

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

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

April 4, 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 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

Time	#	Item	Page	Contact
8:30	I	CALL TO ORDER		A. Stein
	II	APPROVAL OF AGENDA		
8:40	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none"> • Draft of March 7, 2019 Regular Session Minutes • Introduction of Interns <ul style="list-style-type: none"> ○ Shakira Kareem – Northeastern ○ Justin Brown - Northeastern 		
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 		
8:50	V	POLICIES and ADVISORIES <ul style="list-style-type: none"> • Policy 2019-01 : Shared Pharmacy Service Models Including Central Fill, Central and Remote Processing 		

9:15	VI	APPLICATIONS <ul style="list-style-type: none"> • Genoa Healthcare, Lynn – New Community Pharmacy • Cambridge Health Alliance(DS90039) – Renovation • Union Pharmacy – New Store Pharmacy • Holyoke Health Center (DS3491) – Renovation/Expansion • CVS #2162 at Childrens Hospital (DS2687)- Renovation/Expansion • Coram/CVS #48630 – (DS90250) – Renovation/Expansion • CVS Pharmacy #209 (DS3597) – Change of Manager 														
10:15	VII	FLEX <ul style="list-style-type: none"> • Approval of NABP Treasurer selection • Approval of NABP resolutions • Approval of NABP Executive Committee candidate • NABP Seeking Volunteers for 2019-2020 Committees and Task Forces 														
10:30	VIII	INVESTIGATIVE CONFERENCE <ul style="list-style-type: none"> • SA-INV-14166- Robert Patrie, Jr.- PH237571 														
11:00	IX	FILE REVIEW														
		<table border="1"> <tr> <td>1</td> <td>PHA-2019-0012</td> <td>Rite Aid #10180-DS90152</td> </tr> <tr> <td>2</td> <td>PHA-2019-0004</td> <td>Walgreens #6739-DS1896</td> </tr> <tr> <td>3</td> <td>PHA-2019-0002</td> <td>CVS #1873-DS2880</td> </tr> <tr> <td>4</td> <td>SA-INV-13964</td> <td>Briova Rx – DS89743</td> </tr> </table>	1	PHA-2019-0012	Rite Aid #10180-DS90152	2	PHA-2019-0004	Walgreens #6739-DS1896	3	PHA-2019-0002	CVS #1873-DS2880	4	SA-INV-13964	Briova Rx – DS89743		
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		2	PHA-2019-0004	Walgreens #6739-DS1896												
3	PHA-2019-0002	CVS #1873-DS2880														
4	SA-INV-13964	Briova Rx – DS89743														
12:00	LUNCH BREAK															
1:00	X	EXECUTIVE SESSION The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Specifically, to approve a pharmacist license and to evaluate the Good Moral Character as required for registration for pending applicants.		CLOSED SESSION												
2:00	XI	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)		CLOSED SESSION												
2:30	XII	M.G.L. c. 112, § 65C SESSION		CLOSED SESSION												
5:00	XIII	ADJOURNMENT		CLOSED SESSION												

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

**MINUTES OF THE GENERAL SESSION
239 Causeway Street, Fourth Floor ~ Room 417A
Boston, Massachusetts, 02114
April 4, 2019**

Board Members Present

Andrew Stein, Pharm D, RPh. President
Julie Lanza, CPhT, Secretary
Sebastian Hamilton, Pharm D, RPh
Stephanie Hernandez, Pharm D, BCGP, RPh
Susan Cornacchio, JD, RN
Patrick Gannon, RPh
Leah Giambarresi, Pharm D, RPh
Timothy Fensky, RPh
Dawn Perry, JD (Arrives 9:25 AM; leaves 12:00 PM)

Board Members Not Present

Carly Jean-Francois, RN, NP
Kim Tanzer, PharmD, RPh. President Elect
Michael Godek, RPh

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, CPhT, Associate Executive Director
Heather Engman, JD Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh Quality Assurance Pharmacist
Joanne Trifone, RPh., Director of Pharmacy Investigations
Kimberly Morton, CPhT, Compliance Officer
Julienne Tran, Pharm D, RPh Investigator/Quality Assurance Pharmacist
Joseph Santoro, RPh Investigator
Christina Mogni, RPh investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:35 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; J. Lanza, yes; S. Hernandez (yes); P. Gannon, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; T. Fensky, yes; (D. Perry arrives at 9:25 AM)

Topic II.

Approval of Agenda

TIME 8:35 AM

Agenda April 4, 2019

DISCUSSION:

Change to Agenda:

1. Defer investigative conference: SA-INV-14166 Robert Patrie, Jr PH237571

ACTION:

Motion by S. Hamilton, seconded by P. Gannon 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 also introduces the Northeastern Pharmacy Students on APPE rotations: Shakira Kareem and Justin Brown.

Topic III

Approval of Board Minutes

TIME: 8:36 AM

Minutes

1. Draft, March 7, 2019, 2019 Session Minutes

No noted Changes.

Action:

Motion by P. Gannon, seconded S. Hamilton, and voted unanimously to approve the regular session minutes of March 7, 2019 with noted changes.

TOPIC IV

REPORTS

Applications approved pursuant to Licensure Policy 13-01

Time: 8:38 AM

Discussion: R. HARRIS noted that during the past month there have been eighteen (18) changes of Manager of Record (MOR), six (6) renovation/expansion applications, and one (1) new community pharmacy application approved pursuant to Licensure Policy 13-01.

So noted

TOPIC IV

REPORTS

Monthly Report from Probation

Time: 8:38 AM

Discussion: M. BOTTO provided the March 1, 2019 - March 27, 2019, Board of Pharmacy Statistics Report for the Probation monitor, which noted that two (2) licensees satisfactorily completed probations, one (1) was issued final notice, and there are currently thirty-four (34) licensees on probation.

So noted

TOPIC IV

REPORTS

Monthly Report from BDR pursuant to Policy 14-02

Time: 8:39 AM

Page 2 of 12

Draft Minutes General Session: 4/4/19

BOP Approved: 5/2/19

Discussion: M. BOTTO that there were no Board Delegated Review cases heard prior to the meeting this month.

So noted

TOPIC IV

REPORTS

Above Action Levels Approved by Staff Action 16-04

Time: 8:39 AM

Discussion: K. MORTON noted that one (1) above action level report has been reported since last Board meeting pursuant to Licensure Policy 16-04.

So noted

TOPIC IV

REPORTS

PSUD Report by Staff Action 17-03

Time: 8:40 AM

Discussion: E. TAGLIERI noted that in March 2019, no new applications were received, and there are currently fourteen (14) active participants.

So noted

TOPIC V

Policies and Advisories

1. Policy 2019-01: Shared Pharmacy Service Models including Central Fill, Central and Remote Processing

TIME: 8:39 AM

DISCUSSION: Presented by M. CHAN

The policy previously presented to the Board on March 7, 2019 was revised and presented again. Specifically, language pertaining to Telepharmacy was removed, pending further study; a definition of shared services from NABP was added; language pertaining to remote processing was added; a requirement for pharmacy technician supervision was added; and minor formatting and wording changes were made. Feedback solicited from other state boards of pharmacy, including Rhode Island, New Hampshire, Virginia, North Dakota, and Oregon, was presented to address the Board's previous concerns.

ACTION: Motion by T. FENSKY, seconded by S. HAMILTON, and voted unanimously to approve Policy 2019-01: Shared Pharmacy Service Models including Central Fill, Central and Remote Processing.

TOPIC VI

APPLICATIONS

1. Genoa Healthcare, Lynn New Community Pharmacy TIME: 8:50 AM

REPRESENTED BY: Kevin O’Connell, Director of Operations, Genoa Healthcare; Hillary Williams, proposed MOR

RECUSAL: None

DISCUSSION: Hillary Williams, proposed Manager of Record for Genoa Healthcare, Lynn, has been licensed in Massachusetts for 8 years. Genoa will be a restricted pharmacy located below a community mental health center and will provide its patients continuity of care by providing pharmacy services specializing in psychotropic drugs and performing injectable medication administrations. It will not offer compounding services. Genoa has petitioned for six waivers: 247 CMR 6.01(5)(a)(4); 247 CMR 6.01(5)(a)(8); 247 CMR 6.02(4); 247 CMR 6.02(5); 247 CMR 9.01(15); and 247 CMR 9.01(16); following Kevin O’Connell and Hillary Williams successfully answered the questions from Board members pertaining to experience and activities of the pharmacy.

ACTION: Motion by S. HAMILTON, seconded by L. GIAMBARRESI, and voted unanimously by those present to approve the application and waivers pending a successful inspection.

2. Cambridge Health Alliance DS90039 Renovation TIME: 8:55 AM

REPRESENTED BY: Kate Magro, MOR; Michelle Ortiz, Supervising Pharmacist; Kenny Hanlon, Operations Manager

RECUSAL: None

DISCUSSION: Cambridge Health Alliance performs manual compliance packaging for approximately 400 patients per month, but has outgrown its current physical space and cannot serve additional patients. It plans to renovate a separate suite, non-contiguous with the pharmacy, within an area of the building inaccessible to patients, and install robotics to expand its compliance packaging services to greater numbers of patients. The compliance packaging suite will be staffed by a pharmacist at all times while operating, and will be secured, alarmed, and video monitored as is the main pharmacy. Representatives successfully answered the questions from Board members pertaining to the plans, security measures, and operations of the pharmacy.

ACTION: Motion by S. HAMILTON, seconded by L. GIAMBARRESI, voted unanimously by those present to approve the application pending a successful inspection.

3. Union Pharmacy – New Community Pharmacy

TIME: 9:01 AM

REPRESENTED BY: Xiaoyan Qin, majority owner and CEO

RECUSAL: None

DISCUSSION: Xiaoyan Qin proposes to open Union Pharmacy, to provide “concierge” pharmacy services, including CMR/MTM and PA services, to local providers and Chinese-speaking patients. The pharmacy will be located in Newton Center below a doctor’s office. Union Pharmacy will have a private consultation room and a large immunization room. The proposed MOR is Iris Pita who has been licensed in Massachusetts for 17 years and has previous experience as MOR. Union Pharmacy initially attested that it intends to perform simple non-sterile compounding only, but after questions from the Board agreed that it will amend the attestation to include moderate compounding.

ACTION: Motion by S. HAMILTON, seconded by L. GIAMBARRESI, voted unanimously by those present to approve the application pending successful inspection and receipt of amended Attestation of Intent to Perform Sterile Compounding.

4. Holyoke Heath Center DS3491 – Renovation

TIME: 9:09 AM

REPRESENTED BY: None

RECUSAL: None

DISCUSSION: W. FRISCH, Board Staff, Director of Pharmacy Compliance presented the revised application of Holyoke Health Center to expand its storage and delivery room. Holyoke plans to add a cased opening between the existing storage and delivery room and the adjacent building maintenance rooms to add space for bags of completed prescriptions going out for delivery. During the renovation, the pharmacy will not store medications in the space, rekey locks on access doors to allow only pharmacist access, and install a new security camera.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, voted unanimously by those present to approve the application pending successful inspection and installation of security measures.

5. CVS 2161 at Children’s Hospital DS2687 – Renovation

TIME: 9:11 AM

REPRESENTED BY: Matthew Litchfield, Pharmacist-In-Charge; Courtney Mosh, Compounding Manager

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

DISCUSSION: CVS 2161 intends to renovate its compounding areas to install ducting and an exterior ventilation fan to comply with USP <800> standards. It also intends to install two dual HEPA filtered containment ventilated enclosures, to handle hazardous and non-hazardous powders.

ACTION: Motion by T. FENSKY, seconded by P. GANNON, voted unanimously by those present to approve the application.

6. Coram/CVS 48630 DS90250 – Renovation

TIME: 9:13 AM

REPRESENTED BY: None

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

DISCUSSION: William Frisch, Board Staff, Director of Pharmacy Compliance presented the application of Coram/CVS 48630 to replace three of its 25-year-old laminar flow hoods with two new units. Coram/CVS intends to remove and replace the hoods and recertify with its environmental monitoring vendor.

ACTION: Motion by T.FENSKY, seconded by L. GIAMBARRESI, voted unanimously by those present to approve the application.

7. CVS 209 DS3597 – Change of Manager

TIME: 9:15 AM

REPRESENTED BY: Christopher Chen

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

DISCUSSION: Christopher Chen came before the Board as the new Manager of Record for CVS #209. He is aware of the store’s previous discipline and is familiar with the value and process of inspections. He has successfully served as MOR for 8 years at previous CVS stores. He reports that his biggest challenge will be to maintain consistent staffing and expand the number of certified technicians at the store.

ACTION: Motion by S. HAMILTON, seconded by L. GIAMBARRESI, voted unanimously by those present to approve the application.

TOPIC VII

FLEX

1. Approval of NABP Treasurer Selection

TIME: 9:22 AM

PRESENTED BY: D. SENCABAUGH

RECUSAL: None

DISCUSSION: The qualifications of the two candidates for NABP treasurer were discussed and both candidates were felt to be qualified. K.TANZER will serve as the delegate and will vote on behalf of the Board at the NABP Annual Meeting. Several Board members will be available at the meeting to discuss any new information that arises prior to the vote if needed.

ACTION: Motion by A.STEIN, seconded by S. HAMILTON, voted unanimously by those present to allow K.TANZER to vote as delegate as seen fit.

2. Approval of NABP Resolutions

TIME: 9:22 AM

PRESENTED BY: D. SENCABAUGH / T. FENSKY

RECUSAL: None

DISCUSSION: The resolutions submitted to the Association by District 1 were reviewed. K.TANZER will serve as the delegate and will vote on behalf of the Board at the NABP Annual Meeting. Several Board members will be available at the meeting to discuss any new information that arises prior to the vote if needed.

ACTION: Motion by A.STEIN, seconded by S. HAMILTON, voted unanimously by those present to allow K.TANZER to vote as delegate as seen fit.

3. Approval of NABP Executive Committee Candidate

TIME: 9:22 AM

PRESENTED BY: D. SENCABAUGH

RECUSAL: None

DISCUSSION: The qualifications of the candidate for the executive committee District 2 position were discussed. The candidate was felt to be qualified. K.TANZER will serve as the delegate and will vote on behalf of the Board at the NABP Annual Meeting. Several Board members will be available at the meeting to discuss any new information that arises prior to the vote if needed.

ACTION: Motion by A.STEIN, seconded by S. HAMILTON, voted unanimously by those present to allow K.TANZER to vote as delegate as seen fit.

D. Perry Arrives 9:25 AM

4. NABP Seeking Volunteers for 2019-2020 Committees and Task Forces

TIME: 9:49 AM

PRESENTED BY: E. TAGLIERI

RECUSAL: None

DISCUSSION: NABP is currently seeking volunteers to serve on committees and task forces. Board members may serve on either a committee or a task force, and Board staff may serve on a task force. Participation is highly recommended and applications should be submitted by June 7, 2019.

So noted

TOPIC VIII

Investigative Conference

Deferred

TOPIC IX:

FILE REVIEW

9:52 AM

Case #1

PHA-2019-0012

Rite Aid #10180, DS90152

Time: 9:52 AM

RECUSAL: NONE

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

- RLCS -#100 oxycodone 5mg tablets on 12/23/18;
- Loss discovered during a back count and reconciliation after filling a prescription for 6 tablets on 12/23/18;
- The perpetual inventory was checked for calculation errors with invoices and dispensing reports reviewed, customers who had been dispensed oxycodone 5mg since last reconciliation were contacted with no result, the pharmacy shelves and trash were searched, and security footage was reviewed with no diversion suspected and no reason determined;
- Suspect a bottle of 100 tablets was inadvertently discarded;

CA: MOR Le reviewed the procedures for security and accountability of controlled substances with pharmacy staff; PDM discussed the proper workflow and security of controlled substances with MOR Le.

ACTION: Motion by T. FENSKY, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2019-0012) 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 #2

PHA-2019-0004

Walgreens #6739, DS1896

Time: 9:54 AM

RECUSAL: NONE

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

- RLCS- #100 oxycodone HCL 10mg tablets as a result of a pharmacist throwing away a bottle. 1 prior reported loss in 2015.
- MOR Winroth noted that it was determined that the full bottle of #100 oxycodone 10mg tablets were discarded in the trash in error while filling a prescription. Medication could not be retrieved as the trash was in the dumpster.
- MOR Winroth communicated to all pharmacists that stock bottles must be verified as empty before discarding and that empty bottles will remain open with no cap to avoid confusion with bottles still containing tablets/capsules. No subsequent losses have occurred to date.
- Pharmacist Eang submitted two continuing education credits on controlled substances best practices. Retail compliance inspection (ISP- 11401) was conducted at Walgreens #6739 on January 24, 2019 was deemed satisfactory.

ACTION: Motion by L. GIAMBARRESI, seconded by S. HAMILTON, and voted unanimously by those present, to DISMISS the matter (PHA-2019-0004), No Discipline Warranted, Remediation Complete.

Case #3

PHA-2019-0002

CVS #1873, DS2880

Time: 9:56 AM

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

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

- RLCS- #76 d-amphetamine salts 20mg tablets as a result of a suspected dispensing error on or about November 2, 2018. Two prior reported losses since 2014.
- MOR Debaggis indicated that the loss was discovered while filling a prescription and referencing the count with the perpetual inventory. Loss is believed to have occurred as a result of a back count of remaining tablets being poured into a patient's prescription vial rather than back into the stock bottle. Video footage was reviewed but showed nothing conclusive.
- Patient outreach was completed but no patients stated that they received additional tablets.
- MOR Debaggis indicated that she has retrained the pharmacists on proper process when filling Schedule II prescriptions.

- Retail compliance inspection (ISP-10468) on September 12, 2018 with deficiencies noted including discrepancy in the perpetual inventory versus the electronic count.

ACTION: Motion by S. HERNANDEZ, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2019-0002) 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 #4

SA-INV-13964

BriovaRx, DS89742

Time: 9:58 AM

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

DISCUSSION: K. MORTON presented and summarized the investigative report that pertained to these matters.

- During an inspection conducted on 9/25/18, it was conveyed to Investigators that BriovaRx was currently having data entry conducted remotely, in an out of state location.
- MOR stated “BriovaRx specialty pharmacies performing prescription data entry or front-end processes hold pharmacy licenses in their home states and non-resident pharmacy licenses, where available”
- Pharmacists and pharmacy technicians performing remote data entry are licensed with the resident state of the facility in which they work. Pharmacy technicians performing remote data entry are supervised by licensed pharmacists and/or the Pharmacist in Charge of the facility in which they work. The pharmacists in charge at all three out of state locations are all Massachusetts licensed.
- BriovaRx uses two verification steps, PV1 and PV2 verification. On most occasions, both verification steps are conducted in Massachusetts. Occasionally, the PV1 verification may be conducted at one of the out of state locations, as a result of inclement weather, staffing issues (sick calls, etc.), or unusually high volume. In one of these instances, the pharmacist who conducts the PV1 verification step is a Massachusetts licensed pharmacist, and PV2 is always conducted at the Massachusetts BriovaRx location.

ACTION: Motion by S. HAMILTON, seconded by P. GANNON, and voted by the majority of those present, with one opposed vote by A. STEIN, to CLOSE the matter (SA-INV-13964), No Discipline Warranted.

Topic X

EXECUTIVE SESSION

Time: 10:03 AM

Read by A. Stein

DISCUSSION:

ACTION: At 10:02 AM President A. Stein read the statement on reasons for Executive Session.

Topic X:

Executive Session Call to Order:

Time: 11:12 AM

By: A. Stein

ACTION: Motion by S. Hamilton, seconded by S. Hernandez, and voted unanimously by roll call to call the April 4, 2019 meeting of the Executive Session to order.

9. Policy 2019-01: Shared Pharmacy Service Models Including Central Fill, Central Processing and Remote Processing
10. Applications: Genoa Healthcare, Lynn new Community Pharmacy
11. Applications: Cambridge health Alliance (DS90039) Renovation
12. Applications: Union Pharmacy: New Community Pharmacy
13. Applications: Holyoke Health Center DS3491: Renovation
14. Applications: CVS #2162 at Children's Hospital DS2687 Renovation
15. Applications: Coram/CVS #48630 DS90250; Renovation
16. Applications: CVS Pharmacy #209 (DS3597): Change of Manager of Record
17. PHA-2019-0012 Rite Aid #10180 DS90152
18. PHA-2019-0004 Walgreens #6739 DS1896
19. PHA-2019-0002 CVS #1873 DS2880
20. SA-INV-13964 Briova RX DS89743

Respectfully Submitted,
Julie Lanza, CPhT, Secretary