licensure Applications Requiring Good Moral Character Evaluation • Rescission of Policy 2017-02: Pharmacy Technician Licensure by Reciprocity • Policy 2022-01: Loss or Theft of Controlled Substances 		
9:00	VIII	ADVISORIES <ul style="list-style-type: none"> • USP <800> in Community Pharmacies 		
9:15	IX	SANCTION HEARING <ul style="list-style-type: none"> • Coco Eng, PT 25569; PHA-2020-0073 		

10:00	X	FILE REVIEW					
		1	CAS-2021-0934	SA-INV-18565			Century Pharmacy, DS89877
		2	CAS-2021-0193	PHA-2021-0076			Galaxy Pharmacy, DS90257
		3	CAS-2021-0828	SA-INV-18404			Galaxy Pharmacy, DS90257
		4	CAS-2021-1232	SA-INV-18990			Dana Proum, PH235705
		5	CAS-2021-0685	SA-INV-18350			Option Care, DS90107
		6	CAS-2021-0594	PHA-2021-0045			Walgreens #11885, DS89774
		7	CAS-2021-0862	SA-INV-18496			Amy Joseph, PH24935
		8	CAS-2021-0654	PHA-2021-0056			CVS #1251, DS3422
		9	CAS-2021-0755	PHA-2021-0072			CVS #861, DS3550
10	CAS-2021-0895	PHA-2021-0084	CVS #860, DS1406				
11:00	XI	EXECUTIVE SESSION 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.				CLOSED SESSION	
11:30	XII	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)					
12:00	XIII	M.G.L. c. 112, § 65C SESSION				CLOSED SESSION	
1:00	XIV	ADJOURNMENT					

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

MINUTES OF THE GENERAL SESSION

Via Remote WebEx Meeting

February 3, 2022

Board Members Present

Sebastian Hamilton, Pharm D, MBA, RPh President
Caryn Belisle, RPh, MBA, President-Elect
Carly Jean-Francois, RN, NP Secretary
Julie Lanza, CPhT
Susan Cornacchio, JD, RN (leaves at 10:01 AM)
Jennifer Chin, RPh
John Rocchio, RPh, PharmD (leaves at 9:38 AM)
Dr. Richard Lopez, MD
Sami Ahmed, Pharm.D., RPh, BCPS, BCSCP
Katie Thornell, RPh, MBA
Delilah Barnes, RPh
Rita Morelli, PharmD, BCACP, RPh
Dawn Perry, JD (arrives at 8:15 AM)

Board Members Not Present

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, CPhT, Assistant Executive Director
Heather Engman, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh, Quality Assurance Pharmacist
Richard Harris, Program Analyst
Joanna Chow, Office Support Specialist
Taylor Lee, Office Support Specialist
Joanne Trifone, RPh, Director of Investigations
Nancy Aleid, Compliance Officer
Christina Mogni, RPh, Investigator
Gregory Melton, RPh, Investigator
Julienne Tran, PharmD, Investigator
Nathan Van Allen, PharmD, Investigator

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:02 AM

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

Roll call attendance: S. Hamilton, yes; C. Belisle, yes; C. Jean-Francois, yes; D. Barnes; J. Rocchio, yes; R. Lopez, yes; J. Chin, yes; K. Thornell, yes J. Lanza, yes; R. Morelli, yes; S. Cornacchio, yes; S. Ahmed, yes. D. Perry joins meeting at 8:15 AM.

Topic II. **Approval of Agenda** **TIME 8:03 AM**

Agenda 02/03/22

DISCUSSION:

Defer: Sanction Hearing and Adjudicatory Session

ACTION:

Motion by K. Thornell, seconded by J. Lanza and voted unanimously by those present to approve the agenda with noted change by roll call vote.

Topic III **Approval of Board Minutes** **TIME: 8:03 AM**

Minutes

1. Draft 1/6/22

Change: no changes

Action:

Motion by S. Ahmed seconded R. Morelli and voted unanimously to approve the regular session minutes of 1/6/22 with noted change by roll call vote. J. Chin abstain.

TOPIC IV **REPORTS** **Time: 8:05 AM**
Applications approved pursuant to Licensure Policy 13-01

Presented by: R. HARRIS

Discussion: R. HARRIS noted that the report in the Board Packet reflects all applications approved by staff action since the last Board meeting.

So noted

TOPIC IV **REPORTS** **Time: 8:05 AM**
Monthly Report from Probation

Presented by: R. HARRIS

Discussion: R. HARRIS noted that a probation report was not available at the time of the meeting.

So noted

TOPIC IV	REPORTS	
Monthly BDCR pursuant to Policy 14-02		Time: 8:06 AM
Presented by: D. SENCABAUGH		

Discussion: D. SENCABAUGH indicated that there was no Board delegated review to report for January.

So noted

TOPIC IV	REPORTS	
PSUD report by Staff Action 17-03		Time: 8:06 AM
Presented by: E. TAGLIERI		

Discussion: E. TAGLIERI reported that there are 13 participants at present in the PSUD program. A successful quarterly meeting was conducted in January with active participants. Within the last two months, it was noted that two participants chose to withdraw without successful completion of the program.

So noted

TOPIC IV	REPORTS	
Research Drug Study Report		Time: 8:06 AM
Presented by: B. FRISCH, M. CHAN		

Discussion: M. CHAN indicated that the Research Drug Study is conducted quarterly and that there was nothing to report at the time of the meeting.

So noted

TOPIC V	Flex	
1. Pharmacy Issues related to Covid-19 and state of emergency.		Time: 8:06 AM
Presented by: D. SENCABAUGH		
Nothing to report.		

2. Delegate to NABP annual meeting, May 19-21 in Phoenix, AZ	Time: 8:06 AM
Presented by: W. FRISCH	

Discussion: At the NABP annual meeting, any resolutions from the states will be voted on by delegates from each state. One delegate is needed along with an alternate in case the delegate cannot be present on a given day. There is one grant available to cover expenses.

The following Board members have stated that they have already planned to attend the meeting: S. HAMILTON, J. ROCCHIO, K. THORNELL, and J. LANZA.

A vote will be taken at next month's Board meeting as to who the delegate and the alternate will be.

TOPIC VI

Applications

1. Wellforce Pharmacy DS90377 Waiver TIME: 8:11 AM
Represented by: Robert Pullano, Pharmacist
Recusal: D. Sencabaugh

Discussion: R. Pillano indicates that Wellforce is requesting two waivers one of them being in regard to consultations within pharmacy space because they are largely a closed-door pharmacy and do not have patients come into the pharmacy, but they speak to them over the phone for consultations. He also states that they are requesting another waiver for signage on the exterior of the facility indicating that there is a pharmacy in the building because they are not visible to the public, they don't have external patients, and only provide services for Tuft's patients. R. Pullano states that the only way to access the pharmacy is through Tufts and provide information for new patients on how to access pharmacy.

Motion to approve the waivers by C. Belisle; Seconded by K. Thornell, then Board Members presented voted unanimously by rollcall to approve motion.

2. Greater Boston Long Term Care Relocation TIME: 8:15 AM
Represented by: Michael Wesinberg, Pharmacist
Recusal: none

Discussion: M. Wesinberg states they are closed door LTC pharmacy servicing assisted living, group home, and rest home patients. M. Wesinberg indicated that Greater Boston Long Term Care leased out of their facility in West Roxbury and purchased a new facility in Walpole with larger square footage and an improved set up so they can better serve their patients. Board member C. Belise asks if the pharmacy needs to go through inspection process when they relocate. Board Staff B. Frisch responds that yes, they do need to complete an inspection. He states that there were some timing issues and the applicant needed to move before the end of the month, they have been already relocated, and are bringing the matter forward for ratification. B. Frisch indicates that an inspection might have already taken place, but it would be a contingency. B. Frisch asks M. Wesinberg if he is already relocated to the new facility and M. Wesinberg responds that they had a preliminary inspection a week and a half ago and have already been relocated.

Motion to approve the relocation by K. Thornell; Seconded by J. Lanza, then Board Members presented voted unanimously by rollcall to approve motion.

3. Healthcare Pharmacy DS1585 Transfer of Ownership

TIME: 8:15 AM

Represented by: Paul Garbarinie , Attorney & Carol McShane, Pharmacist

Recusal: none

Discussion: P. Garbarinie states that this transfer of ownership is a stockswap transaction and they are seeking to retain provider IDs, drug store, controlled substance, & DEA numbers. P. Garbarinie also states that the value of the stockswap as opposed to a purchase agreement is that they would have no disruption in continuity of care of patients and that it is his understanding that they would be able to do that or would be able to proceed administratively. P. Garbarinie indicates that if the board insists that the drug store and controlled substance numbers must be changed as a result of this transfer, he would ask that the board withhold a vote on this matter. Board counsel H. Engman states that a new license number is issued in every instance where this a transfer of ownership. H. Engman indicates that if there is a change in the type of ownership for the pharmacy it is possible that a transfer of ownership is not necessarily required and that if the client were to proceed with the transfer and if the board approves it, there would be a new license number issued. P. Garbarinie asked the board to withhold the vote so that they can proceed administratively because the same corporate structure will be maintained, and the transfer will be a smooth transition. He states that if the board would require them to issue new permit numbers, he would ask the board to withhold their vote to proceed administratively. H. Engman responds that there is no separate path to proceed administratively because it is either a transfer of ownership under the regulations or it is not. In the past this issue has come up with the stockswap situations where it doesn't fall into a formal transfer under the regulations and the board would have to make that determination. P. Garbaraine indicates that he would like to withdraw the matter at the time. Board staff D. Sencabaugh states that it is possible depending on the transaction that if approved they can issue a new license number that is inactive to address continuity of care issues. P. Garabarine responds by saying that due to third party contracting and Medicaid contracting he would ask the board to withdraw the matter from the board's consideration at the time.

No vote required- deferred matter.

4. Signature Healthcare Pharmacy

New Community Pharmacy

TIME: 8:27 AM

Represented by: Leandra Battisti

Recusal: none

Discussion:

L. Battisiti states that they are requesting to manage and operate a new pharmacy that is being built in the first level of 110 Liberty Street which is their ambulatory care center. L. Battisiti indicates that they are looking to open their first pharmacy at Signature Healthcare and that she would be the manager of record. C. Belisle asked L. Battisiti if that was going to be the first time that she was going to be the

manager of record at a pharmacy and L. Battisti responded that this would be the second time because she was previously a manager of record at CVS. C. Chen inquired if Signature Health is currently operating as a pharmacy and L. Battisti responded that it is brand new and there was recent construction done where their lab was moved into a separate section of the building and are now working to build this pharmacy from the ground up. C. Jean Francois inquired as to whether L. Battisti would be the lead pharmacist or if they hired all the staffing. L Battisti responded that she will be the manager of record, but they haven't hired anyone yet due to the construction timeline and are anticipating opening in June. They plan on hiring staff in the next month for their anticipated opening in June. C. Belisle asked what the purpose of opening a pharmacy in that location is and if there is currently a need that is being unmet. L. Battisti responded that there's no pharmacy on campus this would be the first one. If a patient needed to be treated, they would have to use one of their contract pharmacies outside of the hospital so it would meet the needs of both the patients and the hospital. C. Belisle inquired as to whether they would be applying for any waivers and L. Battisti responded that they would not. J. Lanza inquired as to what the pharmacy would have for a contingency plan on Saturdays and Sundays and on days when the pharmacy is closed. L. Battisti responded that they have an automated system and voicemail system for refills and would be utilizing IVR as the building is also closed during that time as well. R. Morelli inquired as to whether they would be servicing patients outside of the system and if they would be providing immunizations. L. Battisti responds that they do allow for patients outside of the system, but she assumes that most of the patients would come from within the system. Initially they will not be offering immunizations because there is not a need for immunizations because there are clinics upstairs which offer those services. Later down the line if the need arises, they are open to offering those services. B. Frisch indicates that the context of the pharmacy will be within the confines of a licensed ambulatory care clinic and would need the approval of the Bureau of Healthcare Safety and Quality as a contingency to the vote in addition to the satisfactory inspection. B. Frisch also states that they have asked the applicant to redraw their drawing because while they did provide the square footage, the board will need the specifics of the pharmacy space. J. Lanza inquired as to whether they would be doing complex non-sterile compounding because it was not checked off on their application. L. Battisti responds that they would not be doing any complex non-sterile compounding.

Motion made by R. Morelli to approve the application pending approval from Healthcare Quality, new plans, and successful inspection; Seconded by S. Cornachio then Board Members presented voted unanimously by rollcall to approve motion.

TOPIC VII

Policies

1. Staff action policy 13-01: Licensure Applications and Notices

Time: 8:38 AM

Presented by: M. CHAN

Discussion: Several wording changes, structural document changes, and clarifications were made. The changes include allowances for Board staff to extend PTT licenses if individuals have not yet reached 500 hours of employment, the ability to approve pharmacy relocations, and applications for transfers of ownership of wholesalers and non-chain pharmacies.

Action: Motion by S. HAMILTON, seconded by J. ROCCHIO, and voted unanimously by roll call of those present, to approve the policy changes.

2. Staff action policy 14-01: Individual Licensure Applications Requiring Good Moral Character Evaluation **Time: 8:40 AM**

Presented by: M. CHAN

Discussion: Structural changes were also made to this policy to be in line with policy 13-01. Some additional circumstances under which staff may proceed with licensure were also added. Those are: (1) criminal convictions for minor traffic violations for which a fine of \$100 or less was imposed; (2) fines or sanctions for continuing education deficiencies that are no longer pending; and (3) fines or sanctions for failure to provide change of manger notifications.

Action: Motion by J. LANZA, seconded by K. THORNELL, and voted unanimously by roll call of those present, to approve the policy changes.

3. Rescission of Policy 2017-02: Pharmacy Technician Licensure by Reciprocity

Time: 8:41 AM

Presented by: M. CHAN

Discussion: Board staff would like to simplify the process for technicians to transfer their pharmacy license from another state. The application already requires disclosure of licenses in other jurisdictions as well as the status of those licenses, and rescinding the policy removes other barriers.

Action: Motion by S. AHMED, seconded by C. BELISLE, and voted unanimously by roll call of those present, to rescind the policy.

4. Policy 2022-01: Loss or Theft of Controlled Substances

Time: 8:42 AM

Presented by: M. CHAN

Discussion: This policy was overhauled to make it simpler for licensees to use and to make it clear that it applies to both wholesalers and pharmacies that are licensed by the Board. Other changes are to report confirmed and possible losses within a 7-calendar day period and final investigatory reports within 21 calendar days of the first submission. The reporting form will also be updated to reflect these changes.

Action: Motion by S. HAMILTON, seconded by K. THORNELL, and voted unanimously by roll call of those present, to approve the policy.

TOPIC VIII**Advisories****1. USP <800> in Community Pharmacies****Time: 8:45 AM****Presented by:** M. CHAN

Discussion: A clarification was made that the containment strategies of USP <800> must be followed when storing antineoplastic HDs requiring any future manipulation. This is regardless of whether the pharmacy is doing the manipulation or is dispensed to another provider who will be doing the manipulation. This position was confirmed by the USP Expert Committee.

Action: Motion by D. BARNES, seconded by S. AHMED, and voted unanimously by roll call of those present, to approve the advisory changes.

TOPIC IX**Sanction Hearing****Deferred**

TOPIC X**File Review**

Case #1 /CAS-2021-0934

SA-INV-18565

Century Pharmacy, DS89877

Time: 08:46 AM**RECUSAL:** NONE

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

- On August 18, 2021, BHPL Investigators conducted a site visit to confirm that Century implemented corrective action undertaken to resolve a complaint (PHA-2021-0022) in which BOP authorized a consent agreement for a reprimand during its meeting on September 17, 2021.
- During the site visit, BHPL Investigators incidentally observed binders which contained pre-printed labels for compounded non-sterile preparations. The binder contained a table of contents which listed 10 different indications with a corresponding formula for a compounded non-sterile preparation. The binder was then divided into 10 sections numbered 1 through 10 corresponding to the table of contents. Each section contained multiple pages of pre-printed labels with formulas for non-sterile compounded preparations according to indication. Each page also contained directions "to place the label below on a prescription form and fax it with patient's demographics to 978-710-6552" which was Century's fax number. Prescribers applied the pre-printed label to their own prescription form along with patient information and faxed the prescription to Century.
- Century indicated that the practice of providing binders with pre-printed labels to prescribers was suspended pending resolution of this matter. Century asserted that the pre-printed labels were not prohibited because the pre-printed labels did not refer to any pharmacist, pharmacy, or pharmacy

department. In addition, the pre-printed labels did not contain any information about specific prescribers or patients. Prescribers were free to modify formulations or issue prescriptions with their own formulations without using the pre-printed labels according to their professional judgment.

- Century emphasized that the pre-printed labels were a mechanism to enhance patient safety by ensuring the accuracy of the prescription. The pharmacy indicated that the use of the pre-printed labels was implemented solely as a patient safety measure and not to circumvent exercising the pharmacy's corresponding responsibility. Furthermore, Century offered to meet with BORP to resolve any remaining issues about this matter.

ACTION: Motion by D. BARNES, seconded by J. CHIN, and voted unanimously by those present, to defer the matter (SA-INV-18565), to a later time in which the exhibits may be reviewed.

Case #2/CAS-2021-0193

PHA-2021-0076

Galaxy Pharmacy, DS90257

Time: 8:56 AM

RECUSAL: NONE

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

- Summary of deficiencies cited on 1/12/21:
 - *Expired Schedule II controlled substances were not reconciled every 10 days. Expired methadone 5 mg tablets #76 and methadone 10 mg tablets #92 were removed from the perpetual inventory on 01/03/2020 but were not reverse distributed until 12/17/2020.
 - *Two balances were last sealed in September 2019.
 - *Freezer temperature logs recorded out of range temperatures from 8°F to 11°F from July 31, 2020- December 31, 2020. Varivax has a storage range of 5°F to -58°F. Two doses of Varivax® were administered. One dose was administered on 8/1/2020, and Merck's data supported the vaccine's potency and effectiveness. The second dose was administered on 12/28/2020 and Merck's data did not support the vaccine's potency and effectiveness.
- A plan-of-correction (POC) was received on January 28, 2021:
 - *All expired medications will be included in the perpetual inventory until reverse distributed. The log was updated to include columns for when medications are received, dispensed, and reverse distributed.
 - *Both scales were sealed on January 13, 2021.
 - *The remaining Varivax vaccine was quarantined and returned to an authorized vendor on March 3, 2021. The patient who received the vaccine on 12/28/2020 was contacted, received a full refund, and offered revaccination at no cost. The patient reported no adverse effects. MOR Truong also reviewed the importance of recording and maintaining proper refrigeration and freezer temperatures with all staff.
- On 07/02/2021, a site visit was conducted, and a plan-of-correction was issued for repeat deficiencies:
 - *Schedule II controlled substances not being maintained in perpetual inventory until reverse distributed.
 - *A temperature excursion on May 25, 2021 - May 26, 2021, with a low reading of -1.73C in the main medication refrigerator. The excursion lasted approximately 15 hours and there was no record of any action taken by staff to ensure medications were not adversely affected by the excursion and were safe for dispensing.

- A plan-of-correction (POC) was received on 07/26/2021:
 - *All expired C-II medications will be included in the perpetual inventory until reverse distributed and the perpetual inventory will be reconciled every week.
 - *Pharmacist on duty is required to check refrigerator and freezer temperatures for the last 14 hours every morning, document actions taken for any temperature excursions, and report excursions to the MOR. MOR will follow up with staff twice weekly to monitor compliance with corrective action.
- Galaxy was notified of this complaint and MOR Truong responded on behalf of the pharmacy on September 27, 2021. MOR Truong submitted a copy of Galaxy's updated policy for handling refrigerator and freezer temperature monitoring and excursions. He also attached the pharmacy's temperature logs from 07/05/2021 to 09/27/2021. Significantly, temperature monitoring was recorded, and no significant temperature excursions occurred during that period according to the temperature logs.
- A Retail Compliance inspection (ISP-17345) was conducted at Galaxy on 11/09/2021 and deemed satisfactory.

ACTION: Motion by C. BELISLE, seconded by J. LANZA, and voted unanimously by those present, to combine with SA-INV- 18404 and refer the matter (PHA-2021-0076), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for PROBATION for 1 year.

Case #3 /CAS-2021-0828

SA-INV-18404

Galaxy Pharmacy, DS90257

Time: 09:00 AM

RECUSAL: NONE

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

- During site visits on 8/30/2021 and 8/31/2021 performed with the DEA, improper documentation of controlled substance recordkeeping was observed. Additionally, Pharmacist Le failed to disclose on the "Application for Transfer of Ownership of Community Pharmacy" for the Pharmacy that his pharmacist license had previously been suspended from 12/13/2013-7/27/2017. MOR Truong and Pharmacist Le were listed as the owners of the Pharmacy on the application. Pharmacist Le did not disclose his suspension on the DEA registration renewal application. Eight controlled substances were audited with significant variances noted on diphenoxylate/atropine tablets, Vimpat solution, diazepam 2mg tablets, and phenobarbital solution.
- MOR Truong stated the overage for diphenoxylate/atropine tablets was due to an improper transfer when 1,000 tablets were physically transferred from Galaxy Pharmacy in South Boston on 12/11/2020 but were still included on the 12/12/2020 biennial inventory. Transfer records were dated 12/14/2020. The overages for Vimpat solution and phenobarbital solution were possibly due to mismanagement of RTS of the undeliverable drugs. The shortage of diazepam 2mg was improper recordkeeping of a reverse distribution on 12/10/2020 and a misfiled transfer record.
- Pharmacist Le stated he was not an owner of the Pharmacy during the transfer of ownership and was unaware that he needed to notify the BORP of his suspension during the transfer process. On 1/3/2022, the OPP was informed by the DEA that the Pharmacy had tentatively agreed to sign a MOU.
- MOR Truong met with the staff to discuss the issues. SOPs for the proper storage and handling of controlled substances, controlled substance recordkeeping, and return to stock were created with copies submitted that were signed and dated by the Pharmacy staff confirming review. MOR Truong

acknowledged that he is responsible for ensuring these SOPs are implemented. He will monitor the corrective actions weekly for 3 months then monthly thereafter.

ACTION: Motion by C. BELISLE, seconded by J. LANZA, and voted unanimously by those present, to elevate the matter (SA-INV-18404), to a complaint and then combine with PHA-2021-0076 and refer the matter to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for PROBATION for 1 year.

CASE #4 / CAS-2021-1232

SA-INV-18990

Dana Proum, PH235705

Time: 09:05 AM

RECUSAL: NONE

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

- NABP Clearinghouse Action Report from 10/15/2019 indicating Pharmacist Proum was issued a fine of \$1,500 by the CA BOP for allowing pharmacy technicians to have keys to access records of dangerous drugs and devices and PHI with no pharmacist present and allowing pharmacy technicians to call prescribers to verify prescriptions, identified during an inspection on 7/1/2015. Pharmacist Proum became PIC of the Pharmacy in April 2015 and worked to ensure the compliance. Due to differences in vision and goals with the Owner, she tendered her 2-week notice on 6/20/2015 and resigned 7/6/2015.
- She did not learn of the violations until she received notification on 1/16/2018. Pharmacist Proum maintained she was unaware the pharmacy technicians had keys with unauthorized access to records and drugs and that they were calling prescribers to clarify prescriptions. After meeting with the CA BOP, a final decision was issued on 12/16/2019 and she paid the fine.
- Pharmacist Proum is now more aware of the importance of providing continuing education and training to the staff including reinforcing pharmacy technician responsibilities, HIPAA, and law updates. Pharmacist Proum pays more attention to pharmacy security ensuring only licensed pharmacy and authorized personnel have access to areas where PHI and dangerous drugs are stored. Additionally, she encourages open communication with staff, clarifying questions from pharmacy technicians regarding their roles and responsibilities.

ACTION: Motion by K. THORNELL, seconded by S. AHMED, and voted unanimously by those present, to CLOSE the matter (SA-INV-18990), No Discipline Warranted, Remediation Complete.

Case #5 / CAS-2021-0685

SA-INV-18350

Option Care. DS90107

Time: 09:09 AM

RECUSAL: NONE

DISCUSSION: N. VAN ALLEN presented and summarized the investigative report that pertained to this matter.

- On or about July 28, 2021, OPP received a consumer complaint regarding instances of non-compliance at Option Care in Marlboro including record keeping violations, controlled substance disposal/waste violations, supervisory ratios, unlicensed practice, and USP <797> standards violations.
- Site Visits conducted at the Pharmacy on 7/28/2021 and 10/13/2021 were utilized to assess compliance with the alleged complaints including review of documentation and also discussions with individuals named in complaint.
- The Pharmacy was able to provide documentation to support their procedures for controlled substance waste and disposal, and supervisory ratios and thus no changes were made.
- The Pharmacy admitted that warehouse staffers were picking and labeling saline flushes. This procedure has been stopped and only licensed individuals complete these tasks.
- The Pharmacy did not admit they were wrong regarding USP <797> violations but did make changes to their sterile compounding operation regarding operating a PEC with 2 technicians and certifying the cleanroom to max capacity with additional testing.

ACTION: Motion by D. BARNES, seconded by C. BELISLE, and voted unanimously by those present, to elevate the matter (SA-INV-18350), to a complaint.

Case #6/CAS-2021-0594

PHA-2021-0045

Walgreens #11885, DS89774

Time: 09:12 AM

RECUSAL: NONE

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

- Unknown loss of #100 oxycodone 30mg tablets on or about June 7, 2021.
- MOR Galvin indicated that on June 8, 2021, the bottle of 100 oxycodone 30mg was discovered missing while completing a drug inventory count.
- MOR Galvin stated that Pharmacist Cox was seen on video at the fill station processing a prescription for oxycodone 30mg tablets on June 7, 2021. She had 3 stock bottles in a red plastic bin at the time. After production, Pharmacist Cox placed the empty stock bottles into the red bin containing the 3rd bottle and as she walked to the verification screen, she was seen throwing out the contents of the red bin containing the stock bottles in the trash.
- MOR Galvin noted that the patient who had picked up the prescription on June 7, 2021, was contacted and she confirmed that she received the correct quantity of 120 tablets. On June 8, 2021, the District Manager was notified of the suspected loss.
- MOR Galvin indicated that corrective actions would include logging in and back counting on-hands to verify inventory counts are correct right after filling prescriptions and putting stock bottles away immediately after filling prescriptions or as soon as possible if medication is in the time delay portion of the safe.
- On December 3, 2021, Board voted to defer the matter pending review of video footage by the investigator. On January 11, 2022, AP manager responded that video footage was unable to be reviewed due to IT issues.

ACTION: Motion by S. HAMILTON, seconded by J. LANZA, and voted unanimously by those present, to refer the matter (PHA-2021-0045), 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 #7 /CAS-2021-0862
SA-INV-18496

Amy Joseph, PH24935

Time: 09:14 AM

RECUSAL: NONE

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

- National Association of Boards of Pharmacy (NABP) notified BOP that Pharmacist Joseph was reprimanded on 04/25/2019 by the Rhode Island Board of Pharmacy as a result of a continuing education (CE) deficiency for the 2017-2018 renewal period.
- Pharmacist Joseph was ordered to complete an additional 10 live and 20 non-live CE hours as remediation. It was also discovered that she did not complete CEs as required for Massachusetts. Her CPE monitor shows no CEs reported for 2017 or 2018, 42.5 CEs reported for 2019 and none for 2020 or 2021.
- Pharmacist Joseph has not responded to the investigation after 4 attempts to communicate via email, phone call and certified letter.

ACTION: Motion by D. BARNES, seconded by K. THORNELL, and voted unanimously by those present, to elevate the matter (SA-INV-18496) to a complaint and notify PH Joseph that a response is required.

Case #8 /CAS-2021-0654
PHA-2021-0056

CVS #1251, DS3422

Time: 09:17 AM

RECUSAL: S. CORNACCHIO, J. ROCCHIO and N. PAGE recused and were not present for the discussion or vote in this matter.

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

- Unknown loss of #463 alprazolam 2mg tablets, #360 clonazepam 1mg tablets, and #389 clonazepam 2mg tablets.
- The loss of clonazepam 2mg tablets was discovered on April 19, 2021, via corporate controlled substance monitoring. Through the investigation, it was discovered that there was also a loss of clonazepam 1mg tablets and alprazolam 2mg tablets. The investigation concluded on 06/29/2021. The cause of the losses remains unknown.
- MOR Wang indicated that the losses occurred as a result of a poor count completed at the biennial inventory which set up the balance on hand reconciliation reports to be incorrect going forward. The last biennial inventory was April 30, 2021.
- Security cameras in the pharmacy were reviewed by the Asset Protection team who conducted the investigation remotely and in the pharmacy.
- MOR Wang indicated that the Loss Prevention policy and procedures including diligent inventory management will be reviewed with the Pharmacy Team to prevent future losses.

ACTION: Motion by K. THORNELL, seconded by C. BELISLE, and voted unanimously by those present, to refer the matter (PHA-2021-0056), 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 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 #9 /CAS-2021-0755

PHA-2021-0072

CVS #861, DS3550

Time: 09:21 AM

RECUSAL: S. CORNACCHIO, J. ROCCHIO and N. PAGE recused and were not present for the discussion or vote in this matter.

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

- During August 2021, CVS 861 submitted a final report for an unknown loss of 335 alprazolam 1mg tablets discovered on June 24, 2021. CVS 861 explained that the losses were discovered during an audit by loss prevention. The pharmacy reported that the reason for the loss was unknown.
- CVS 861 indicated that loss prevention policies would be reviewed with pharmacy staff including “diligent inventory management” to mitigate recurrence of a similar loss of a controlled substance.

ACTION: Motion by C. BELISLE, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to refer the matter (PHA-2021-0072), 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 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 #10/CAS-2021-895

PHA-2021-0084

CVS #860, DS1406

Time: 09:23 AM

RECUSAL: S. CORNACCHIO, J. ROCCHIO and N. PAGE recused and were not present for the discussion or vote in this matter.

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

- On September 13, 2021, BHPL Investigator Stephen Horn observed a pharmacy cashier who was not licensed by BORP as pharmacy technician trainee or pharmacy technician performing duties which required licensure as a pharmacy technician trainee or pharmacy technician during a retail compliance inspection. Specifically, Investigator Horn described that he observed the unlicensed cashier “processing return to stocks, putting up the truck order, and pulling drugs to fill prescription” during the inspection. Investigator Horn then notified CVS 860 that the unlicensed cashier cannot perform technician duties until duly licensed and issued a plan of correction, in part, due to the unlicensed practice.

- POC: CVS indicated that “all cashiers assisting in the pharmacy have received feedback regarding not being allowed to perform technician duties” and “only pharmacy employees with current pharmacy trainee or technician licenses will perform technician duties.”
- BORP opened a complaint against CVS 860 due to the nature of the violation. MOR Allen acknowledged that she failed to properly vet the unlicensed cashier. MOR Allen indicated that a miscommunication with CVS 860’s front store manager caused the unlicensed cashier to be included in group training with seasonal employees who were licensed pharmacy technician trainees. Group training for licensed individuals included duties which required licensure. Unfortunately, the unlicensed trainee was trained to perform duties which required a license as part of their workflow, and, in fact, performed those duties when they worked as a cashier.
- MOR Allen indicated that she would be vigilant going forward when vetting pharmacy technician trainees and pharmacy technicians She also attested that she reviewed 247 CMR 8.00: Pharmacy Interns and Technicians and BORP’s “Table of Duties” for pharmacy technicians with all pharmacy staff.

ACTION: Motion by C. JEAN-FRANCOIS, seconded by K. THRONELL, and voted unanimously by those present, to refer the matter (PHA-2021-0084), 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 to include review of Board Policy 2020-15: Licensee Scope of Practice.

Topic XI: Executive Session Call to Order: Time: 9:29 AM
By: S. Hamilton

Executive Session Language Read to Public by S Hamilton

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

Topic XII Adjudicatory

Deferred

Topic XIII: 65C Sessions MGL c. 112 section 65C Time: 9:45 AM

DISCUSSION: None

ACTION: President S. Hamilton request a motion to enter 65C.

At 9:45 AM R. Lopez, seconded by J. Lanza and voted unanimously by all those present to enter 65C by roll call vote.

J. Rocchio leaves meeting 9:38 AM

S. Cornacchio leaves meeting 10:01 AM

Topic XIV

ADJOURNMENT OF MEETING

TIME: 10:08 AM

ACTION: Motion by J. Lanza seconded by R. Morelli 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 2/3/22 General Session
2. Draft Minutes of the 1/6/22 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. Report Research Drug Study Report
9. Application: Wellforce Pharmacy; DS90377 – Waiver
10. Application: Greater Boston Long Term Care; DS3306 – Relocation
11. Application: Healthcare Pharmacy; DS1585 – Transfer of Ownership
12. Application: Signature Healthcare Pharmacy – New Community Pharmacy
13. Application: Walmart Pharmacies – Waiver
14. Staff action policy 13-01: Licensure Applications and Notices
15. Staff action policy 14-01: Individual Licensure Applications Requiring Good Moral Character Evaluation
16. Rescission of Policy 2017-02: Pharmacy Technician Licensure by Reciprocity
17. Policy 2022-01: Loss or Theft of Controlled Substances
18. USP <800> in Community Pharmacies
19. Coco Eng, PT 25569; PHA-2020-0073
20. CAS-2021-0934 SA-INV-18565 Century Pharmacy, DS89877
21. CAS-2021-0193 PHA-2021-0076 Galaxy Pharmacy, DS90257
22. CAS-2021-0828 SA-INV-18404 Galaxy Pharmacy, DS90257
23. CAS-2021-1232 SA-INV-18990 Dana Proum, PH235705
24. CAS-2021-0685 SA-INV-18350 Option Care, DS90107
25. CAS-2021-0594 PHA-2021-0045 Walgreens #11885, DS89774
26. CAS-2021-0862 SA-INV-18496 Amy Joseph, PH24935
27. CAS-2021-0654 PHA-2021-0056 CVS #1251, DS3422
28. CAS-2021-0755 PHA-2021-0072 CVS #861, DS3550
29. CAS-2021-0895 PHA-2021-0084 CVS #860, DS1406

Respectfully Submitted,
Carly Jean-Francois, NP, Secretary

