COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

December 5, 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.

Time	#	Item	Page	Contact
8:30	Ι	CALL TO ORDER		A. Stein
	II	APPROVAL OF AGENDA		
8:40	ш	 APPROVAL OF BOARD MINUTES Draft of November 7, 2019 Regular Session Minutes 		
8:45	IV	 REPORTS 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 		
8:50	V	 POLICIES and ADVISORIES Advisory on implementation of USP <800> in community pharmacies Advisory regarding animals in the pharmacy 		W. Frisch M. Chan

Agenda

		APPLICATIONS		
	VI	 ProCare (DS90042) - Pilot Project 		
9:00		• Stop & Shop (DS89834) – Change of Manager		
		Custom Medicine Pharmacenter (DS3323) – Renovation		
		 Medminder Systems (DS90072) - Renovation 		
		FLEX		
		Election of 2020 Board officers		
		o <u>President-Elect</u>		
		 Stephanie Hernandez 		
9:30	VII	 Julie Lanza 		
		o <u>Secretary</u>		
		 Sebastian Hamilton 		
		 Leah Giambarresi 		
		ASHP mid-year meeting		
		FILE REVIEW		
		1 SA-INV-15415 Western MA Compounding Center, DS89965		
10:00	VIII	2 PHA-2019-0084 CVS #669, DS2846 2 PHA-2010 0004 CVS #669, DS2846		
10.00	VIII	3 PHA-2019-0091 CVS #382, DS89637		
		4 PHA-2019-0093 CVS #2161, DS2832		
		5 PHA-2019-0098 CVS #5493, DS89634		
12:30				
		EXECUTIVE SESSION		
		The Board will meet in Executive Session as authorized pursuant to		
1.20		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,		
1:30	IX	or complaints or charges brought against, a public officer, employee,		
		staff member or individual. Specifically, to evaluate the Good Moral		
		Character as required for registration for pending applicants.		
2:00	X	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)		
2:30	XI	M.G.L. c. 112, § 65C SESSION		
5:00	XII	ADJOURNMENT		

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION 239 Causeway Street, Fourth Floor ~ Room 417A Boston, Massachusetts, 02114 December 5, 2019

Board Members Present

Andrew Stein, Pharm D, RPh. President Kim Tanzer, PharmD, RPh. President Elect Julie Lanza, CPhT, Secretary Stephanie Hernandez, Pharm D, BCGP, RPh Susan Cornacchio, JD, RN Patrick Gannon, RPh Leah Giambarresi, Pharm D, RPh Dr. Richard Lopez

Board Members Not Present

Timothy Fensky, RPh Carly Jean-Francois, RN, NP Michael Godek, RPh Sebastian Hamilton, Pharm D, RPh Dawn Perry, JD

Board Staff Present

David Sencabaugh, RPh, Executive Director Monica Botto, CPhT, Associate Executive Director Vita Berg, JD, Counsel William Frisch, RPh Director of Pharmacy Compliance Samuel Penta RPh., Senior Investigator Joanna Chow, CPhT, Office Support Specialist Julienne Tran, Pharm D, RPh Investigator/Quality Assurance Pharmacist Christina Mogni, RPh Investigator Gregory Melton, 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; S. Hernandez, yes; P. Gannon, yes; S. Cornacchio, yes; L. Giambarresi, yes; R. Lopez, yes.

Topic II.

Approval of Agenda

Agenda March 7, 2019

DISCUSSION:

Change to Agenda: 1. None

ACTION:

Motion by P. Gannon seconded by K. Tanzer and voted unanimously by those present to approve the agenda with no noted change.

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

Topic III	Approval of Board Minutes	TIME: 8:38 AM	
Minutes 1. Draft, 11/7/19 Sessio	on Minutes		
No noted Changes.			
Action: Motion by L. Giambarre minutes of 11/7/19 with	si, seconded J. Lanza and voted unanimously to n no noted changes.	approve the regular session	
•• ••	REPORTS pursuant to Licensure Policy 13-01 reported that there were no applications approv	Time: 8:38 AM ved pursuant to Licensure Policy	
So noted			
TOPIC IV	REPORTS		
Monthly Report from P	robation	Time: 8:39 AM	
•	provided the October 30, 2019 – November 26, 2 noted that there are thirty-three (33) active case	•	
So noted			
TOPIC IV	REPORTS		
Monthly Report from B	DR pursuant to Policy 14-02	Time: 8:39 AM	
Discussion : M. BOTTO noted that there was two (2) Board Delegated Review case heard on November 26, 2019. There was one CE self-disclosure (SA-INV-15552) which was closed with discipline not Page 2 of 12			
Draft Minutes Genera	0		
BOP Approved: 1/9/2			

warranted and remediation complete and one renewal of waivers for Fresenius. The Board Delegated Review session was attended by A. STEIN as the Board Member, W. FRISCH Director of Pharmacy Compliance, M. CHAN as Quality Assurance, H. ENGMAN as Board Counsel, and Executive Director D. SENCABAUGH.

So noted

TOPIC IV REPORTS
Above Action Levels Approved by Staff Action 16-04

Discussion: J. TRAN noted that there was one (1) above action level report that has been remediated and closed since the last Board meeting pursuant to Licensure Policy 16-04.

So noted			
ΤΟΡΙΟ Ιν	REPORTS		
PSUD Report by Staff Action 17-03		Time:	8:40 AM

Discussion: E. TAGLIERI noted that in November 2019, there was one (1) successful graduate from the program with a job, one (1) pending admission, and fourteen (14) active participants.

So noted

ΤΟΡΙϹ V	Policies and Advisories	
1. Advisory on Implementation of USF	< 800> in Community Pharmacy	TIME: 8:36AM

Presented by: W. Frisch Recusal: None

Discussion: Advisory on implementation of USP <800> in Community Pharmacies is intended to provide practical guidance for community pharmacies in order to comply with the requirements of USP <800> and is not intended to be all inclusive; refer to USP <800> for all requirements. This will help pharmacy inspectors guide community pharmacies towards a path to compliance.

Action: Motion by K. TANZER, seconded by P. GANNON, and voted unanimously by those present to approve Advisory on implementation of USP <800> in Community Pharmacies.

2. Advisory regarding animals in the pharmacy

Time: <u>8:37AM</u>

Time: 8:40 AM

Presented by: W. Frisch Recusal: None

Discussion: The Massachusetts Board of registration in Pharmacy recommends licensees do not permit pets, therapy animals, or emotional support animals in the licensed pharmacy space (e.g. prescription filling area) at any time. Animals are prohibited from sterile compounding areas and facilities. There was an update to include language "This does not apply to service animals to the extent authorized by law."

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Action: Motion by P. GANNON, seconded by L. GIAMBARRESI, and voted unanimously by those present to approve Advisory regarding animals in the pharmacy.

Pilot Project

TOPIC VI

APPLICATIONS

TIME: 8:49 AM

<u>REPRESENTED BY</u>: Thomas Hyde (CEO), Thomas Lachapelle (Chief Operations Officer), and Rajiv Dhadwal (Chief Compliance Officer.)

RECUSAL: None

1. ProCare DS90042

<u>DISCUSSION:</u> An overview of the project was explained; order entry will be done remotely with a pharmacist on site. The pharmacy technicians are monitored by video conference and can also communicate through text and email. They are HIPAA compliant. They will start with four (4) in house certified technicians and plan to hire more. New hires will be trained in state for one month. ProCare has success using this model in other states. They would like to shift the order entry from pharmacist to technician so the pharmacists can focus on clinical work. The proposed start date is January 2, 2020.

P. GANNON suggested assessing pharmacist satisfaction with the project and gathering their feedback through an anonymous survey. S. HERNANDEZ asks if consultant pharmacists can be included in this survey as well. ProCare agreed to make a survey and send it to their pharmacists and consultant pharmacists involved. R. LOPEZ suggested a qualitative assessment for more robust data on HIPAA violations, technical glitches, types of error and if they were remediated. J. LANZA asked Procare if there is a plan in place to mentor pharmacy technicians when errors occur. ProCare responded that they have a process set up for technicians to learn from their mistakes and they will continue this.

<u>ACTION:</u> Motion by S. CORNACCHIO, seconded by L. GIAMBARRESI, voted unanimously by those present to approve the pilot project with the following conditions: ProCare will expand their error measurements to assess for error type, technical difficulties, and if remediated; an anonymous survey be sent to pharmacists/consultant pharmacists involved.

2. Stop and Shop DS89834 Change of Manager TIME: 9:11 AM

REPRESENTED BY: Chelsea Clifford, MOR

RECUSAL: None

<u>DISCUSSION</u>: Chelsea Clifford came before the Board as the new Manager of Record for Stop and Shop DS89834. She is not aware of any incidents or outstanding Plans of Correction at this pharmacy. Her pharmacy career at Stop and Shop began in 2017, and this will be her first position as Manager of Record. She has worked with the previous MOR. She is registered with PMP and for immunizations.

<u>ACTION:</u> Motion by L. GIAMBARRESI, seconded by J. LANZA, voted unanimously by those present to approve the application.

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Draft Minutes General Session: 12/5/19 BOP Approved: 1/9/20

3. Custom Medicine Pharmcenter DS3323 Renovation TIME: 9:15 AM

REPRESENTED BY: William Beckman, Owner & MOR

RECUSAL: None

<u>DISCUSSION</u>: William Beckman is the manager of record and presented his plan for adding a containment area for the preparation of hazardous drugs to be compliant with USP <800>. It will be a negative pressure, single-person room with minimal impact to the existing pharmacy space. The HVAC for the room will be connected to an existing exterior venting HVAC system for the primary engineering control (PEC) and secondary engineering control (SEC). Framing has started with approval from Board staff. The policies and procedures are in the process of being written by the compounding pharmacist. The construction will take 2 weeks.

<u>ACTION:</u> Motion by P. GANON, seconded by L. GIAMBARRESI, voted unanimously by those present to approve the application for renovation pending a successful inspection.

4.	MedMinder Systems DS90072	Renovation	TIME: 9:21 AM

<u>REPRESENTED BY</u>: Eran Shavelsky (CEO), Thuan Nguyen (MOR), and David Brass (Privacy and Compliance Officer)

RECUSAL: None

<u>DISCUSSION</u>: Medminder came before the Board to request approval for a renovation. The renovation is to expand the pharmacy fulfillment and inventory areas. A blueprint of the pharmacy was shown to the Board and demonstrated where three walls will be removed and where the safe is being moved to. The safe will be in an area where the pharmacists are working. More security will be added to the outside of the building.

<u>ACTION:</u> Motioned by L. GIAMBARRESI, seconded by K. TANZER, voted unanimously by those present to approve the application for renovation pending a successful inspection.

TOPIC VII

FLEX

Time: <u>9:48 AM</u>

1. Election of 2020 Board Officers

Presented by: D. Sencabaugh

Recusal: None

Discussion: Board members present by phone were D. PERRY, C. JEAN-FRANCOIS, T. FENSKY, M. GODEK.

Vote for President-Elect: Nominee 1. S. HERNANDEZ VOTE BY ROLL CALL: A. STEIN yes, S. HERNANDEZ yes, C. JEAN-FRANCOIS yes, D. PERRY yes

Vote for President-Elect: Nominee 2. J. LANZA VOTE BY ROLL CALL: K. TANZER yes, J. LANZA yes, S. CORNACCHIO yes, P. GANNON yes, Dr. R. LOPEZ yes, L. GIAMBARRESI yes, M. GODEK yes, T. FENSKY yes

FINAL VOTE: HERNANDEZ: 4 LANZA: 8

President-Elect elected for 2020: J. LANZA

Vote for Secretary:

Nominee 1. S. HAMILTON

VOTE BY ROLL CALL: P. GANNON yes, Dr. R. LOPEZ yes, S. HERNANDEZ yes, C. JEAN-FRANCOIS yes, D. PERRY yes

Nominee 2. L. GIAMBARRESI

VOTE BY ROLL CALL: A. STEIN yes, K. TANZER yes, J. LANZA, S. CORNACCHIO yes, L. GIAMBARRESI yes, M. GODEK yes, T. FENSKY yes

FINAL VOTE: HAMILTON: 5 GIAMBARRESI: 7

Secretary elected for 2020: L. GIAMBARRESI

2. ASHP Mid-Year Meeting

TIME: <u>9:45 AM</u>

Presented by: D. Sencabaugh Recusal: None

Discussion: J. LANZA was asked to speak on the practice advancement panel on Sunday December, 2019. A vote by the Board will allow J. LANZA to be able to state she is on the Board of Pharmacy in Massachusetts and take questions that she receives back to the Board.

Action: Motioned by L. GIAMBARRESI, seconded by P. GANNON, voted able to state she is on the Massachusetts Board of Pharmacy and take questions back to the Board.

TOPIC VIII	FILE REVIEW	
Case #1		
SA-INV-15415	Western MA Compounding Center, DS89965	Time: 9:48 AM

RECUSAL: NONE

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

- Probation effective 06/26/2019 06/26/2020 for compounding preparations that are essentially copies of a commercially available drug products.
- On 7/29/19, WMCC provided a list of 666 compounds prepared from 6/26/19 to 7/26/19 to the BORP in accordance with the terms of the Consent Agreement for Probation. A review of the list of compounded preparations identified compounds that were potentially copies of commercially available products. BORP staff recommended OPP Pharmacy Investigators perform a Site Visit (ISP-12883) which occurred on 8/13/19.
- On 8/22/19, WMCC was notified of the staff assignment with a request for compounding logs with corresponding prescriptions for 50 preparations that were potential copies of commercially available products and any relevant documentation obtained from providers.
- In a response received 9/16/19, MOR Sprecher stated the "FDCA does not outright ban compounding of drug products that are essentially copies of commercially available drug products, only that such compounding shall not occur routinely, in 'regular or inordinate amounts'". Additionally, "the FDA unequivocally states that the whole of section 503(A), itself, does not apply to drugs compounded for animals". Of note, the requirements of USP 795 applies to humans and animals and MGL 112 39D(a)(1) defines the parameters of compounding related to commercially available products. MOR Sprecher contended that veterinary drugs are not available to retail pharmacies; therefore, if he received a prescription for an animal, it would be reasonable to assume the intention of the veterinarian was the medication was to be compounded.
- 14 of 17 compounds for veterinary preparations and 12 of 23 compounds for human preparations (26 total of 50) were identified as potential copies of commercially available drug products; all veterinary compounds used API which is not permitted per 21 CFR 530.13.
- A formal evaluation process was implemented to avoid routinely compounding drugs that are essentially copies of commercially available drugs. The new SOP states, "The pharmacist must make a reasonable effort to determine the commercial availability of a drug product before he or she compounds a replacement preparation and also determine whether the compounded drug is essentially a copy of a commercially available drug. According to FDA guidance, section 503A does not apply to prescriptions for animal patients".

<u>ACTION</u>: Defer Action on SA-INV-15415 while more information is being gathered and reviewed. While this is being done, to send out a notification reminder to DS89965 regarding the conditions for compounding copies of commercially available products.

Case #2 PHA-2019-0084

CVS #669, DS2846

Time: 10:06 AM

<u>RECUSAL</u>: S. CORNACCHIO recused and was not present for the discussion or vote on this matter.

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

- Untimely RLCS on 8/5/19 for an unknown loss of #728 lorazepam 1 mg tablets and #494 lorazepam 1 mg tablets for 2 NDC numbers discovered on 06/12/2019 via corporate controlled substance monitoring.
- MOR Heang stated that loss prevention performed multiple reconciliations but the reason for the loss could not be identified. Security camera footage was reviewed and was inconclusive. A copy of the reconciliation report for lorazepam 1 mg tablets indicated the balance on hand (BOH) for both NDC numbers was zero on 05/01/2018, the date of the 2018 CIII-CV annual inventory which was used as the start date of the audit.
- In the response, MOR Heang stated the 2019 CIII-CV annual inventory was used for the internal audit which contradicted the reconciliation report. Reconciliation reports for all NDC numbers of lorazepam 1mg tablets confirmed the losses were based on the 2018 CIII-CV annual inventory and there were no further active losses based on the 2019 CIII-CV annual inventory.
- CA: All pharmacy staff reviewed the policy and procedure for the proper handling of regarding 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. MOR Heang will sign off on the BOH modification report and will follow up on any large discrepancies of controlled substance with loss prevention. Cycle counts will be completed daily for system prompted cycle counts and an official monthly count is completed as a loss prevention measure as well as to ensure compliance with MA rules and regulations. Only pharmacists are to review and conduct cycle counts of controlled substances.

<u>ACTION</u>: Motion by P. Gannon, seconded by J. Lanza, and voted unanimously by those present, to refer the matter (PHA-2019-0084) 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 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 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 #3 PHA-2019-0091

CVS #382, DS89637

Time: 10:09 AM

<u>RECUSAL</u>: S. CORNACCHIO recused and was not present for the discussion or vote on this matter.

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

• RLCS on 9/6/19 an untimely report of an unknown loss of #475 lorazepam 0.5 mg tablets discovered on 6/17/19 while completing cycle counts. MOR Keough stated the untimely submission was due to

her being out of the pharmacy so she was unable to complete the reporting requirements prior to conducting her investigation.

- The internal investigation included daily counts of each NDC of lorazepam which CVS Loss Prevention then reviewed and conducted reconciliations. The reconciliations were reviewed along with the 2018 and 2019 CIII-CV annual inventories.
- Video footage of the warehouse delivery order being put away which showed a bottle of 500 tablets being checked in and placed on the shelf. The variance occurred between 06/11/2019 and 06/15/2019 but from video footage, no evidence of diversion was present. The cause of the loss could not be determined.
- Copies of letters of continuation dated 07/16/2019 and 08/14/2019 addressed to the DEA were provided which showed "CC" to the BORP. These letters were not received by the BORP.
- CA: MOR Keough reviewed best practices and regulations regarding the timely submission of controlled substance losses. Controlled substance inventory best practices were reviewed with the pharmacy team. All pharmacy staff completed training modules on the proper handling of controlled substances and signed off on relevant policies and procedures. 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.

<u>ACTION</u>: Motion by P. Gannon, seconded by K. Tanza, and voted unanimously by those present, to refer the matter (PHA-2019-0091) 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 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 #4 PHA-2019-0093 CVS #2161, DS2832 Time: 10:18 AM

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

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

- RLCS on 9/5/19 for an untimely, unknown loss of #528 tramadol 50 mg tablets identified on 06/12/2019 via corporate controlled substance monitoring as a variance. The untimely reporting was due to miscommunication during a change of the District Leader and the MOR for the Pharmacy.
- An investigation included twice daily cycle counts for the NDC at the opening and closing of the Pharmacy and review of all inventory cycle counts, orders, and returns of the drug since the previous CIII-CV annual inventory. Security footage was reviewed but was inconclusive. The cause of the loss was not determined.
- Letters of continuation dated 07/11/2019 and 08/09/2019 were sent to the DEA but not the BORP.
- CA: All Loss Prevention policies and procedures were reviewed with the pharmacy team to prevent future losses. The best practice of double counting all controlled substances has been strictly

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Draft Minutes General Session: 12/5/19 BOP Approved: 1/9/20 enforced. All controlled substances are double counted by the individual at production and the quantity is circled and initialed on the prescription to indicate to the verifying pharmacist that it has been double counted, per CVS policy. A copy of that policy (CVS ROPP-05970), signed and dated by all pharmacy staff was provided. More diligent inventory management and daily bag/smock checks have also been conducted.

<u>ACTION</u>: Motion by P. Gannon, seconded by K. Tanzer, and voted unanimously by those present, to refer the matter (PHA-2019-0093) 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 #5 PHA-2019-0098 CVS #5493, DS89634 Time: 10:31 AM

<u>RECUSAL</u>: S. CORNACCHIO recused and was not present for the discussion or vote on this matter.

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

- Untimely RLCS for an unknown loss of #322 buprenorphine/naloxone 8/2 mg tablets identified on 7/15/19 via corporate controlled substance monitoring.
- An internal investigation was conducted including employee interviews but the cause of the loss was not determined. Security footage was not reviewed and there was no current loss.
- Documentation with varying discrepancies was provided including the initial reconciliation for 5/1/18 to 8/12/19 showing -322; a reconciliation from 5/1/19 to 7/16/19 showing +60; and cycle counts from 5/3/18 to 10/17/19 showing overall -130. No explanation was given for the additional discrepancies. Exact counts were performed for the CIII-CV annual inventories on 5/1/18 and 5/1/19. A letter of continuation dated 08/14/2019 was filed with the DEA but was not received by the BORP.
- CA: The waiting bin was reorganized. 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. MOR Yann indicated she is completing official monthly count as a preventive measure and to ensure compliance with MA laws and regulations. The Pharmacy will continue to complete system prompted cycle counts weekly which will be signed off by another pharmacist.

<u>ACTION</u>: Motion by P. Gannon, seconded by K. Tanzer and voted unanimously by those present, to refer the matter (PHA-2019-0098) 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 Buprenorphine-Naloxone containing products for 12 months, staff retraining in the areas of inventory management, prescription production,

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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.

Topic IX Read by A. Stein	EXECUTIVE SESSION	Time: 10:34 AM
-		
DISCUSSION: ACTION: At 10:34 AM Pre	esident A. Stein read the statement on reasons fo	r Executive Session.
Topic IX: By: A. Stein	Executive Session Call to Order:	Time: 1:34 PM
<u>ACTION</u> : Motion by J. Lar meeting of the Executive	nza seconded by L. Giambarresi, and voted unanir Session to order.	mously by roll call to call the
	tein, yes; K. Tanzer, yes; J. Lanza, yes; S. Hernande mbarresi, yes; R. Lopez, yes.	ez, yes; P. Gannon, yes;
Topic X:	Adjudicatory Session (M.G.L. ch 30A § 18	i) Time: 4:05 PM
DISCUSSION: None ACTION: President A. Ste	in request a motion to enter Adjudicatory Sessior	٦.
At 4:05 PM L. Giambarres Adjudicatory Session:	si, seconded by J. Lanza and voted unanimously b	y all those present to enter
Topic XI:	M.G.L. 65 C #1	Time: 10:42 AM
DISCUSSION: None ACTION: President A. Ste	in request a motion to enter M.G.L 65 c Session.	
At 2:04 PM J. Lanza, seco chapter 65 c Session:	onded by K. Tanzer and voted unanimously by all t	those present to enter M.G.L.
Topic XII	ADJOURMENT OF MEETING	TIME: 4:10 PM
ACTION: Motion by J. Lar from General Session.	nza seconded by K. Tanzer and voted unanimously	y by those present, to adjourn
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EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

- 1. Draft Agenda of the 12/5/19 General Session
- 2. Draft Minutes of the 11/7/19 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. Advisory on implementation of USP <800> in community pharmacies
- 9. Advisory regarding animals in the pharmacy
- 10. Applications: ProCare DS90042 Pilot Project
- 11. Applications: Stop and Shop DS89834 Change of Manger
- 12. Applications: Custom Medicine Pharmacenter DS3323 Renovation
- 13. Applications: Medminder Systems DS90072 Renovation
- 14. SA-INV-15415 Western MA Compounding Center, DS89965
- 15. PHA-2019-0084 CVS #669 DS2846
- 16. PHA-2019-0091 CVS #382 DS89637
- 17. PHA-2019-0093 CVS #2161 DS2832
- 18. PHA-2019-0098 CVS #5493 DS89634

Respectfully Submitted, Leah Giambarresi, PharmD, RPh Secretary