

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

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

November 7, 2019
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

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
8:30	I	CALL TO ORDER		A. Stein
	II	APPROVAL OF AGENDA	1	
8:40	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none"> • Draft of October 3, 2019 Regular Session Minutes • Introduction of Interns: <ul style="list-style-type: none"> ○ Kayla Carlson- MCPHS Boston ○ Michelle Ban – Northeastern University 	4	
8:45	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 • Above Action Levels approved by Staff Action 16-04 • PSUD Report-Policy 17-03 	22 24 25	
8:50	V	POLICIES and ADVISORIES <ul style="list-style-type: none"> • Policy 2019-07: Pilot Projects in Pharmacy Practice • Policy 2019-08: Sterile Compounding Pharmacy Response to Above Action Level Environmental Monitoring Results • Staff Action Policy 13-01: Licensure Applications and Notices • A request by Procure LTC regarding Policy 2019-01: Shared Pharmacy Services 	26 28 33 39	W. Frisch M. Chan

9:50	VI	APPLICATIONS			
		<ul style="list-style-type: none"> • Rose Marie Thevenin (PI155378) – Pharmacy Intern Extension 47 • Boulevard Pharmaceuticals (DS90300) – Waivers 49 • Lahey Pharmacy - Clinic to Retail Pharmacy 57 • Conely Drug (DS2654) - Renovation 103 • Genoa Healthcare – New Community Pharmacy 111 • Village Pharmacy of Marblehead (DS9701) – Transfer of Ownership 154 • Dedham Pharmacy (DS89988) - Waiver 168 • CVS 1031 (DS89682) – Change of Manager 183 			
10:45	VII	FLEX			
		<ul style="list-style-type: none"> • 2020 Board officers nominations • NEU & GLFHC Opioid Buyback Update • Advisory Committee meeting summary 			
11:00	VIII	FILE REVIEW			
		1	SA-INV-15473	Walgreens #18415, DS90135	188
		2	PHA-2019-0072	Walgreens #3020, DS2492	190
		3	PHA-2019-0077	Walgreens #11797, DS89665	194
		4	PHA-2019-0089	Walgreens #10427, DS3611	197
		5	SA-INV-15472	The Hilsinger Company, WD450	199
		6	PHA-2019-0086	Greater Boston Long Term Care, DS3306	202
		7	PHA-2019-0081	CVS #1248, DS2875	207
		8	PHA-2019-0082	CVS #746, DS2818	209
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		10	PHA-2019-0087	CVS #1007, DS90074	214
		11	PHA-2019-0026	CVS #1056, DS1646	217
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		13	SA-INV-14604	Hopkinton Drug, DS8191	223
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		15	SA-INV-15283	Johnson Compounding & Wellness, DS90089	230
		16	SA-INV-15271	Amex Pharmacy, NO00026	232
12:30	LUNCH BREAK				

1:30	IX	<p>EXECUTIVE SESSION</p> <p>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, consider a request for termination of probation, and to evaluate the Good Moral Character as required for registration for pending applicants.</p>	237	
2:00	X	M.G.L. c. 112, § 65C SESSION	258	
5:00	XI	ADJOURNMENT		

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

**MINUTES OF THE GENERAL SESSION
239 Causeway Street, Fourth Floor ~ Room 417A
Boston, Massachusetts, 02114
November 7, 2019**

Board Members Present

Andrew Stein, Pharm D, RPh. President
Kim Tanzer, PharmD, RPh. President Elect
Julie Lanza, CPhT, Secretary
Sebastian Hamilton, Pharm D, RPh
Susan Cornacchio, JD, RN
Patrick Gannon, RPh
Timothy Fensky, RPh
Michael Godek, RPh
Dr. Richard Lopez, MD
Stephanie Hernandez, Pharm D, BCGP, RPh
Carly Jean-Francois, RN, NP
Leah Giambarresi, Pharm D, RPh

Board Members Not Present

Dawn Perry, JD

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, Assistant Executive Director
Heather Engman, JD Board Counsel
Michelle Chan, RPh Quality Assurance Pharmacist
Joanne Trifone, RPh., Director of Investigations
Julienne Tran, PharmD RPh, Investigator
Gregory Melton, Pharm D, JD, RPh Investigator
Christina Mogni, RPh Investigator
Nathen Van Allen, PharmD RPh Investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:34 AM

A quorum of the Board was present, established by roll call. President A. Stein chaired the meeting and asked if anyone was recording hearing, no one responded. He explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: A. Stein, yes; K. Tanzer, yes; J. Lanza, yes; M. Godek, yes; S. Hernandez (yes); P. Gannon, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; T. Fensky; R. Lopez, yes.

Topic II.

Approval of Agenda

TIME 8:34 AM

Agenda November 7, 2019

DISCUSSION:

Change to Agenda:

1. none

ACTION:

Motion by L. Giambarresi, seconded by J. Lanza and voted unanimously by those present to approve the agenda with noted change.

Dave asks for the Pharmacy Interns to stand and introduce themselves and introduces the MCPHS Boston APPE Intern: Kayla Carlson and Northeastern University APPE Intern: Michelle Ban

Topic III

Approval of Board Minutes

TIME: 8:34 AM

Minutes

1. Draft, October 3, 2019

No noted Changes.

Action:

Motion by M. Godek, seconded P. Gannon and voted unanimously to approve the regular session minutes of October 3, 2019 with noted changes.

TOPIC IV

REPORTS

Applications approved pursuant to Licensure Policy 13-01

Time: 8:35 AM

Presented by: Ed Taglieri

Discussion: E. TAGLIERI noted that there have been thirty-one (31) change of managers, four (4) renovations, and two (2) closings approved pursuant to Licensure Policy 13-01.

So noted

TOPIC IV

REPORTS

Monthly Report from Probation

Time: 8:35 AM

Presented by: Ed Taglieri

Discussion: E. TAGLIERI provided the September 26, 2019 – October 29, 2019 Pharmacy Board Probation Monthly Report, which noted that five (5) licensees satisfactorily completed probation, thirty-one (31) year-to-date completions, and there are currently twenty-six (26) licensees on probation.

So noted

TOPIC IV**REPORTS**

Monthly Report from BDCR pursuant to Policy 14-02

Time: 8:36 AM

Presented by: Ed Taglieri

Discussion: E. TAGLIERI noted that there were none this month

So noted

TOPIC IV**REPORTS**

Above Action Levels Approved by Staff Action 16-04

Time: 8:37 AM

Presented by: Julienne Tran

Discussion: J. TRAN noted that there were seven (7) above action level reports that have been remediated and closed since the last Board meeting pursuant to Licensure Policy 16-04.

So noted

TOPIC IV**REPORTS**

PSUD report by Staff Action 17-03

Time: 8:37 AM

Presented by: Ed Taglieri

Discussion: E. TAGLIERI noted that in October 2019, there were two (2) inquiries with applications mailed, one (1) will proceed to admission, and fifteen (15) active participants.

So noted

TOPIC V**Policies and Advisories****1. Policy 2019-07: Pilot Projects in Pharmacy Practice****TIME: 8:38 AM****PRESENTED BY: M. CHAN**

DISCUSSION: This revised policy reflects the updated request process for innovative pharmacy practice projects and replaces policy 2001-02 *Guidelines for Pilot Project Approval*.

Licensees proposing such a project must petition the Board with project details as outlined in the policy. Board staff would perform an initial review of the petition and request any additional information before the licensee presents it to the Board. The Board will reserve the right to terminate the project if the applicant fails to comply with any terms set by the Board.

ACTION: Motion by S. HAMILTON, seconded by P. GANNON, and voted unanimously by those present to approve Policy 2019-07 Pilot Projects in Pharmacy Practice.

2. Policy 2019-08: Sterile Compounding Pharmacy Response to Above Action Level Environmental Monitoring Results**TIME: 8:42 AM****PRESENTED BY: M. CHAN**

DISCUSSION: Upcoming regulatory changes were the impetus for this policy that will replace the current advisory: *Recommended Pharmacy Response to Above Action Level Environmental Monitoring Results*. The reporting specifics will be removed from 247 CMR 6.00 upon promulgation and the remediation specifics originally outlined in DRAFT 247 CMR 17.00 now defer to a policy.

With the Advisory Committee's input, the policy was developed to include the following:

- compounding during remediation is permitted only after a risk assessment and with restrictions based on the area affected
- BUDs are now less restrictive
- significant loss of control in the ISO-5 hood is defined as >15 CFU by USP <1160>
- significant loss of control in the ISO-5 necessitates a recall

To balance public safety with pharmacy operational needs and continuity of patient care, there is also a provision designed for small institutional pharmacies with only one ISO-5 hood to be able to continue operate after remediation and risk assessment, but only with an immediate use BUD.

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present to approve Policy 2019-08: Sterile Compounding Pharmacy Response to Above Action Level Environmental Monitoring Results.

3. Staff Action Policy 13-01: Licensure Applications and Notices TIME: 8:35 AM

PRESENTED BY: M. CHAN

DISCUSSION: Edits to this policy would allow Board staff to inactivate intern licenses when a student leaves pharmacy school as well as inactivate technician licenses when a student gets an intern license. The changes would also allow staff to issue a controlled substance registration for a pharmacy's ADD (automated dispensing device) to be located in an approved facility in accordance with *Policy Joint Policy 2019-02: Automated Dispensing Device Use*.

ACTION: Motion by T. FENSKY, seconded by P. GANNON, and voted unanimously by those present to approve revisions to Staff Action policy 13-01: Licensure Applications and Notices.

4. A request by Procure LTC regarding Policy 2019-01: Policy 2019-01: Shared Pharmacy Service Models Including Central Fill, Central and Remote Processing, and Telepharmacy

TIME: 8:47 AM

PRESENTED BY: Procure representatives: Thomas Hyde, Donna Gorke, Rasjiv Dhadwal

RECUSAL: None

DISCUSSION: Procure presented the following points in order to have a pharmacy technician work remotely:

- will adhere to Massachusetts staffing ratios
- all technicians will be Massachusetts licensed and nationally certified regardless of where they are located (i.e. other states)
- a pharmacist will be able to electronically supervise the technicians via live-streaming visuals as well as screen-sharing
- a pharmacist will be immediately available for any questions

- Procure to adhere to technology requirements per Policy 2019-01: *Shared Pharmacy Service Models Including Central Fill, Central and Remote Processing, and Telepharmacy*
- technicians will not be handling pharmaceuticals and only perform data entry

M. CHAN noted that when the initial policy was approved, remote technician processing had not been contemplated. Also, the Board has not traditionally recognized electronic supervision as “direct supervision” as required by regulation.

Extensive discussion ensued over technology utilization to protect patient information and promote safe practices. The Board suggested Procure develop a pilot project petition with all the details for them to consider at the next Board meeting.

ACTION: Motion by T. FENSKY, seconded by S. HERNANDEZ, and voted by the majority of those present to have Procure work with Board staff to develop a pilot project petition. A. STEIN voted against this action.

TOPIC VI

APPLICATIONS

1. Rose Marie Thevenin (PI155378) Pharmacy Internal Extension Time: 9:44 AM

Represented by: Rick Harris

Recusal: None

Discussion: R. HARRIS discussed the case to extend the pharmacy intern license. The licensee is enrolled full time in MCPHS-Worcester’s PharmD program and requires an active license for the required rotations. The licensee failed to pass the pharmacy foreign equivalency exam and enrolled in pharmacy school.

Action: Motion by K. TANZER, seconded by L. GIAMBARRESI, voted unanimously by those present to approve the request for an extension of the Pharmacy Intern License.

2. Boulevard Pharmaceuticals DS90300 Waivers TIME: 9:46 AM

Represented by: Rick Harris

Recusal: None

Discussion: R. HARRIS discussed Boulevard Pharmaceuticals is seeking a waiver for 247 CMR 6.02(4) and 247 CMR 9.01.15. The petitioner claimed this regulation does not apply since the current environment of the pharmacy is currently compounding non-sterile and sterile compounded medications only; due to the quantity and form of medications they carry to compound the prescriptions, it would be in the best interest to stay with a specialized focus on the areas of these medications only. There are a sufficient amount of practices in place to serve the community with their non-sterile compounding needs.

Action: Motioned by S. HAMILTON, seconded by L. GIAMBARRESI, voted unanimously by those present to approve the request to waive 247 CMR 6.02(4) and 247 CMR 9.01(15).

3. Lahey Pharmacy

Clinic to Retail Pharmacy

TIME: 9:47 AM

Represented by: Rochelle Rubin, Manager of Record; Nancy Huff, Director of Pharmacy Services

Recusal: H. ENGMAN, J. LANZA

Discussion: Rochelle Rubin discussed the need for converting the current clinic pharmacy to a retail pharmacy. It is currently licensed under Lahey hospital. It is located on the outskirts of the property. They have merged with other hospitals, this would allow those patients to be able to fill their prescriptions at the pharmacy. Currently only a Lahey employee or a patient with a prescription from a doctor at Lahey Hospital can fill at the pharmacy. They are additionally submitting a waiver for compounding materials as they will not compound non-sterile medications. Only reconstitution in a manufacturer’s container will be allowed. Rochelle Rubin was asked if there have been actions against her license since she has many. She denied any actions against her licenses, as she has moved around a lot.

Action: Motion by M. GODEK, seconded by S. HERNANDEZ, voted unanimously by those present to approve the transition from a clinic pharmacy to retail pharmacy pending an updated waiver for compounding materials, pending approval from the Bureau of Healthcare Safety and Quality, and a successful compliance inspection.

4. Conley’s Drug Store

Renovation

TIME 9:52 AM

Represented by: Not present

Recusal: None

Discussion: M. CHAN did not have any objections.

Action: Motioned by K. TANZER, seconded by M. GODEK, voted unanimously by those present to approve the application for renovation.

5. Genoa Healthcare LLC

New Community Pharmacy

TIME 9:53 AM

Represented by: Kevin O’Connell

Recusal: L. GIAMBARRESI

Discussion: Kevin O’Connell discussed the opening of a new community pharmacy in Shrewsbury, MA. There are 9 locations currently in Massachusetts. A Massachusetts controlled substance registration application was submitted with appropriate fees. Genoa operates over 480 mental health pharmacies throughout the United States. Three pharmacies are located inside Mental Health Centers (MHC) and serve the patients of the clinic as well as any associated inpatient facilities, residential treatment centers, and group homes. They are also requesting waivers for 247 CMR 6.02(5), 247 CMR 9.01(15), 247 CMR 6.01 (a)(a)(8), 247 CMR 9.01 (16), 247 CMR 6.01 (5)(a)(4), 247 CMR 6.02(4), and 247 CMR 6.02 (4).

Action: Motioned by K. TANZER, seconded by M. GODEK, voted unanimously by those present to approve the application for a new community pharmacy.

6. Village Pharmacy of Marblehead DS9701

Transfer of Ownership

TIME 9:55 AM

Represented by: Sabino Russo & Paul Garbarini

Recusal: None

Discussion: Sabino Russo discussed becoming the sole owner and manager of record of Village Pharmacy of Marblehead. He has worked as a pharmacist at the pharmacy for over 12 years and is familiar with the patient population and staff. Prior to working at this pharmacy, Sabino Russo has worked and been the manager of record for both CVS and Osco pharmacies. The current owner and manager of record sold the pharmacy to retire.

Action: Motioned by M. GODEK, seconded by L. GIAMBARRESI, voted unanimously by those present to approve the application for change in ownership and manager of record.

7. Dedham Pharmacy DS89988

Waiver

TIME 9:59 AM

Represented by: Carolyn Arnish

Recusal: None

Discussion: Carolyn Arnish is a staff pharmacist at Dedham Pharmacy and a therapy dog trainer, she is petitioning to have her therapy dog, Tupper, be at the pharmacy. A pharmacy inspection took place and the investigator told Carolyn that dogs are not allowed until the Board is petitioned. She stated that Tupper is a standard poodle, non-shedding breed of dog who is bathed weekly. Tupper passed his therapy dog training exam a week prior to this meeting. M. GODEK stated he is a dog owner and lover, but is concerned about access issues due to the presence of a dog. There was discussion amongst the Board about policies and advisories to having a dog in the pharmacy, there are none to date

A. STEIN: there needs to be compliance with the USP chapters. M. GODEK: indicated that he was uncomfortable with a dog in the pharmacy. L. GIAMBARRESI: Is the dog in the area now? MOR ARNISH: the pharmacy compounds simple and moderate medications including magic mouthwash. The dog is away from the pharmacy counter. She noted that the investigator was in the pharmacy over the summer and observed the dog paraphernalia. D. SENCABAUGH: He noted that he is a dog-lover but wanted to ask regarding access issue for patients who would not go to the pharmacy because of a dog. MOR noted that she would need a sign at the pharmacy and that there are 2 dogs in the state of Connecticut in which there are dogs in the pharmacies without any issues. She noted that having a dog helps the patient open up dialogue with the pharmacy staff. R. LOPEZ: Does DPH have any policy for or against having an animal? H. ENGMAN: Not that she knows but research should be completed regarding information in DPH about service dogs. MOR Arnish noted that the dog is only available when she works but she could register and train other people but ultimately it is her dog and her responsibility. The MOR noted that the dog was in doggie daycare for 3 years and can acclimate with other dogs. J. TRIFONE: Do you have any other responsibilities? MOR noted that she does have other responsibility when in the pharmacy and she is the handler and talks to patients. She noted that she completed her PGY1 in veterinary pharmacy and has worked at Ethos veterinary and Tufts veterinary. The Board discussed writing an advisory for animals in the pharmacy.

Action: No action warranted and the Board will take the information under advisement. Board staff will write an advisory for animals in the pharmacy.

8. CVS Pharmacy#1031 DS89682

Change of Manager

TIME 10:27 AM

Represented by: Laerta Kamberi

Recusal: S. CORNACCHIO

Discussion: Laerta Kamberi has been a pharmacist for over 10 years and has previously been a manager of record at a different CVS Pharmacy. She is being brought in from corporate to fix some issues in the store.

Action: Motioned by S. HAMILTON, seconded by T. FENSKY, voted unanimously by those present to approve the application for change in manager of record.

TOPIC VII

FLEX

1. Nominations for 2020 Board Officers

TIME: 10:29 AM

PRESENTED BY: D. SENCABAUGH

DISCUSSION: Nominations for Secretary and President-elect for 2020 were discussed. It was noted that self-nominations are permitted and the final vote will take place at the December 2019 Board meeting.

President-Elect Nominee 1: J. LANZA

Nominated by: M. GODEK, seconded by S. HAMILTON

President-Elect Nominee 2: S. HERNANDEZ

Nominated by: A. STEIN, seconded by S. HAMILTON

President-Elect Nominee 3: S. CORNACCHIO

Nominated by: P. GANNON, seconded by K. TANZER

- D. SENCABAUGH later brought to the Board's attention that S. CORNACCHIO is not eligible since her final term as a Board member will be over by then.

Secretary Nominee 1: S. HAMILTON

Nominated by: J. LANZA, seconded by S. HERNANDEZ

Secretary Nominee 2: L. GIAMBARRESI

Nominated by: M. GODEK, seconded by S. HAMILTON

2. NEU & GLFHC Opioid Buyback Update

TIME: 10:33 AM

PRESENTED BY: E. TAGLIERI

DISCUSSION: Due to a delay in the production of their kiosks, Greater Lawrence Health Centers implemented their Opioid Buyback program on 9/8/2019, later than projected. They will provide an update in a few months once they have collected sufficient data.

3. Advisory Committee Meeting Summary

TIME: 10:34 AM

PRESENTED BY: E. TAGLIERI and J. LANZA

DISCUSSION: E. TAGLIERI summarized the Recommendation Document 19-02, which contained the points that the Board had asked for Advisory Committee provide input on:

- 1) Advisory on Sterile Compounding Pharmacy Response to HVAC Excursions in Sterile Compounding Environments
- 2) Discussion of the implementation of USP Chapters
- 3) Review of Policy 2019-01: Shared Pharmacy Service Models Including Central Fill, Central and Remote Processing, and Telepharmacy

J. LANZA noted that considerable discussion was on the advisory for proper response to HVAC excursions. The committee agreed that standard operating procedures regarding power outages and temperature, pressure, and humidity excursions should be developed individually by each pharmacy due to variances in facilities. They also recommended that the updated advisory indicate that a “prolonged excursion” must be defined by each individual institution.

TOPIC VIII

FILE REVIEW

Case #1

SA-INV-15473

Walgreens #18415, DS90135

Time: 10:55 AM

RECUSAL: M. GODEK and S. HAMILTON recused and were not present for the discussion or vote on this matter.

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

- 8/12/19 BORP received an application for the extension for the license of PTT Mao-Nhem who had worked at the Pharmacy beyond the one-year limitation from 5/24/19-8/12/19.
- MOR Tuccelli stated he had PTT Mao-Nhem complete an application for an extension in early May 2019 but never followed up to ensure it had been granted. MOR Tuccelli indicated that he had been unaware of the PTT training program Walgreens had in place as he was not informed of it when Rite Aid transitioned to Walgreens. Once he became aware of the expired status of the license, MOR Tuccelli had PTT Mao-Nhem work in the front store, complete the PTCB test, and submit all forms to the appropriate offices for licensing.
- PTT Mao-Nhem indicated she submitted her application for her PT license after becoming nationally certified on 8/19/19. Because of the long wait time to be issued the PT license, she submitted an extension request for her PTT license. She indicated she had worked at the Pharmacy from 10/26/18 to 9/13/19 and is now employed at BMC.
- CA: To prevent a future occurrence, MOR Tuccelli reviewed Walgreens PTT Program and fully understands his role. An employee roster of all PTTs has been created and the total hours worked is recorded. Each month the hours are tallied and added to the previous month's total. MOR Tuccelli also reviewed 247 CMR 8.03. PTT Mao-Nhem was issued a pharmacy technician license (PT25211) on 9/13/19.

ACTION: Motion by P. GANNON, seconded by J. LANZA, and voted unanimously by those present, to CLOSE the matter (SA-INV-15473), No Discipline Warranted, Remediation Complete.

Case #2

PHA-2019-0072

Walgreens #3020, DS2492

Time: 10:58 AM

RECUSAL: M. GODEK recused and was not present for the discussion or vote on this matter.

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

- Incomplete RLCS on 6/10/19 for an unknown loss of #28 morphine sulfate 30 mg ER tablets and #28 oxycodone 10 mg tablets discovered 6/2/19 during the perpetual inventory reconciliation. The BORP RLCS form indicated both losses but the final DEA 106 only reported a loss of #29 morphine sulfate 30 mg ER tablets (incorrect quantity reported).
- MOR Flanagan (Martini) only addressed the loss of morphine sulfate 30 mg ER in response to the complaint stating after the conclusion of the internal investigation it was determined the loss of oxycodone 10 mg was deemed not a loss based on a paper audit.
- The investigation included review of invoices and dispensing reports, a search of the prescription bins, and a bin reconciliation to ensure a prescription had not been deleted and not returned to stock. Security footage was reviewed but was inconclusive.
- MOR Flanagan (Martini) attributed the loss possibly to a dispensing error or an accidental disposal of a bottle but theft could not be ruled out. Only 1 prescription for morphine had been dispensed since the last reconciliation. The patient was contacted and denied an over-dispense.
- Copies of the perpetual inventory for morphine sulfate 30 mg ER tablets and oxycodone 10 mg tablets showed that both drugs reconciled with no discrepancies on the previous reconciliation date.
- CA: Pharmacy staff were retrained on the proper filling of controlled substances standard operating procedures. Only pharmacists are allowed to count CII medications for the next six months to ensure certified pharmacy technicians are properly trained. MOR Flanagan (Martini) will determine when/if any certified technician should count CII prescriptions after the 6-month period. On 09/04/2019, an amended DEA 106 was submitted to the DEA to reflect both losses.

ACTION: Motion by T. FENSKY, seconded by J. LANZA, and voted unanimously by those present, to refer the matter (PHA-2019-0072) 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 REPRIMAND.

Case #3

PHA-2019-0077

Walgreens #11797, DS89665

Time: 11:01 AM

RECUSAL: M. GODEK recused and was not present for the discussion or vote on this matter.

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

- Untimely, incomplete RLCS on 07/03/2019 for an unknown loss of #30 amphetamine salts 20mg ER capsules discovered on 06/13/2019 when the pharmacist filled the prescription that had been

“stored”. The pharmacist realized the prescription had been deleted and put on hold but it was not indicated as RTS in the perpetual inventory.

- Pharmacist Nguyen adjusted the perpetual inventory to reflect the actual balance on hand, checked the bins, reviewed all filled prescriptions with the perpetual inventory to verify all prescriptions had been logged, and counted the medication on hand to confirm the discrepancy.
- MOR Shah indicated daily counts for 2 months were initiated and loss prevention interviewed some of the pharmacy staff. Security footage of the camera that is on the fill counter was broken and could not be reviewed. Other security footage viewed was inconclusive. MOR Shah indicated PT Ramsey who filled-in at the Pharmacy on 06/12/2019 was the person who deleted the original prescription fill. PT Ramsey was interviewed and denied any wrongdoing.
- CA: A new policy was implemented by MOR Shah requiring that only the pharmacist can fill a CII prescription and only the pharmacist can delete a CII prescription that is in the ready status. Once a CII prescription has been deleted, the pharmacist must immediately put the returned to stock medication into the CII safe. The pharmacist must back count all CII medications prior to dispensing to ensure there is no discrepancy.

ACTION: Motion by T. FENSKY, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to refer the matter (PHA-2019-0077) 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

PHA-2019-0089

Walgreens #10427, DS3611

Time: 11:03 AM

RECUSAL: M. GODEK recused and were not present for the discussion or vote in this matter.

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

- Incomplete reporting of Appendix I information only received on 8/9/19 for an unknown loss of #100 amphetamine salts 20 mg tablets discovered on 8/3/19. On 8/13/19, the DEA 106 was submitted.
- The loss was realized during the reconciliation of the perpetual inventory on 8/3/19. The investigation included a reconciliation of receipt of drug with the perpetual inventory, the pharmacy and CII safe were searched for any misplaced drug and the item movement report was reviewed. Security footage of receipt of CII orders and filling of prescription for amphetamine salts 20 mg tablets was reviewed. The cause of the loss could not be determined but MOR Caisse stated, “We are leaning heavily towards accidental disposal”.
- In a response received 10/8/19, MOR Caisse stated the RLCS report was inadvertently omitted in the reporting but did not provide it. MOR Caisse indicated patients that had been dispensed amphetamine salts 20 mg tablets were contacted and all denied receiving an over-dispense.
- An untimely RLCS was submitted on 10/16/19 indicating the investigation concluded on 8/13/19.
- CA: An area for audit of received CII orders in sight of the security camera was designated. The pharmacist double counts the product dispensed for every CII prescription filled and the remaining quantity within the stock bottle which is compared to the perpetual inventory. Walgreens policies and procedures for the handling of controlled substances were reviewed by all pharmacy staff.

ACTION: Motion by S. HAMILTON, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2019-0069) 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 REPRIMAND.

Case #5

SA-INV-15472

The Hilsinger Company, WD450

Time: 11:08 AM

RECUSAL: NONE

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

- 8/9/19 - Untimely report of discipline by the AL Board of Pharmacy on 7/22/19 in response to a \$25,000 non-disciplinary fine imposed on 2/15/17 by the SC Board of Pharmacy for shipping into the state without a license.
- Hilco Sr. Manager of N. American Operations indicated the fine imposed by SCBOP was not considered discipline but it was a condition of licensure for shipping into SC at that time without a license. The discipline imposed by AL for violation of ALBOP rules with a \$1,000 fine was considered “domino discipline”.
- Hilco provided copies of all current state licenses and a report of all drugs shipped including addresses from 1/1/18 to 9/25/19. Hilco is not licensed in HI, IN, and ND but has shipped drugs there. HI does not require wholesale distributor licenses to ship into the state. Hilco confirmed shipping into IN and ND without an out-of-state wholesale distributor license which immediately ceased
- CA: Hilco was issued a SC license on 2/27/17. Hilco engaged State License Servicing Inc. to handle state licensing and keep the company current on regulatory compliance changes shortly before filing for SC licensure. An appropriately licensed third-party logistics provider was engaged to ship prescription medications into Indiana and North Dakota as a continuity of care. Hilco is in the process of obtaining out-of-state wholesale distributor licenses in Indiana and North Dakota.
- During a compliance inspection on 10/22/19 it was discovered that Hilco had also been shipping into Indiana, Iowa, Maryland, North Dakota and Wyoming without licenses in those states.
- Licensing in some of non-licensed states require VAWD survey which Hilco’s currently pursuing.

ACTION: Motion by S. HERNANDEZ, seconded by K. TANZER, and voted unanimously by those present, to elevate the matter (SA-INV-15472) and refer 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 REPRIMAND.

Case #6

PHA-2019-0086

Greater Boston Long Term Care, DS3306

Time: 11:19 AM

RECUSAL: NONE

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

- Inspectional deficiencies from a retail inspection (ISP-12947) conducted on 8/20/19 including but are not limited to, the re-dispensing of medications returned to the pharmacy, labels on blister cards without expiration dates assigned, patient labels that did not reflect the current prescription number, fill date, and/or prescriber, vials and blister cards of medications in active stock without labels, medications filled at other pharmacies in active stock, no policy and procedure available for the

cleaning of daily dose planners, no policy and procedure available for medication changes, and no disposal records available for medication waste to an authorized reverse distributor. PT Hayes and MOR Wessenberg admitted to removing medications from multi-dose blister cards and returning them to active stock. During the inspection MOR Wessenberg agreed to cease the practice of re-dispensing returned medications.

- POC indicated the use of daily planners was discontinued, P&P for cleaning cassettes was implemented with staff training, P&P for medication changes was implemented with staff training, the computer software was reprogrammed to reflect the original date of fill, refill date, and expiration date on the labels, labels for pre-packed blister cards and DOSIS generated blister cards were updated to reflect a 6-month expiration date.
- In response to the complaint, MOR Wessenberg stated the Pharmacy services 2100 patients residing in 202 MAP group homes who receive single-dose blister cards and 31 assisted living facilities who receive multi-dose cards. The Pharmacy has an automation unit for 70 medications that packages blister cards with barcodes. There is no other barcode scanning technology. The Pharmacy has a two-step pharmacist check of manually packaged cards but only facility, date, PT name, start and end time of packaging, number of cards and whether the cards were single- or multi-dose is documented.
- MOR Wessenberg reiterated that prior to 8/20/19, returned medications were removed from the blisters packs by PT Hayes and checked before being returned to stock bottles by a pharmacist or CPhT Manager McAbee.
- MOR Wessenberg stated that as of 2/26/19, the reverse distributor stopped accepting pharmaceutical waste and he had no contract in place with another authorized reverse distributor.
- CA: No medications are returned back into active stock. A system was implemented for tracking medication returned for re-dispensing to the same patient after a medication change. If the medication expires during storage, it will be returned to the authorized reverse distributor. MOR Wessenberg implemented and trained pharmacy staff on the new P&Ps for cleaning cassettes and medication changes. The Pharmacy is currently working on implementing barcode scanning for all single- and multi-dose cards. The pharmacy technician responsible for labeling multi-dose cards was retrained on the placement of patient labels on the cards to avoid overlapping the labels ensuring all required information is visible.
- Site visit conducted on 11/5/19-all deficiencies were remediated and additional processes for improvement were implemented.

ACTION: Motion by S. HAMILTON, seconded by S. HERNANDEZ, and voted unanimously by those present, to refer the matter (PHA-2019-0086) 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 REPRIMAND.

Case #7

PHA-2019-0081

CVS #1248, DS2875

Time: 11:25 AM

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote in this matter.

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

- Untimely RLCS on 7/25/19 for an unknown loss of #416 tramadol 50 mg identified on 6/12/19 via corporate controlled substance monitoring.

- Daily counts were initiated immediately occurring until 7/7/19 with reconciliations performed. It was determined there was no active loss or concern of diversion. Security footage was not reviewed. The cause of the loss was not identified.
- The BOH in the 2018 Biennial Inventory was used as the start date of the internal audit. Although it was an exact count, MOR Coorie stated the count in the 2018 Biennial Inventory could have been incorrect resulting in a loss shown.
- CA: Pharmacy staff completed training modules on the proper handling of controlled substances. BOH modification and order adjustment reports are reviewed weekly to assist in identifying any inventory areas of concern and to prevent against any future drug losses.

ACTION: Motion by T. FENSKY, seconded by L. GIAMBARRESI, and voted unanimously by those present, to refer the matter (PHA-2019-0081), 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 TRAMADOL containing 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 #8

PHA-2019-0082

CVS #746, DS2818

Time: 11:28 AM

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote in this matter.

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

- Untimely RLCS on 7/25/19 for an unknown loss of #517 acetaminophen/codeine 300/30 mg tablets identified on 6/12/19 via corporate controlled substance monitoring.
- Although the BOH for the NDC number of acetaminophen/codeine 300/30 mg tablets on 6/12/19 was zero, daily counts were initiated immediately occurring until 7/7/19 with reconciliations performed for other NDCs in stock indicating an overall variance of (-) 325 tablets for all NDCs of the medication. The BOH in the 2018 Biennial Inventory, which was an exact count, was used as the start date of the internal audit. It was determined there was no active loss or concern of diversion. Security footage was not reviewed. The cause of the loss was not identified but the 2018 Biennial BOH may have been incorrect.
- CA: Pharmacy staff completed training modules on the proper handling of controlled substances. BOH modification and order adjustment reports are reviewed weekly to assist in identifying any inventory areas of concern and to prevent against any future drug losses.

ACTION: Motion by S. HAMILTON, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2019-0082), 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 ACETAMINOPHEN/CODEINE SOLD DOSAGE FORM 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

PHA-2019-0085

CVS #693, DS3250

Time: 11:30 AM

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote in this matter.

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

- RLCS on 8/2/19 of an untimely, unknown loss of #340 tramadol 50 mg tablets discovered on 6/12/19 via corporate controlled substance monitoring.
- The reconciliation report indicated the starting BOH was used from the 2018 CIII-CV annual inventory but MOR Patel reported the internal audit was based on the 2019 CIII-CV annual inventory. Exact counts were performed for both inventories. Loss Prevention initiated daily cycle counts, tramadol was removed from the automation unit, and security footage was reviewed. Diversion was not suspected but a reason for the loss was not determined.
- CA: The pharmacy team was coached to double count all controlled substance medications prior to dispensing to prevent any reoccurrences. All baseline loss prevention procedures were reviewed with the pharmacy staff, especially those related to drug diversion prevention. The lead pharmacy technician and the pharmacists only will cycle count tramadol. Each week, the BOH of tramadol is noted so that in the event there is another discrepancy there will be an accurate count to use for the investigation.

ACTION: Motion by K. TANZER, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2019-0085), 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 TRAMADOL containing 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

PHA-2019-0087

CVS #1007, DS90074

Time: 11:32 AM

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote in this matter.

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

- Untimely RLCS on 7/30/19 of an unknown loss of #100 methylphenidate 5mg tablets confirmed on 6/25/19.
- While filling a prescription for oxycodone 5mg on 6/21/19, Pharmacist Li found methylphenidate 5mg co-mingled with oxycodone 5mg in the CII safe. After back-counting both drugs, she discovered the

discrepancy. The investigation included review of dispensing reports, the perpetual inventory, and security footage.

- MOR Shooshani suspected that because the drugs were co-mingled, a bottle of methylphenidate 5mg was removed from the safe during an oxycodone 5mg dispensing and was identified, but then inadvertently disposed of although this was not confirmed.
- CA: MOR Shooshani instituted a store specific action plan for the process of checking-in CII orders. The pharmacist on duty will only check-in CII orders at the pharmacist work station instead of at the consultation counter. All pharmacy staff were coached on the process to include asking the delivery driver to wait when the Pharmacy is unusually busy.

ACTION: Motion by S. HAMILTON, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2019-0087), 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 #11

PHA-2019-0026

CVS #1056, DS1646

Time: 11:34 AM

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote in this matter.

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

- Untimely RLCS on 2/12/19 for an unknown loss of #100 methadone 5mg tablet discovered on 12/30/18 during the reconciliation of the perpetual inventory.
- The internal investigation presumed that an unopened bottle of methadone 5mg may have been inadvertently discarded after a prescription was filled. The pharmacist is viewed removing 2 bottles of methadone 5mg from the safe and placing them on the counter above the trash for empty bottles. The pharmacist is then viewed using the open bottle and returning only one bottle to the safe. A second pharmacist is seen cleaning the area and it is assumed the unopened bottle was discarded. Security footage was reviewed but was inconclusive as there was not a clear view. Diversion was not suspected.
- Documentation provided showed the reconciliation of the perpetual inventory and discovery of the loss occurred on 1/2/19, not 12/30/18 as stated by MOR Nwabueze.
- CA: The pharmacist will immediately return the unused CII bottles back into the safe after filling and before moving on to the next verification. The trash for empty CII bottles was moved away from the verification station.
- Untimely RLCS on 3/25/19 for an unknown loss of #442 clonazepam 0.5 mg tablets identify via corporate controlled substance monitoring.
- The internal investigation included cycle counts of all NDCs of clonazepam 0.5 mg tablets and interviews with the pharmacy staff but the cause of the loss was not determined.
- Four letters of continuation were provided that had been filed with the DEA but were not received by the BORP.
- CA: All pharmacy staff completed modules on the proper handling of controlled substances and were reminded to follow proper policies and procedures when filling and performing cycle counts of controlled substances. BOH modification and order adjustment reports are reviewed weekly to assist

in identifying any inventory areas of concern and to prevent against any future drug losses. Cycle counts will be completed daily for system prompted cycle counts and an official monthly count is completed.

ACTION: Motion by L. GIAMBARRESI, seconded by M. GODEK, and voted unanimously by those present, to refer the matter (PHA-2019-0026), 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 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 #12

SA-INV-14659

CVS #2172, DS2817

Time: 11:38 AM

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote in this matter.

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

- OPP received a consumer complaint that alleges on or about January 11, 2019, the patient reported a delay in therapy. The complainant dropped off two prescriptions, one of which was a prescription for amphetamine salts, to be picked up the following day. The complainant went to the pharmacy to pick up both prescriptions and received only one prescription. The prescription in question was the amphetamine salts prescription which was returned to stock and he was told that the prescription could not be filled again because it already expired.
- MOR Brown stated, "the prescription in question for amphetamine salts ER 20mg was written by the doctor on December 12, 2018. This means that the prescription expired after the anticipated pickup date of January 11, 2019. CVS software now flags the pharmacy when prescriptions in the waiting bin have expired. The software prompts the pharmacy to return to stock any expired prescriptions that are filled in the waiting bin in order to remain compliant and only dispense valid prescriptions."
- The complainant came to the pharmacy to pick up his prescriptions on January 20, 2019. It was Sunday evening; the doctor's office was closed and the pharmacist assured the complainant that she would contact the doctor's office the following morning to obtain a new prescription. The new prescription was ready for the patient the following day.
- MOR Brown stated, "In order to prevent such misunderstandings in the future, all pharmacy staff will make sure to counsel patients that CII medications expire 30 days after written when they are dropping off their prescriptions."

ACTION: Motion by M. GODEK, seconded by L. GIAMBARRESI, and voted unanimously by those present, to CLOSE the matter (SA-INV-14659), No Discipline Warranted, Remediation Complete.

Case #13

SA-INV-14604

Hopkinton Drug, DS8191

Time: 11:42 AM

RECUSAL: NONE

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

- USP <795> inspection conducted on 1/30/19 with deficiencies related to expired compounded products on the shelf, improperly labeled compounded products, and had active pharmaceutical ingredient (API) methylcobalamin sourced from a non-FDA licensed facility.
- Failure to observe the USP <795> standards including:
 - a. Observed expired compounded product on the shelves including but not limited to: DHEA (Dehydroepiandrosterone)/progesterone/testosterone cream (expired on 1/22/19); observed abbreviations on the patient labels, observed product purchased outside of traditional drug distribution networks or through secondary wholesalers - methylcobalamin pure, LOT #: PB20180304, wholesaler: pure assay, and country of origin: China. The API was used to make methylcobalamin nasal spray 2mg/ml. There were about 20 patients who had methylcobalamin nasal spray compounded from methylcobalamin from Pure Assay (Lot#: PB20171101) from Dec. 2018-Jan 2019.
- MOR Zaia indicated that to minimize this occurrence in the future we plan to set up Google alerts regarding compounded meds and API suppliers. A questionnaire for suppliers to fill out is also being planned so that we can verify their FDA registration and search for 483 violations/warning letters. Also, the computer vendor was able to adjust the pharmacy labels to include the ingredient names, strengths and concentration.
- On July 25, 2019, MOR Zaia provided an additional response and stated, "The only thing I do not have a list of the patients who received the methylcobalamin from the affected product (Lot #: PB20180304) which was destroyed as it was unopened and never used to compound any prescriptions."
- On August 1, 2019, MOR Zaia stated, "All remaining methylcobalamin product manufactured by Pure Assay (Lot#: PB20171101) will be 'quarantined' and 'do not use' as has been segregated from our active inventory shelf. We will be sending this out for destruction on Thursday August 8 along with our other expired and unusable products."

ACTION: Board member P. GANNON requested another inspection and defer action until hear the results of inspection.

Case #14

PHA-2019-0071

Kabafusion, DS89700

Time: 11:49 AM

RECUSAL: NONE

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

- Kabafusion failed to report an above action level result (highly pathogenic pathogen) from environmental monitoring performed as part of testing for cleanroom certification on February 20, 2019. Furthermore, Kabafusion did not implement corrective action in response to the above action level result.
- Kabafusion admitted that they received notification of the above action level result from the company certifying the cleanroom but due to an oversight failed to recognize the result. Routine monthly

environmental monitoring was performed by Kabafusion’s own staff in March 2019 and the sample of the same location showed no growth.

- On the other hand, surface samples from the March 2019 monitoring were positive for microbial growth in two new areas. In addition, the new growth was not sent out for identification by a credentialed laboratory. Kabafusion instead identified the new growth as “staph” by colony morphology only. The pharmacy also failed to determine the coagulase status of the staph.
- CA: Kabafusion explained that the pharmacy was undergoing a renovation/expansion at the time of the oversight in February 2019. They added that a pharmacist had just returned from a 3 month leave of absence and was being reoriented. Kabafusion then indicated that corrective action included scheduling dedicated time with electronic alerts to remind staff to properly manage environmental monitoring results. In addition, Kabafusion establish a dual notification system of email and telephone or text message for notification of above action level results rather than only by email.
- Kabafusion also hired an outside consultant to review and improve policy and procedures for the cleanroom. In addition, the consult will develop an ongoing monitoring plan to ensure compliance. Kabafusion’s MOR, Fidelis Fynn, indicated that he planned to complete 5 additional hours of CE as part of corrective action.

ACTION: Motion by S. HAMILTON, seconded by K. TANZER, and voted unanimously by those present, to refer the matter (PHA-2019-0071), 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. A second motion by K. TANZER, seconded by M. GODEK, and voted unanimously by those present, to open a complaint on the MOR Fidelis Fynn (PH27655).

Case #15

SA-INV-15283

Johnson Compounding & Wellness, DS90089

Time: 11:54 AM

RECUSAL: A. STEIN and C. JEAN-FRANCOIS recused and were not present for the discussion or vote in this matter.

DISCUSSION: N. VAN ALLEN presented and summarized the investigative report that pertained to these matters.

- In April 2019, BORP received an email regarding sale of cannabis products in the Pharmacy which prompted opening of the staff assignment.
- Review of the Pharmacy website identified CBD products for sale in their online store.
- A site visit (ISP-15283) was conducted on July 12, 2019, observed CBD was available for sale within the wellness section of the business but adjacent to the register and not within the pharmacy. The MOR relocated the products further away from the register during visit.
- MOR had removed all products for sale from their website including all advertisements.
- MOR confirmed that no Pharmacist or technician provides therapeutic/medicinal claims to patients and confirmed that they never bring the product into the Pharmacy for compounding of patient prescriptions.

ACTION: Motion by S. HERNANDEZ, seconded by T. FENSKY, and voted unanimously by those present, to CLOSE the matter (SA-INV-15283), No violation.

Case #16

SA-INV-15271

Amex Pharmacy, NO00026

Time: 11:56 AM

RECUSAL: NONE

DISCUSSION: N. VAN ALLEN presented and summarized the investigative report that pertained to these matters.

- SA-INV-15271 was opened on July 9, 2019 subsequent to a FDA issued 483b to the Pharmacy from an April 15 to May 31, 2019 inspection.
- The 483b included observed systems issues related to environmental monitoring, cleaning and disinfection, procedures for preventing contamination of drug products, lack of validation of aseptic and sterilization methods, quality assurance, determining expiration dates, identification of incoming products, training and onboard new staff, container closure testing, aseptic procedures, protective apparel, labeling, and retention of samples.
- Facility received #287 complaints since 2016 including “floaters, plunger not advancing, fibers found on needle, eye inflammation, loss of visual acuity.”
- Pharmacy declined FDA’s initial request to voluntarily recall all dispensed medications within expiry stating that all secondary compendial testing passed acceptance criteria and therefore no reason for recall.
- On September 3, 2019, the Pharmacy voluntarily recalled all dispensed medications within expiry stating that they wanted to avoid further action by FDA.
- BORP received notification on October 9, 2019 that the Pharmacy de-registered with the FDA as an Outsourcing Facility on September 23, 2019.

ACTION: Motion by P. GANNON, seconded by M. GODEK, and voted unanimously by those present, to CLOSE the matter (SA-INV-15271), without prejudice.

Topic IX **EXECUTIVE SESSION** **Time: 12:01 PM**
Read by A. Stein

DISCUSSION:

ACTION: At 12:01 PM President A. Stein read the statement on reasons for Executive Session.

LUNCH: **Time Out: 12:25 PM** **Time Back: 1:35 PM**

Topic IX: **Executive Session Call to Order:** **Time: 1:36 PM**
By: A. Stein

ACTION: Motion by L. Giambarresi, seconded by K. Tanzer, and voted unanimously by roll call to call the November 7, 2019 meeting of the Executive Session to order.

Roll call attendance: A. Stein, yes; K. Tanzer, yes; J. Lanza, yes; M. Godek, yes; S. Hernandez (yes); P. Gannon, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; T. Fensky; R. Lopez, yes.

Topic X:

M.G.L. 65 C #1

Time: 12:05 PM

DISCUSSION: None

ACTION: President A. Stein request a motion to enter M.G.L 65 c Session.

At 12:05 PM, M. Godek seconded by L. Giambarresi and voted unanimously by all those present to enter M.G.L. chapter 65 c Session:

Topic XI

ADJOURNMENT OF MEETING

TIME: 2:31 PM

ACTION: Motion by M. Godek seconded by J. Lanza, and voted unanimously by those present, to adjourn from General Session.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 11/7/19 General Session
2. Draft Minutes of the 10/3/19 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. Policy 2019-07: Pilot Projects in Pharmacy Practice
9. Policy 2019-08: Sterile Compounding Pharmacy Response to Above Action Level Environmental Monitory Results
10. Staff Action Policy 13-01: Licensure Applications and Notices
11. A request by Procure LTC regarding Policy 2019-01: Shared Pharmacy Services
12. Applications: Rose Marie Thevenin PI155378-Pharmacy Intern Extension
13. Applications: Boulevard Pharmaceuticals DS90300 Waivers
14. Applications: Lahey Pharmacy Clinic to Retail Pharmacy
15. Applications: Conley Drug DS2654 Renovation
16. Applications: Genoa Healthcare New Community Pharmacy
17. Applications: Village Pharmacy of Marblehead DS9701 Transfer of Ownership
18. Applications: Dedham Pharmacy DS89988 Waiver
19. Applications: CVS 1031 Ds89682 Change of Manager of Record
20. SA-INV-15473 Walgreens #18415, DS90135
21. PHA-2019-0072 Walgreens #3020, DS2492
22. PHA-2019-0077 Walgreens #11797, DS89665
23. PHA-2019-0089 Walgreens #10427, DS3611
24. SA-INV-15472 The Hilsinger Company, WD450
25. PHA-2019-0086 Greater Boston Long Term Care, DS3306
26. PHA-2019-0081 CVS #1248, DS2875
27. PHA-2019-0082 CVS #746, DS2818

28. PHA-2019-0085 CVS #693, DS3250
29. PHA-2019-0087 CVS #1007, DS90074
30. PHA-2019-0026 CVS #1056, DS1646
31. SA-INV-14659 CVS #2172, DS2817
32. SA-INV-14604 Hopkinton Drug, DS8191
33. PHA-2019-0071 Kabafusion, DS89700
34. SA-INV-15283 Johnson Compounding & Wellness, DS90089
35. SA-INV-15271 Amex Pharmacy, NO00026

Respectfully Submitted,
Julie Lanza, CPhT, Secretary