

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

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

August 2, 2018  
239 Causeway Street ~ Room 417 A&B  
Boston, Massachusetts 02114

**PLEASE NOTE: For this Board meeting only, the Board will open its meeting at 8:30am and immediately enter closed session. The remainder of the open session will begin at 11:00 am. The Board will not discuss matters in Reports, Flex, File Review, Applications, or Regulations prior to 11:00 am.**

*If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Beth Rabasco, Phone: 617-624-5291 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**

<b>Time</b>	<b>#</b>	<b>Item</b>	<b>Page</b>	<b>Contact</b>
<b>8:30</b>	<b>I</b>	<b>CALL TO ORDER</b>		M. Godek
	<b>II</b>	<b>APPROVAL OF AGENDA</b> <ul style="list-style-type: none"> <li>• Introduction of Interns: Northeastern Mathieu Larouche</li> <li>• Introduction of new Board member</li> </ul>		
	<b>III</b>	<b>APPROVAL OF BOARD MINUTES</b> <ul style="list-style-type: none"> <li>• Draft of June 28, 2018 Regular Session Minutes</li> </ul>	3	
<b>8:40</b>	<b>IV</b>	<b>EXECUTIVE SESSION</b> The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Specifically, review requests for reinstatement and to evaluate the Good Moral Character as required for registration for pending applicants.	199	CLOSED SESSION
<b>10:00</b>	<b>V</b>	<b>M.G.L. c. 112, § 65C SESSION</b>	383	CLOSED SESSION

11:00	VI	<b>REPORTS</b>		
		<ul style="list-style-type: none"> <li>• Applications approved pursuant to Licensure Policy 13-01</li> </ul>	22	R. Harris
		<ul style="list-style-type: none"> <li>• Monthly report from probation</li> </ul>	24	K. Fishman
		<ul style="list-style-type: none"> <li>• Board Delegated Complaint Review pursuant to licensure policy 14-02</li> </ul>		M. Botto
		<ul style="list-style-type: none"> <li>• Above Action Levels approved by Staff Action 16-04</li> </ul>	25	K. Morton
11:10	VII	<b>FLEX</b>		
		<ul style="list-style-type: none"> <li>• APhA Institute on Alcoholism &amp; Drug Dependencies</li> </ul>		C. Jean-Francois
		<ul style="list-style-type: none"> <li>• Pharmacy Technician in Training License Update</li> </ul>		M. Botto
		<ul style="list-style-type: none"> <li>• NABP Resolutions and Updates</li> </ul>		T. Fensky
		<ul style="list-style-type: none"> <li>• Public Comment for USP General Chapter &lt;795&gt;</li> </ul>		
11:15	VIII	<b>FILE REVIEW</b>		
		1 PHA-2018-0038- CVS #301- DS89652	40	
		2 SA-INV-13113- CVS #2322- DS2827	43	
		3 PHA-2018-0016- Smith Drug- DS2198	46	
		4 SA-INV-12933- Galaxy Pharmacy- DS90030	52	
12:00		<b>LUNCH BREAK</b>		
1:00	IX	<b>APPLICATIONS</b>		
		<ul style="list-style-type: none"> <li>• Pharmscript of MA (DS90251) – Renovation/Expansion</li> </ul>	56	
		<ul style="list-style-type: none"> <li>• PharmaLuxe Pharmacy – New Community Pharmacy</li> </ul>	102	
		<ul style="list-style-type: none"> <li>• SavCare Health-New Community Pharmacy</li> </ul>	117	
		<ul style="list-style-type: none"> <li>• Bravo Pharmacy (DS89981) – Renovation/Expansion</li> </ul>	133	
		<ul style="list-style-type: none"> <li>• Genoa Healthcare/Quincy New Community Pharmacy with Waivers</li> </ul>	140	
		<ul style="list-style-type: none"> <li>• Brown’s Rexall Drug (DS1240) – Transfer of Ownership</li> </ul>	164	
<ul style="list-style-type: none"> <li>• Partners Pharmacy of MA, LLC (DS3419)- Petition to Waiver</li> </ul>	176			
		<ul style="list-style-type: none"> <li>• Walgreens Pharmacy 10375 (DS3527) – Change of Manager</li> </ul>	188	
1:45	X	<b>REGULATIONS</b>		
		<ul style="list-style-type: none"> <li>• 247 CMR 22.00: Fines (proposed new regulation)</li> </ul>		
		<ul style="list-style-type: none"> <li>• 247 CMR 17.00: Sterile Compounding (proposed new regulation)</li> </ul>		
5:00	XI	<b>ADJOURNMENT</b>		

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

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

**August 2, 2018**

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**Board Members Present**

Michael Godek, RPh. President  
Andrew Stein, Pharm D, RPh. President Elect  
Susan Cornacchio, JD, RN,  
Patrick Gannon, RPh  
Julie Lanza, CPhT  
Leah Giambarresi, Pharm D, RPh  
Dawn Perry, JD  
Timothy Fensky, RPh  
Ali Raja, MD, MBA, MPH  
Carly Jean-Francois, RN, NP  
Sebastian Hamilton, MBA, Pharm D, RPh

**Board Members Not Present**

Stephanie Hernandez, Pharm D, BCGP, RPh  
Kim Tanzer, PharmD, RPh. Secretary

**Board Staff Present**

David Sencabaugh, RPh, Executive Director  
Monica Botto, CPhT, Associate Executive Director  
Heather Engman, JD Board Council  
William Frisch, RPh Director of Pharmacy Compliance  
Joanne Trifone, RPh., Director of Pharmacy Investigations  
Kimberly Morton, CPhT, Compliance Officer  
Greg Melton, JD, PharmD, BCPS, RPh, Investigator  
Julienne Tran, Pharm D, RPh Investigator/Quality Assurance Pharmacist  
Christina Mogni, RPh Investigator  
Joseph Santoro, RPh Investigator  
Richard Harris, Program Analyst

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**TOPIC I.**

**CALL TO ORDER: 8:33AM** by M. GODEK

**DISCUSSION:** A quorum of the Board was present, established by a roll call. President M. GODEK chaired the meeting and asked if anyone was recording. Hearing “no”, he explained that the Board of Pharmacy was recording the meeting

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**TOPIC II.**

**Approval of Agenda**

**Time: 8:34AM**

**Agenda: August 2, 2018**

DISCUSSION: None

ACTION: Motion by L GIAMBARRESI, seconded by T. FENSKY, and voted unanimously to approve the agenda

Executive Director D. SENCABAUGH introduced new Board Member S. HAMILTON and thanked P. BOUVIER for his service, wishing him well with retirement. D. SENCABAUGH also introduced APPE Intern M. LAROCHE and M. GODEK asked other interns in the audience to stand up and introduce themselves

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**Topic III**

**Approval of Board Minutes**

**Time: 8:37AM**

**Draft: June 28, 2018 Regular Session Minutes**

DISCUSSION: None

ACTION: Motion by P. GANNON, seconded by L. GIAMBARRESI, and voted affirmatively to approve, with S. HAMILTON, C. JEAN-FRANCOIS, D. PERRY, and A. RAJA abstaining, as they were not present at the June meeting.

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**Topic IV:**

**EXECUTIVE SESSION**

**Time: 8:38 AM**

**Read by M.GODEK**

DISCUSSION:

ACTION: At 8:38 AM President M. GODEK read the statement on reasons for Executive Session.

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**Topic IV:**

**Executive Session Call to Order:**

**Time: 8:39 AM**

By: M. GODEK

ACTION: Motion by P. Gannon, seconded by T. Fensky, and voted unanimously by roll call to call the June 28, 2018 meeting of the Executive Session to order.

M. GODEK; yes, S. CORNACCHIO; yes, T. FENSKY; yes, S. HAMILTON; yes, A. RAJA, yes;  
P. GANNON; yes, J. LANZA; yes, D. PERRY, yes; L. GIAMBARRESI, yes; A. STEIN, yes;  
C. JEAN-FRANCOIS, yes

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**Topic V:**

**M.G.L. 65 C**

**Time: 10:15AM**

DISCUSSION: None

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

At 10:15 PM, Motion by P. Gannon, seconded by L. Giambarresi and voted unanimously to enter M.G.L. chapter 65 c Session:

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**TOPIC VI**

**REPORTS**

**Time: 11:05AM**

Applications approved pursuant to Licensure Policy 13-01

PRESENTED BY: R. HARRIS

DISCUSSION: R. HARRIS noted that during the past month there have been thirty-four (34) changes of manager on record (MOR) and one (1) renovation expansion applications approved pursuant to Licensure Policy 13-01.

So noted

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**TOPIC VI**

**REPORTS**

**Time: 11:05AM**

Monthly Report from Probation

PRESENTED BY: D. SENCABAUGH and M. BOTTO

DISCUSSION: M. BOTTO provided the June 1, 2018 – July 25, 2018, Board of Pharmacy Statistics Report for the Probation monitor, which noted that there are currently forty-eight (48) licensees on probation. One (1) licensee was given the opportunity to cure and four (4) licensees satisfactorily completed probations.

So noted

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**TOPIC VI**

**REPORTS**

**Time: 11:05AM**

Monthly Report from BDCR pursuant to Policy 14-02

PRESENTED BY: M. BOTTO

DISCUSSION: There were four (4) Board Delegated Review cases heard on July 30, 2018. Three cases were CE deficiencies (SA-INV-13496, SA-INV-13475, and SA-INV-12680) which were closed with no discipline warranted and remediation complete. One case was a failure to fill a prescription properly (SA-INV-12559) which was closed with no discipline warranted and remediation complete. The Board Delegated Review session was attended by M. GODEK as the Board Member, W. FRISCH Director of Pharmacy Compliance, H. ENGMAN as Board Counsel, and Executive Director D. SENCABAUGH.

So noted

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**TOPIC VI**

**REPORTS**

**Time: 11:05AM**

Above Action Levels Approved by Staff Action 16-04

PRESENTED BY: K. MORTON

DISCUSSION: K. MORTON reported that there were four (4) above action level reports. All reports had been successfully remediated and closed

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**1. APhA institute on Alcoholism & Drug Dependencies**

PRESENTED BY: C. JEAN-FRANCOIS

DISCUSSION: The conference was very eye-opening, especially in regard to the stigma people have towards addiction to alcohol and drugs and she has used the information that she learned to help educate other colleagues at her institution. It is highly recommended any interested Board members attend the next conference.

**2. Pharmacy Technician in Training License Update**

Time: 11:10AM

PRESENTED BY: M. BOTTO

DISCUSSION: She indicated that there are 2,552 applicants licensed in the state. R. HARRIS noted that he receives on average about 40 applications weekly.

**3. NABP Resolutions and Updates**

Time: 11:12AM

PRESENTED BY: D. SENCABAUGH and T. FENSKY

DISCUSSION: T. FENSKY mentioned that NABP published a white paper on white and brown bagging. Last year, he attended the meeting along with L. GIABARESSI and M. GODEK.

He noted that the next NABP conference to be held in Washington DC for Districts 1 and 2 (Northeast and Mid-Atlantic). Recommend all Board members to consider going and will need to send a delegate. NABP meeting is an excellent opportunity to bring issues to NABP for comment and guidance. Additionally, consider bringing forth some proposed resolutions for the upcoming meeting.

D. SENCABAUGH noted that J. TRIFONE, E. TAGLIERI, K. TANZER, S. HERNANDEZ, and former board members, Donna Horn and Karen Ryles were appointed to various NABP Task Forces.

**4. USP <795> Public Comments Submission**

Time: 11:16AM

PRESENTED BY: W. FRISCH

DISCUSSION: He stated that at the last meeting, the Board Authorized Board Staff to submit public comments on behalf of the Board. Board Staff provided comments on the categories of compounding, compounding for animal patients, training, patient counseling, personnel qualifications, personal hygiene and garbing, buildings and facilities, cleaning and sanitizing, equipment and components, SOPS and Master formulation and compounding records, labeling, establishing beyond-use-dates, adverse event reporting and documentation. Full comments on each section are provided in the board packet and will be available on the board's website.

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**TOPIC VIII**

**FILE REVIEW**

**1. PHA-2018-0038**

**CVS #301, DS89652**

**Time: 11:18PM**

**Presented by:** J. SANTORO

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

DISCUSSION:

- Reported loss of controlled substances- #444 clonazepam 1mg tablets and #404 lorazepam 1mg tablets discovered missing during corporate monitoring on or about February 13, 2018 and March 13, 2018, respectively.
- MOR Sheehan provided reconciliation reports for both the lorazepam 1 mg and clonazepam 1mg tablets from the Biennial/Annual Inventory taken on May 1, 2017 to April 22, 2018.
- An investigation was conducted and after review of the perpetual inventory logs, dispensing reports, warehouse deliveries, and outside vendor deliveries, a reason for the loss could not be confirmed
- Pharmacy will review BOH modification reports, ordering and cycle count activity in sufficient detail to quickly identify and prevent drug count discrepancies or diversion. Lorazepam 1 mg tablets will be removed from automation to prevent any inaccurate counts when dispensing. The team was reminded to double count all controlled medication prior to dispensing to reduce any miscounts. In addition, during all inventories, the pharmacist on duty will be responsible for a double check on all controlled substances most commonly dispensed and prescriptions in the waiting bin to accurately count all medications. MOR indicated that technicians were retrained on the proper procedures in handling damage/outdates to prevent inaccuracies and reviewed all baseline loss prevention procedures with the staff, specifically those that prevent drug diversion.

ACTION: Motion by P.GANNON, seconded by L.GIAMBARRESI, and voted on unanimously to refer 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 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.

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**2. SA-INV-13113**

**CVS #2322, DS2827**

**Time: 11:21PM**

**Presented by:** J. TRAN

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

DISCUSSION:

- RLCS- #100 Focalin XR 5mg capsules due to an alleged manufacturer shortage.
- The loss was discovered on January 4, 2018 when staff pharmacist Nguyen opened a sealed stock bottle of Focalin XR 5mg capsules, removed the desiccant, and found that no capsules had been included in the bottle by the manufacturer. The loss was not reported to the manufacturer.
- MOR Among viewed video footage which verified the staff pharmacist's account.

- District Leader Friedman indicated that the staff will continue to keep detailed records of perpetual inventories for schedule II medications and report any potential losses immediately. In addition, unsealing all full stock bottles during perpetual inventory and counting contents.
- The pharmacy has had 5 prior losses since 2013.

ACTION: Motion by T. FENSKY, seconded by L.GIAMBARRESI, and voted unanimously to close the staff assignment with no discipline warranted, contingent upon the pharmacy reporting the shortage to the manufacturer.

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**3. PHA-2018-0016**

**Smith Drug, DS2198**

**Time: 11:25AM**

PRESENTED BY: C. MOGNI

RECUSAL: None

DISCUSSION:

- Inspectional deficiencies (ISP-9094) on 3/5/18 for lack of a naloxone standing order, incomplete controlled substance recordkeeping, utilizing medications dispensed from other pharmacies in specialty multi-dose packaging, discontinued medications co-mingled with patient's active medications in the patient boxes, failure to consistently record refrigeration temperatures (repeat deficiency), out of range refrigeration temperatures, expired progesterone powder and suppositories in the pharmacy, and non-compliance of labeling for medications in specialty multi-dose packaging.
- The Pharmacy has approximately 400 patients on a specialty multi-dose packaging system with approximately 140 patients using Dis-pill as of 3/5/18; MOR/Owner Fournier stated she has been transitioning patients to Dis-pill (noted on previous inspection). The Pharmacy also dispenses medications with non-compliant labeling in daily planners and cold-sealed blister cards.
- The Pharmacy was notified of the complaint on 3/30/18.
- In an untimely POC received on 4/17/18, MOR/Owner Fournier remediated the lack of a naloxone standing order, incomplete controlled substance recordkeeping and retrained staff regarding refrigeration monitoring.
- MOR/Owner Fournier did not adequately address remediating all deficiencies and indicated the Pharmacy would continue to fill specialty multi-dose packaging with medications filled at other pharmacies.
- In an untimely response to the complaint received 05/25/18, MOR/Owner Fournier stated it was never her intent to violate any statutes and she has always put her patients first. MOR/Fournier explained the rationale for re-dispensing medications was due to the insurance declining such claims due to early refill rejections and it is wasteful to not use medications the patient has already paid for.
- Re-inspection (ISP-10060) on 7/17/18, the Pharmacy was cited for inaccurate and incomplete controlled substance recordkeeping, improper disposal of controlled substances (disposing via local police department Take-Back box), not properly securing controlled substances, outdated API in the backroom of the Pharmacy, non-compliant labeling of daily planners and cold-sealed blister cards, and no documentation of authorization to dispense medications in non-safety closures i.e. daily



planners. Only approximately 175 of 400 patients have been converted to Dis-pill with compliant labeling.

- On 7/18/18 Board staff recommended the Pharmacy discontinue the use of non-compliant labeling and packaging and no longer accept medications dispensed from other pharmacies for re-packaging in multi-dose packaging.
- On 7/19/18, MOR Fournier agreed to the Board Staff's recommendations and stated she intended to convert the majority of the multi-dose packaging to Dis-pill by the end of the following week (7/28/18).

ACTION: Motion by A. STEIN, seconded by P. GANNON, and voted unanimously to defer decision until the September 5, 2018 board meeting pending secondary inspection

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**4. SA-INV-12933**

**Galaxy Pharmacy, DS90030**

**Time: 11:32AM**

PRESENTED BY: G. MELTON

RECUSAL: None

DISCUSSION:

- On 2-2-18, POC issued after retail inspection (ISP-8729) found biennial inventory outdated, no naloxone SO, and no immunization SO. Galaxy completed a biennial inventory and obtained a naloxone SO to remediate.
- However, Galaxy was unable to find the hard copy of the immunization SO signed in 09-17 and the physician that originally authorized the immunization SO stated he only intended authorized immunizations for two of his patients and d/c'd the order as a result in 02-18. Copy of authorization unable to be provided by pharmacy or physician. Galaxy chose to stop immunizing until a replacement standing order could be obtained. However, the pharmacy has not replaced the order as of this report.

ACTION: Motion by P. GANNON, seconded by A. STEIN, and voted unanimously to close staff assignment, no discipline warranted, and remediation already completed

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**Lunch:**

**Time out: 11:36AM**

**Time back: 1:00PM**

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**TOPIC IX**

**APPLICATIONS**

**1. Pharmscript of MA, DS90251 Renovation/Expansion**

**TIME: 1:00PM**

RECUSAL: None

DISCUSSION: Pharmscript of MA located in Marlborough, MA, was represented by Brett Gancarz (MOR), Justin Fink (Regional Manager) and Anthony Tiknor (QleanAir Scandinavia Production Engineer). Pharmscript was expanding their pharmacy space into an adjacent warehouse and building a clean room. Anthony Tiknor responded to the Board's inquiries regarding the specifications of the clean room to their satisfaction. MOR has demonstrated proper experience with sterile compounding

and conveyed adequate plans for hiring and training proper IV room staff. Pharmscript anticipated that the construction phase will take about 10 weeks in all with the room itself built in about 2 weeks.

ACTION: Motion by T. FENSKY, seconded by L. GIAMBARRESI, and voted unanimously to approve the application for Pharmscript of MA to start renovation/expansion

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**2. PharmaLuxe Pharmacy**

**New Community Pharmacy**

**TIME: 1:15PM**

RECUSAL: None

DISCUSSION: PharmaLuxe Pharmacy located Roxbury, MA, was represented by Michael McNamara (owner, RPh.) and Jessica Andrade (MOR). They responded to the Board's questions to their satisfaction. MOR stated she would not be PIC once the pharmacy opened and the pharmacy would come back to the Board for a change in MOR. The pharmacy would be conducting simple non-sterile compounding.

The owner indicated having one pharmacist and one technician to work initially and increase staff as the business grew. They will not offer immunizations to start but will have blister-seal packaging for compliance. They will offer delivery service and outsource medium-risk compounding.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously to approve the application for PharmaLuxe Pharmacy, pending successful inspection

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**3. Save Care Health**

**New Community Pharmacy**

**TIME: 1:25PM**

RECUSAL: None

DISCUSSION: Save Care Health located in Foxborough, MA, was represented by Shivang Patel (MOR). Mr. Patel responded to the Board's questions to their satisfaction. Mr. Patel already is a part-time owner of MetroWest Pharmacy in Framingham, MA. Mr. Patel was reminded that since his business partners were not RPh's, they should have no control in the daily operations of the pharmacy. Mr. Patel would staff the pharmacy six days a week. M. GODEK indicated that he should consider hiring another pharmacist to help staff with him in case of emergency.

ACTION: Motion by T. FENSKY, seconded by P. GANNON, and voted unanimously to approve the application for the new Save Care Health, pending successful inspection

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**4. Bravo Pharmacy, DS89981**

**Renovation/Expansion**

**TIME: 1:31PM**

RECUSAL: None

DISCUSSION: Bravo Pharmacy located in Jamaica Plain, MA, was represented by Donald Burns (MOR) and Dimitry Linkiv (Owner). Bravo Pharmacy is applying to expand into the business next door that they have acquired. The renovation would include adding security measures to the space next door and adding a door into the wall connecting the two spaces. The Board demonstrated concern on the security of the new space and the ability for the pharmacist to supervise pharmacy staff while attending their duties. The Board recommended adding security cameras to blind spots, and possibly adding windows between the new space and old dispensing area. The MOR and Owner were very receptive of these new ideas and would like to implement more security cameras to ensure security and prevention of diversion.

ACTION: Motion by P. GANNON, seconded by S. HAMILTON, and voted unanimously to approve Bravo Pharmacy's application contingent on satisfactory monitoring of the new space and successful inspection.

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**5. Genoa Healthcare/Quincy**

**New Community Pharmacy with Waivers**

**TIME: 1:55PM**

RECUSAL: None

DISCUSSION: Genoa Healthcare in Quincy, MA, was represented by Kevin O'Connell (Director of Operations) and was applying for a new closed-door pharmacy with the following waivers:

- 247 CMR 6.02 (5) – Signage
- 247 CMR 9.01 (15) – Limited Services
- 247 CMR 6.01 (5)(a)(8) – OTC Medications
- 247 CMR 9.01 (16) – Compounding
- 247 CMR 6.01 (5)(a)(4) – Compounding Scales
- 247 CMR 6.02 (4) – Compounding Chemicals

Genoa Healthcare was requesting these waivers due to the closed-door nature of their pharmacy within a specialized mental and behavioral health center with no intentions of performing compounding. Genoa Healthcare answered all the Board's questions to their satisfaction

ACTION: Motion by T. FENSKY, seconded by L. GIAMBARESSI, and voted unanimously to approve Genoa Healthcare's application with waivers pending successful inspection

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**6. Brown's Rexall Drug, DS1240 Transfer of Ownership**

**TIME: 1:58PM**

RECUSAL: H. ENGMAN

DISCUSSION: Brown's Rexall Drugs was represented by John Ofilos (Attorney and one of proposed managers of the new limited liability company purchasing Brown's Rexall Drug, DS1241) regarding a transfer of ownership. Mr. Ofilos answered all the Board's questions to their satisfaction. The current owner of Brown's Rexall Drug, DS1240, has passed away and was on probation. John and Jeanine Ofilos are relatives of the deceased and have set up a new limited liability company, Brown's Pharmacy LLC, to purchase and operate the pharmacy. Board made a comment on amending application to correct pharmacist's license numbers to include "PH" and not "PM" as well as amending the schedules of medications to be dispensed. Mr. Ofilos stated that all current staff will remain the same and this is a straight transfer of ownership. The new owner's goal is to run the pharmacy within compliance. Probation would end on DS1240 with the sale being finalized.

ACTION: Motion by L. GIAMBARESSI, seconded by P. GANNON, and voted unanimously to approve the transfer of ownership.

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**7. Partners Pharmacy, DS3419 Pilot Project Update/Expansion  
Petition to Waiver**

**TIME: 2:00PM**

RECUSAL: None

DISCUSSION: Partners Pharmacy was represented by Derek Corniveau (Director of Pharmacy), Nicholas Brunett (MOR) and Jodie Fenelon (Director of Compliance) regarding an update and request to expand their deployment of the AP Passport automated dispensing machine. They have currently completed Stage I, II, and III of the pilot program and would like to start Stage IV which includes deploying two machines each month. The Board demonstrated some concern on deploying two machines a month when the institutions that would receive these machines were undetermined at this point. The Board was impressed by the accuracy record at this point and did not have any concerns with safety. If an error is detected, the RN would send in a form to the pharmacy, but no forms have been sent yet. P. GANNON stated that he did not personally feel that two machines a month was particularly aggressive and would feel that it was an achievable goal. Partners Pharmacy mentioned that they would be limited to a maximum of two machines a month due their use of an implementation team that was separate from pharmacy staff. D. SENCABAUGH offered agenda time in meetings so that Partners Pharmacy could quickly get approval when they determined which institute they were working.

ACTION: Motion by T. FENSKY, seconded by P. GANNON, and voted unanimously to approve commencement of Stage IV contingent upon maximum of 2 machines/month and disclosure of facility names.

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**8. Walgreens Pharmacy 10375, DS3527Change of Manager**

**TIME: 2:19PM**

RECUSAL: M. GODEK

DISCUSSION: New MOR Salvatore Mellace was present for discussion. MOR has previous experience as a manager of a pharmacy at a Rite-Aid in Dartmouth, MA and a Walgreens in Yarmouth, MA. Mr. Mellace answered the Board's questions to their satisfaction

ACTION: Motion by S. HAMILTON, seconded by L. GIAMBARESSI, and voted unanimously to approve change of MOR.

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**TOPIC X**

**REGULATIONS**

**TIME: 2:32 PM**

**1. 247 CMR 22.00 Fines (proposed new regulations)**

**Presented by: W. FRISCH and J. TRAN**

**Discussion:**

- B. FRISCH provided background on where 247 CMR 22 stands in terms of the process of promulgating the regulations;
- Today looking for feedback on the Staff Action Policy and the Fining Matrix;
- B. Frisch responded to Board Member P. Gannon's recommendation from the last Board meeting to seek benchmarks from NABP or other states. B. Frisch indicated that NABP did not have any;
- Staff Action Policy discussed-B. Frisch described that the policy allows staff action to issue the fine based on clearly provided (objective) guidelines.
- No vote required today;
- Board member T. FENSKY asked who would be on the assessment team. B. Frisch indicated that it was not yet determined but may be a makeup similar to the Board Delegated Review team (which includes one Board Member);
- Board Member M. GODEK indicated that he would like to see it consist of more than the makeup of BDR team, specifically to include Board Members from both retail (chain/independent/LTC) as well as hospital;
- Executive Director, D. SENCABAUGH pointed out that the guidelines in the policy are objective and that a lot of background work has been done in preparing the matrix;
- B. FRISCH reviewed the matrix with Board Members. M. GODEK asked for an example of a Level I inspectional deficiency. Board Member D. PERRY asked how they arrived at the inspectional deficiency threshold;
- It was indicated that the matrix was a tool for continuous noncompliance issues. Board Members requested a soft rollout (grace period);
- Executive Director, D. SENCABAUGH reminded Board Members that the regulation would go out for public comment;
- B. FRISCH indicated that Compliance Office K. MORTON reviewed a few Plans of Correction from recent inspections and tabulated the proposed fine. The 2 examples added up to a \$2000 and \$5000 fine;
- New Board Member, Sebastian Hamilton spoke to his experience with fining as a previous Board Member in Delaware;
- D. SENCABAUGH stated that a notification of the fine would be sent to licensee and there would be an appeal process;
- Board Counsel, H. ENGMAN indicated the fines would be limited to evidence that is clear cut, with documentation;

- It was stated that Continuing Education deficiencies is the only reason an individual licensee can be fined (max \$1000);
- Board Member, P. GANNON asked if the Board would be determining the fine for the “one offs” not included in the matrix;
- B. FRISCH stated that Board Staff is continuing to work on this. He asked Board Members to think about the matrix and the fining amounts. Board Staff will send out a survey to Board Members to get anonymous feedback and aggregate the results then report back to the Board at the September Board meeting.

**2. 247 CMR 17.00 Sterile Compounding (proposed new regulations) Time: 3:01PM**  
**Presented by: W. FRISCH and J. TRAN**

**Discussion:**

- Board Counsel, H. ENGMAN stated that following the public hearing/public comment period the Board has an obligation to review and respond. H. ENGMAN stated she went through all the public comment in detail and created a grid with summary/paraphrasing, pulling out the salient points. H. ENGMAN encouraged all Board Members to read all the comments which are on the Board’s website. Today only a portion of the grid/comments was distributed to Board Members;
- B. FRISCH indicated this was the first attempt to go through the public comments. There were a lot of comments requesting waiting until <797> came out and to align with <797> based on evidence based practice, its effect on the ability to operate as well as the significant capital expense;
- B. FRISCH indicated that a lot effort was put into reviewing the public comments and an effort is being made to strike a good balance. It is a lengthy process to get through the amount of public comment and get Board Members feedback;
- B. FRISCH stated that the concept of a Segregated Compounding Area (SCA), meaning an unclassified compounding area with a hood, prompted a lot of public comment. Draft 247 CMR 17 abolished the option of a SCA and replaced it with Designated Compounding Room (DCR), Board Staff heard the comments of stakeholders;
- B. FRISCH indicated that they were going to add back in the SCA and delete the DCR;
- Board Member, P. GANNON stated that eliminating the SCA pushes back to the bedside (less safe). Agreed to having SCAs as an option with appropriate BUDs;
- B. FRISCH indicated that they would develop standards around SCAs (e.g. out of traffic areas);
- B. FRISCH stated that the revised draft of USP <797> came out last week;
- B. FRISCH stated that Board Staff was going to strike the DCR and moved toward the SCA. This would not preclude having a DCR if wants. Standard does not allow you to extend BUD in SCA. This change would substantially change the language in the document;
- See grid for further comments.

ACTION: Motion by T. FENSKY and seconded by J. LANZA, and voted unanimously by those present, to strike the language in draft 247 CMR 17 referring to Designated Compounding Room (DCR) and move toward language referring to Segregated Compounding Area (SCA).

**Topic XI: ADJOURNMENT OF MEETING Time: 4:10 PM**

ACTION: Motion by P. Gannon seconded by L. Giambaressi, 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 8/2/18 General Session
2. Draft Minutes of the 6/28/18 Meeting
3. Report on Applications approved pursuant to Licensure Policy 13-01
4. Report on probation (none for this meeting)
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. PHA-2018-0038 CVS #301 DS89652
8. SA-INV-13113 CVS #2322 DS2827
9. PHA-2018-0016 Smith Drug DS2198
10. SA-INV-12933 Galaxy Pharmacy DS90030
11. Pharmacript of MA (DS90251); Renovation/Expansion
12. PharmaLuxe Pharmacy; New Community Pharmacy
13. Bravo Pharmacy (DS89981); Renovation/Expansion
14. Save Care Heath; New Community Pharmacy
15. Genoa Healthcare/Quincy; New Community Pharmacy with Waivers
16. Brown's Rexall Drug (DS1240); Transfer of Ownership
17. Partner's Pharmacy of MA, LLC (DS3419); Petition to Waiver/Expansion Pilot Program
18. Walgreens Pharmacy 10375 (DS3527); Change of Manager
19. 247 CMR 22.00 Fines
20. 247 CMR 17.00 Sterile Compounding

Respectfully Submitted,  
Kim Tanzer, PharmD, RPh  
Secretary