

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

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

May 2, 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 Nahomi Carlisle, 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>		
	<b>II</b>	<b>APPROVAL OF AGENDA</b>		
<b>8:40</b>	<b>III</b>	<b>APPROVAL OF BOARD MINUTES</b> <ul style="list-style-type: none"> <li>• Draft of April 4, 2019 Regular Session Minutes</li> <li>• Introduction of Interns</li> </ul>		
<b>8:45</b>	<b>IV</b>	<b>REPORTS</b> <ul style="list-style-type: none"> <li>• Applications approved pursuant to Licensure Policy 13-01</li> <li>• Monthly report from probation</li> <li>• Board Delegated Review pursuant to Licensure Policy 14-02</li> <li>• Above Action Levels approved by Staff Action 16-04</li> <li>• PSUD Report-Policy 17-03</li> </ul>		
<b>8:50</b>	<b>V</b>	<b>POLICIES and ADVISORIES</b> <ul style="list-style-type: none"> <li>• Joint Policy 2019-02: Automated Dispensing Device Use</li> <li>• Policy 2019-03: Non-Resident Inspection Requirements</li> <li>• Advisory: Use of Technology to Check Inventory Management Activities Performed by Certified Pharmacy Technicians</li> <li>• Shared Services memo</li> </ul>		

9:30	VI	<b>APPLICATIONS</b> <ul style="list-style-type: none"> <li>Andrews Pharmacy; DS1429 : Renovation/Expansion</li> <li>Louis &amp; Clark Drug; DS2543: Relocation</li> <li>Walgreens #19840; DS90121; Change of Manager</li> <li>Winchester Pharmacy; DS89848; Pilot Project</li> </ul>																																
10:15	VII	<b>FLEX</b> <ul style="list-style-type: none"> <li>Pharmacy Advisory Committee meeting- June 9:00 – 12:00</li> <li>Proposed Amendments to the NABP Constitution and Bylaws</li> </ul>																																
10:30	VIII	<b>INVESTIGATIVE CONFERENCE</b> <ul style="list-style-type: none"> <li>SA-INV-14166- Robert Patrie, Jr.- PH237571</li> </ul>																																
11:00	IX	<b>FILE REVIEW</b> <table border="1"> <tr> <td>1</td> <td>PHA-2018-0077</td> <td>Injured Workers Pharmacy-DS89727</td> </tr> <tr> <td>2</td> <td>PHA-2018-0087</td> <td>Metrowest Pharmacy-DS90075</td> </tr> <tr> <td>3</td> <td>SA-INV-14346</td> <td>V-Care Pharmacy and Surgical Supplies-DS89813</td> </tr> <tr> <td>4</td> <td>PHA-2019-0017</td> <td>Rite Aid #10115-DS90151</td> </tr> <tr> <td>5</td> <td>PHA-2019-0014</td> <td>Maryesther Fournier-PH16359</td> </tr> <tr> <td>6</td> <td>PHA-2019-0008</td> <td>CVS #7530-DS3564</td> </tr> <tr> <td>7</td> <td>PHA-2019-0016</td> <td>CVS #861-DS3550</td> </tr> <tr> <td>8</td> <td>PHA-2019-0003</td> <td>CVS #2500-DS3606</td> </tr> <tr> <td>9</td> <td>PHA-2018-0044</td> <td>CVS #2071-DS3589</td> </tr> <tr> <td>10</td> <td>PHA-2018-0086</td> <td>CVS #2162-DS2687</td> </tr> </table>	1	PHA-2018-0077	Injured Workers Pharmacy-DS89727	2	PHA-2018-0087	Metrowest Pharmacy-DS90075	3	SA-INV-14346	V-Care Pharmacy and Surgical Supplies-DS89813	4	PHA-2019-0017	Rite Aid #10115-DS90151	5	PHA-2019-0014	Maryesther Fournier-PH16359	6	PHA-2019-0008	CVS #7530-DS3564	7	PHA-2019-0016	CVS #861-DS3550	8	PHA-2019-0003	CVS #2500-DS3606	9	PHA-2018-0044	CVS #2071-DS3589	10	PHA-2018-0086	CVS #2162-DS2687		
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<b>12:00</b>																																		
1:00	X	<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, to evaluate the Good Moral Character as required for registration for pending applicants.		CLOSED SESSION																														
2:00	XI	<b>ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)</b>		CLOSED SESSION																														
2:30	XII	<b>M.G.L. c. 112, § 65C SESSION</b>		CLOSED SESSION																														
5:00	XIII	<b>ADJOURNMENT</b>		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  
May 2, 2019**

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**Board Members Present**

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

**Board Members Not Present**

Susan Cornacchio, JD, RN  
Dawn Perry, JD

**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  
Julienne Tran, Pharm D, RPh Investigator/Quality Assurance Pharmacist  
Joseph Santoro, RPh Investigator  
Christina Mogni, RPh investigator  
Gregory Melton, PharmD, JD, RPh investigator  
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor  
Richard Harris, Program Analyst  
Joanna Chow, Office Support Specialist

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**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; T. Fensky, yes; L. Giambarresi, yes.

**Topic II.**

**Approval of Agenda**

**TIME 8:35 AM**

**Agenda May 2, 2019**

**DISCUSSION:**

No Changes,

**ACTION:**

Motion by M. Godek, seconded by T. Fensky and voted unanimously by those present to approve the agenda with noted change.

Dave asks for the Pharmacy Interns to stand and introduce themselves; currently we have no Interns on APPE rotations with the board due to it being year-end for programs.

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**Topic III**

**Approval of Board Minutes**

**TIME: 8:36 AM**

**Minutes**

**1. Draft, April 4, 2019 Session Minutes**

No noted Changes.

**Action:**

Motion by P. Gannon, seconded K. Tanzer, and voted unanimously to approve the regular session minutes of April 4, 2019 with noted changes.

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**TOPIC IV**

**REPORTS**

**Applications approved pursuant to Licensure Policy 13-01**

**Time: 8:34 AM**

**Discussion:** M. BOTTO noted that during the past month there have been twenty-three (23) changes of Manager of Record (MOR), one (1) renovation/expansion applications, and one (1) new community pharmacy application approved pursuant to Licensure Policy 13-01.

So noted

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**TOPIC IV**

**REPORTS**

**Monthly Report from Probation**

**Time: 8:34 AM**

**Discussion:** M. BOTTO provided the March 27, 2019 – April 23, 2019, Board of Pharmacy Statistics Report for the Probation monitor, which noted that four (4) licensees satisfactorily completed probations, zero (0) was issued final notice, and there are currently forty (40) licensees on probation.

So noted

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**TOPIC IV**

**REPORTS**

**Monthly Report from BDR pursuant to Policy 14-02**

**Time: 8:35 AM**

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

So noted

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**TOPIC IV** **REPORTS**  
**Above Action Levels Approved by Staff Action 16-04** **Time: 8:35 AM**

**Discussion:** J. TRAN noted that zero (0) above action level report has been reported since last Board meeting pursuant to Licensure Policy 16-04.

So noted

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**TOPIC IV** **REPORTS**  
**PSUD Report by Staff Action 17-03** **Time: 8:35 AM**

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

So noted

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**TOPIC V** **Policies and Advisories**

**1. Joint Policy 2019-02: Automated Dispensing Device Use** **Time: 8:38 AM**

**Presented by:** M. CHAN

**Discussion:** M. CHAN explained that this is a joint policy with the Drug Control Program and is intended to simplify and update the current joint guidelines for use of automated devices for the dispensing of controlled substances in health care facilities.

The policy allows licensed healthcare facilities with an onsite pharmacy to use ADDs to store and dispense prescription products. If there is no onsite pharmacy, the facility must obtain approval from whoever licenses them in order to place and use an ADD.

The machine and its contents remain the pharmacy's property until dispensed, and stocking of E-kit medications must be done by either licensed pharmacy personnel or a licensed nurse.

Use of an ADD for routine medication administration will require a separate MCSR and DEA number specific to the machine.

The policy is intended to address the use of the machine only. Details for specific uses can be found in other policies or circular letters such as the LTC facility e-kit circular letter.

Board members requested to add requirements for updated the authorized user lists, editing the report of medication losses to be more consistent with the licensing bodies, and changing the language in bullets 11 and 12 to medication "dispensing".

**Action:** Motion by T. FENSKY, seconded by S. HERNANDEZ and voted unanimously by all those present to approve the policy with the noted changes.

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**2. Policy 2019-03: Non-Resident Pharmacy Inspection Requirements for Licensure**

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Draft Minutes General Session: 5/2/19

BOP Approved: 6/6/19

**Time: 8:44 AM**

**Presented by:** M. CHAN

**Discussion:** Based on the specific license the pharmacy is applying for, the document provides the details of which inspectors and inspection forms would be accepted for either initial licensure or renewal. This will be shared with NABP who can notify pharmacies in other states as to what the requirements will be once licensure is in place. The Board members would like to clarify that the inspection be the most recent one.

**Action:** Motion by S. HAMILTON, seconded by L. GIAMBARRESI and voted unanimously by all those present to approve the policy with noted changes.

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**3. Advisory: Use of Technology to Check Inventory Management Activities Performed by Certified Pharmacy Technicians**

**Time: 8:46 AM**

**Presented by:** M. CHAN

**Discussion:** This is a joint advisory with the Drug Control Program to provide acceptable conditions for use of technology to check the work of a certified pharmacy technician. Much of this document was based on the successful Baystate and Brigham & Women's pilot. Essentially, certified technicians can transfer non-patient specific CVI stock to a patient care area without a prior RPh check. The process would require electronic validation checks at various steps in the stocking process starting from removal from the pharmacy inventory system to addition to the ADD and a final electronic bedside verification by a licensed health care professional.

**Action:** Motion by S. HERNANDEZ, seconded by J. LANZA and voted unanimously by all those present to approve the advisory.

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**4. Shared Services Memo**

**Time: 8:49 AM**

**Presented by:** M. CHAN

**Discussion:** This memo is in regard to the implementation timeline of the shared services policy that the Board approved last month. There have been several questions about how quickly pharmacies must come into compliance, especially in light of the fact that non-resident licensure is not yet in effect. We have suggested a grace period of August 2 or the date of final promulgation of the licensing regulation, whichever is later.

P. GANNON asked how shared services will affect transfer of sterile products between hospitals. W. FRISCH noted that the policy excludes sterile compounds from central fill unless a petition is made to the Board.

**Action:** Motion by S. HAMILTON, seconded by M. GODEK and voted unanimously by all those present to approve the memo.

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## TOPIC VI

## APPLICATIONS

### 1. Winchester Pharmacy

TIME: 9:02 AM

REPRESENTED BY: Steve McNeil, CEO & Owner; Kyle O'Connor, MOR and Bill McGuire, Omnicell representative

RECUSAL: M.BOTTO

#### DISCUSSION:

##### In Scope

- PHASE I -Any adherence medication cards that are packaged by the VBM are 100% checked and verified by the pharmacist for accuracy. Any errors related to an adherence card being packaged incorrectly are documented
- PHASE II -Request that any card processed by the VBM is considered a final verification by the pharmacist by the following processes:
  1. Pharmacist Verification 1(PV1)- verifies prescription for appropriateness including review and clinical DUR
  2. Pharmacist Verification 2(PV2)- verifies all drugs placed in the cassettes using both RFID and Barcode check
  3. PV2 verified by all drugs by the VBM. Each drug must be photographed 5 times and must matched with the drug image in the database.
  4. PV2 verified database by a pharmacist only
  5. Photo images are retained for 10 years

Tech-check-tech review will occur on the final card to check for any physical issues (double drops, omissions and crushed tablets). No label can be produced unless the VBM can verify the image 5 times. Otherwise the pharmacist MUST authorize and release the card and label.

- Out of Scope
  - Any error due to human intervention

Summary of the pilot project includes:

- Pharmacists to work at the top of their license while also allowing technicians to work at the top of their registration
- Improved employee practice
- Utilizing technology to enhance employee satisfaction while decreasing medication errors

Request:

Winchester is requesting start "Phase II" of the pilot.

- This includes an additional 180 days with a 10% pharmacist verification on all adherence cards instead of 100% check.
- Technicians will do 100% check for physical defects.
- Report back monthly to the board thru August 2019

Revisit CMR 8.04 to allow technology to enhance tech-check-tech





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

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**TOPIC VII**

**FLEX**

**1. Pharmacy Advisory Committee Meeting, June 20, 9am-12pm**

**Time: 10:20 AM**

**Presented by:** E. TAGLIERI

**Discussion:** In order to obtain more information about Telepharmacy and to convert the existing advisory for response to above action levels to a policy, it is requested that the Advisory Committee to the Board discuss and bring forth recommendations.

**Action:** Motion by P. GANNON, seconded by L. GIAMBARRESI and voted unanimously by all those present for T. FENSKY to attend and represent the Board members and request for the Advisory Committee to discuss the noted topics.

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**2. Proposed Amendments to the NABP Constitution and Bylaws**

**Time: 10:25 AM**

**Presented by:** D. SENCABAUGH / T. FENSKY

**Discussion:** There have been minor changes to the NABP Constitution including the addition of Canadian provinces and territories. Changes will be voted on at the meeting.

**Action:** Motion by P. GANNON, seconded by L. GIAMBARRESI and voted unanimously by all those present for K. TANZER to attend and use her discretion to make voting choices.

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**TOPIC VIII**

**INVESTIGATIVE CONFERENCE**

**1. SA-INV-14166 Robert Patrie, JR PH237571**

**Time: 10:26 am**

Presented by: C. Mogni

RECUSAL: None

DISCUSSION: Robert Patrie, Jr., MOR of CVS Pharmacy #257 DS3331, located in Pittsfield, MA, Tricia (Supervisor) and George Parcell (counsel for Robert) was present.

- On August 29, 2018, a retail compliance inspection (ISP-10360) was conducted at the Pharmacy with deficiencies cited including, but not limited to, failure to reconcile the perpetual inventory, a repeat deficiency, in violation of 247 CMR 9.01 (14). Failure to remedy or correct a violation cited by the date specified in the Plan of Correction (POC)

- First time as a MOR, was not aware of store deficiencies. Tricia did not know the whole history of the store.

- Large MOR turnover. MOR sees supervisor, Tricia, once a month. Board recommended seeing the MOR more often to offer more support, send advisors to help Robert review policies by scheduling extra staff to cover and sending new technicians to less busy stores so they can all be trained appropriately.
- Board comments MOR is being set up to fail
- Temp logs request was denied
- Staff RPh licensed 8/18, MOR vouched for him.

ACTION: Motion by T. Fensky, seconded by S. Hamilton, and voted unanimously in the affirmative to close SA-INV-14166 no discipline warranted, remediation complete.

**TOPIC IX**

**FILE REVIEW**

Case #1

PHA-2018-0077

Injured Workers Pharmacy, DS89727

Time: 11:04 AM

RECUSAL: NONE

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

- RLCS of #28 hydrocodone/acetaminophen 5/325 mg tablets on 09/26/2018 and #100 morphine sulfate ER 30 mg tablets on 10/24/2018.
- On 09/25/2018, the entire pharmacy had a loss of power with failure of the generator.
- About 5 minutes prior to the loss of power, Pharmacist Strasnick left the narcotic room while CPhT Colon was filling; when the power went out CPhT Colon exited the room and another pharmacist closed the door (confirmed with security footage review).  
The unknown loss of #28 hydrocodone/acetaminophen 5/325 mg tablets was discovered on 09/26/2018 during the weekly count. All pharmacy staff who had worked in the narcotic room were interviewed and provided a signed statement.
- On 10/24/2018, the Script Pro “reported empty” but the transaction history for morphine sulfate ER 30 mg tablets indicated there should have been 100 tablets in the cell.  
The Script Pro which was last filled on 10/20/2018 by CPhT Gandotra when 800 tablets were supposedly added to the cell.
- Current MOR Welch reviewed security footage which showed CPhT Gandotra fill the cell with 7 bottles of 100 and inadvertently discard 1 full bottle with the empty ones as the empty bottles and full bottles were put into the same bin during the process.
- Pharmacist Mailloux failed to verify the replenishment of the correct quantity.
- The “Perpetual Inventory Report” provided does not indicate reconciliation of the perpetual inventory and shows numerous unexplained adjustments without indicating who made the adjustment.
- CA: Former MOR Scandura indicated a new process will be implemented to perform a back-count as the prescription is prepared to ensure variances are identified and resolved immediately; Current MOR Welch indicated pharmacy staff who work in the narcotic room were re-trained on best practices

of filling prescriptions and were reminded to not intermingle empty and full bottles per the amended SOP; the Script Pro was reprogrammed to require a pharmacist verification during replenishment.

ACTION: Motion by T. FENSKY, seconded by M. GODEK, and voted unanimously by those present, to refer the matter (PHA-2018-0077) 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.

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Case #2

PHA-2018-0087

Metrowest Pharmacy, DS90075

Time: 11:08 AM

RECUSAL: NONE

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

- Inspectional deficiencies for ISP-11017 on December 6, 2018, including missing SOPs, recordkeeping violations, medications mislabeled and not properly segregated, no hot water, BUDs listed as month/year, no toll-free number for counseling for delivered prescriptions, and standing orders from 29 prescribers for eye medications that are automatically switched if not covered by insurance;
- POC received 01/02/2019 indicated SOPs were revised and provided, the Pharmacy has hot water, BUDs will include month/day/year, a toll-free number was added, and if a prescription for an eye medication is not covered by insurance, the pharmacist will contact the prescriber and reduce the new prescription to writing;
- The Attorney indicated that 70% of the medications dispensed by the Pharmacy are for eye medications;
- Of 1,261 prescriptions filled/refilled for eye medications 10/1/18-12/19/18, 282 were substituted as noted on 178 by pharmacists, 4 by pharmacy interns, 46 by a pharmacy technician trainee/pharmacy technician/certified pharmacy technician, 49 by both a pharmacist and a pharmacy technician trainee/pharmacy technician/certified pharmacy technician, 1 with no name, (4 had no notes) and the notes were not always complete;
- CA: Effective 1/3/19 all changes for eye medications will require a new prescription authorized by the prescriber, will be reduced to writing, and will be filed appropriately.

ACTION: Motion by M. GODEK, seconded by K. TANZER, and voted unanimously by those present, to DISMISS the matter (PHA-2018-0087), No Discipline Warranted, Remediation Complete.

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Case #3

SA-INV--14346

V-Care Pharmacy and Surgical Supplies, DS89813

Time: 11:11 AM

RECUSAL: NONE

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

- Inspectional deficiencies for ISP-11018 on 12/11/18 for 2 standing orders for 5 prescribers titled as "Benefits Investigation Forms" containing multiple drug products for ophthalmic medications for use pre- and post-surgery that are switched if not covered by insurance.

- A standardized form with boxes for check marks for multiple medications listed was used to obtain a verbal order from the prescriber but at times a note was placed electronically on the prescription and a new prescription was not obtained.
- POC received 1/3/19 indicated a new prescription will be obtained for a change of medication and the verbal prescription templates were revised to limit one prescription medication selection per form.
- Of 1,570 prescriptions filled/refilled for eye medications 10/1/18-12/30/18, 489 were substituted as noted on 3 by pharmacists, 446 by pharmacy interns, 27 by a pharmacy technician, 11 with illegible initials, and 5 with no initials; additional 332 electronic prescriptions for brand Vigamox were interchanged to generic moxifloxacin with only an electronic note of authorization obtained; 3 were changed using the revised template but were not initialed.
- CA: Templates were revised by therapeutic class so that only one prescription will be selected per form with copy submitted on 12/17/18; all staff at the Pharmacy acknowledged review of 105 CMR 721.050 and Board Policy 2018-01 and attested to maintain compliance.

ACTION: Motion by S. HAMILTON, seconded by P. GANNON, and voted unanimously by those present, to CLOSE the matter (SA-INV-14346), No Discipline Warranted, Remediation Complete.

Case #4

PHA-2019-0017

Rite Aid #10115, DS90151

Time: 11:22 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.

- 1/25/19 PCS received a Pharmacy Technician license application for Mikayla McCauliff.
- In April 2018, Mikayla McCauliff submitted an incomplete application for PTT license to the BORP and was notified of such via email from the BORP.
- MOR Dascoli indicated when the PTT licensing was implemented, she was not fully aware of the requirements and assumed Ms. McCauliff was issued a PTT license. Ms. McCauliff claimed she did not receive the email notification from the BORP. PTT hours are tracked by corporate and verified by the MOR.
- Ms. McCauliff completed the corporate Pharmacy Technician University Program, passed the exam for Pharmacy Technician licensing. She then submitted her application to PCS at which time she learned she was unlicensed.
- Ms. McCauliff worked as a Pharmacy Technician in Training from 01/09/18 to 02/14/19 without a PTT license (accruing 1,322 hours) then worked 2/14/19 to 3/9/19 accruing 1,558.7 hours total per documentation submitted by MOR Dascoli, exceeding 1,500 hours/1-year limit.
- CA: MOR Dascoli has familiarized herself with the technician licensing BORP regulations and will review new regulations when approved or changed. Ms. McCauliff was issued license PTT04165 on 2/14/19 then PT24473 on 3/25/19.

ACTION: Motion by K. TANZER, seconded by P. GANNON, and voted unanimously by those present, to DISMISS the matter (PHA-2019-0017), No Discipline Warranted, Remediation Complete.

Case #5

PHA-2019-0014

Maryesther Fournier, PH16359

Time: 11:24 AM

RECUSAL: NONE

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

- Companion Complaint to PHA-2018-0016 Smith Drug in Wakefield as Owner/MOR for failure to correct inspectional deficiencies cited on 3/5/18, 7/17/18, and 1/16/19 including controlled substance recordkeeping and security, repackaging medications dispensed from other pharmacies, lack of labeling on multi-dose packaging or non-compliant labeling, improper disposal of medications via police Take-Back box, filling multi-dose packaging with bare hands, and storing medications in reused patient vials in dirty patient bins.
- Board vote on 2/7/19 included increased visits to the Pharmacy and a request that a new MOR be appointed.
- 2/25/19 site visit to ensure cleanliness and compliant labeling found technician using gloves while filling multi-dose packaging, new patient vials in clean patient bins, installation of a counter-top dishwasher for cleaning daily planners, and almost all patients converted to compliant labeling.
- Owner Fournier entered a formal agreement with a consultant on 2/12/19 to assist with developing and implementing policies and procedures to ensure compliance. A new MOR was appointed on 3/3/19. All damaged/expired medications were returned to a reverse distributor. All labeling is compliant and only a few patients with identified physical or cognitive disabilities still receive medications in daily planners.
- Owner Fournier expressed her devotion to her patients and her commitment to remain compliant.
- 3/13/19 re-inspection was deemed satisfactory.

ACTION: Motion by T. FENSKY, seconded by P. GANNON, and voted unanimously by those present, to DISMISS the matter (PHA-2019-0014), No Discipline Warranted, Remediation Complete

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Case #6

PHA-2019-0008

CVS #7530, DS3564

Time:11:28 AM

RECUSAL: A. STEIN 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.

- Inspectional deficiencies on 11/8/18 for temperature excursions of 29°F - 34°F on 26 occasions from 06/03/2018 to 10/04/2018 with action not documented for the refrigerator containing insulin, vaccines, and other refrigerated products with an insufficient POC indicating there were no products in the refrigerator to quarantine.
- In response to the complaint, MOR Do responded he recorded all the excursions contrary to the temperature logs indicating that MOR Do recorded excursions on 11 out of 26 occasions with 3 additional recordings undetermined.
- Pharmacist Jurik recorded excursions on 12 out of 26 occasions. No explanation for the deficiency was provided by Pharmacist Jurik who is no longer working at this CVS location.

- MOR Do stated twice daily temperature logs are used along with electronic monitoring that goes above and beyond MA policy and that electronic logs are for internal purposes only. None of the requested information for the electronic monitoring was provided including how the pharmacy is alerted of a temperature excursion.
- No documentation was provided confirming the integrity of the refrigerated products affected by the excursions as CVS did not identify anything as affected.
- CA: CVS policy and procedure for temperature excursion guidelines was reviewed with pharmacy staff. MOR Do and Pharmacist Jurik provided verbatim detailed steps to be taken for any excursion. Pharmacist Jurik confirmed reviewing Board Policy 2011-01 and CVS policies and procedures for action and documentation of refrigeration excursions.

ACTION: Motion by M. GODEK, seconded by S. HERNANDEZ, and voted unanimously by those present, to refer the matter (PHA-2019-0008) 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.

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Case #7

PHA-2019-0016

CVS #861, DS3550

Time: 11:30 AM

RECUSAL: NONE

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

- Inspection on 1/2/19 - noted on temperate logs, which didn't identify which refrigerator they accompanied, 62°F on morning of 8/16/18 with note "door ajar, closed door" and morning of 11/10/18 23°F with a note of "adjusted temp nob"
- No documentation of actions taken in response to the excursions to support medications had not been adversely affected and were safe and effective for use. Pharmacy was unable to provide such documentation in response to the POC. On the previous inspection, a recommendation that pharmacy add identifiers to refrigerator logs was noted.
- Floater Pharmacist Allen was identified as the person who recorded the excursion on 8/6/18 and Floater Pharmacist Duarte was identified as the person who recorded the excursion on 11/10/18; both excursions had with no supporting action documented.
- MOR Madrigal stated temperature logs are used along with electronic monitoring to record temperatures and that electronic logs are for internal purposes only. None of the requested information for the electronic monitoring was provided including how the pharmacy is alerted of a temperature excursion. Allegedly the alarm sounded for each excursion, but no evidence was submitted.
- No documentation was provided confirming the integrity of the refrigerated products affected by the excursions as CVS did not identify anything as affected.
- CA: CVS policy and procedure for temperature excursion guidelines was reviewed with pharmacy staff. MOR Madrigal provided detailed steps to be taken for any excursion.

ACTION: Motion by S. HAMILTON, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2019-0016) 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.

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Case #8

PHA-2019-0003

CVS #2500, DS3606

Time: 11:34 AM

RECUSAL: NONE

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

- RLCS-failure to timely report a confirmed loss of #100 hydrocodone/APAP 10/325mg that occurred on or about October 23, 2018. According to the final report, an investigation was concluded on November 14, 2018 and confirmed an unknown loss of #100 hydrocodone-acetaminophen 10-325 tablets. The loss was not reported to the BORP until November 30, 2018. The investigation did not identify theft or diversion and the loss was suspected to be a dispensing error.
- On 10/23/18, after filling a prescription, a pharmacist discovered a shortage of hydrocodone/APAP 10/325mg by one bottle of a one hundred-count. On 10/28/2018 an overage of hydrocodone/APAP 7.5/325mg by one bottle of one hundred-count was documented in the perpetual inventory log.
- Between the cycle count on 10/17/2018 and the state count on 10/28/2018 there were 3 prescriptions filled for hydrocodone/APAP 7.5/325 mg tablets. A prescription was dispensed on 10/18/2018 for #120 tablets required a bottle of 100-fill and a partial of 20 tablets from a second bottle. The pharmacy suspects but could not confirm, the patient may have received 100 hydrocodone 10/325 in error.
- MOR indicated that the untimely reporting of the loss was due to the investigation by her and the staff pharmacists to determine the identity of the customer who received the bottle of hydrocodone/ APAP 10.325mg instead of the hydrocodone/APAP 7.5/325mg tablets.
- MOR Dumond indicated that stock bottles of hydrocodone/APAP 10/325mg and hydrocodone/APAP 7.5/325mg were separated into two different safes. She indicated that when using multiple bottles, each bottle will be scanned before proceeding to fill the prescription. MOR Dumond and Pharmacist Dinnes completed 2 CE credits related to preventing medications errors and safe use of opioids. They attested to reading 247 CMR 15, in its entirety.

ACTION: Motion by M. GODEK, seconded by P. GANNON, and voted unanimously by those present, to DISMISS the matter (PHA-2019-0003), No Discipline Warranted, Remediation Complete.

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Case #9

PHA-2018-0044

CVS #2071, DS3589

Time: 11:38 AM

RECUSAL: NONE

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

- On February 19, 2018, CVS submitted an initial RLCS- #2,451 tramadol 50mg tablets as a result of an unknown loss. Investigation was conducted, and the pharmacy was unable to determine the cause of the loss. No evidence of diversion or violation of any company policy.
- The DEA also conducted an investigation at the pharmacy following the loss, they found no further significant discrepancies & closed their investigation. On June 5, 2018 CVS submitted an untimely final report.
- The complaint was reviewed by the Board on September 6, 2018. The Board voted to refer the complaint to the Office of Prosecution, for an Order to Show Cause, and to authorize resolution of the matter with a Non-Disciplinary Consent Agreement for Stayed Probation.
- Addendum: On February 7, 2019, CVS submitted an untimely RLCS. The reports indicated that there was a loss at the Pharmacy of #320 lorazepam 0.5mg tablets on or before December 13, 2018 identified via corporate controlled substance monitoring. The loss prevention team was able to rule out active losses or diversion by current team members, however an explanation of the loss was not uncovered
- To prevent a re-occurrence of similar drugs, CVS #2017 have taken the following action: All pharmacy staff to complete training regarding proper handling of controls in the pharmacy; All controls were removed from automation; All controls are double counted and initialed by counter; Cycle counts are performed by hand; Tramadol is now stored in the control drug safe and lorazepam is in the fast mover section which is visible to the pharmacist; The Pharmacy is completing monthly cycle counts and signing off on the counts; Weekly review of BOH reporting and order adjustments to identify any areas of concern and help prevent future loss.
- CVS #2701 has one prior reported loss. A retail compliance inspection was conducted on June 1, 2018 with no deficiencies noted.

ACTION: Motion by S. HERNANDEZ, seconded by K. TANZER, and voted unanimously by those present, to rescind the previous vote on 9/6/18 and refer the matter (PHA-2018-0044) 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 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 and all benzodiazepines 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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Case #10

PHA-2018-0086

CVS #2162, DS2687

Time: 11:42 AM

RECUSAL: NONE

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

- Multiple inspectional deficiencies noted during a <795> Inspection (ISP-11083) conducted on December 5, 2018, as well as a failure to implement a plan of correction from a <795> Compliance Inspection (ISP-9855) conducted on 5/23/2018
- On 12/5/2018 OPP Inspectors observed -compounding room had two missing ceiling tiles that are open to unknown air quality. Also, one tile is open to chilled water pipes. Ante room has one tile slid back with open access to ductwork. Compounding room is used as both hazardous and non-



hazardous increasing cross contamination risk. No additional mitigation provided, pressure cascade in room is inappropriate as compounding room is positive and ante room is negative.

- Previous inspection on May 23, 2018 resulted in POC for Contamination concerns associated with the BSC. Response included a mitigation strategy via a conference call with CVS Regulatory to only compound hazardous medications within the room and relocate non- hazardous to the main pharmacy plus additional items. Satisfactory POC submitted on 6/19/2018.
- <795> Compliance inspection on April 2, 2019 was deemed satisfactory, no POC issued.
- April 4, 2019, MOR and a CVS representative presented a Renovation/Expansion Plan at BORP monthly meeting. Plan was approved.
- MOR Litchfield indicated that bleach was purchased and is being used prior to using alcohol in the cleaning process. After proper decontamination has taken place, compounding will occur on the pharmacy counter and non-hazardous compounding will never occur at the same time as hazardous compounding. Employee compounding hazardous medications will continue to wear the following garb: Double gloves (chemo rated); full body gown; N97 mask; goggles; booties; and hair cover. MOR Litchfield indicated that a work order was issued and facilities has corrected the ceiling tile concern. He indicated that all Pharmacist are current on their LearNet trainings.
- MOR Litchfield stated, "In reference to the powder containment hoods, an outside venting plan has been identified by the BCH engineering team and will be expedited contingent on availability of the BCH contractor and ordering of two custom powder containment hoods after the Board has approved the necessary documents, which is a current process we are undergoing. The engineering plan allows for a "tunneling" straight up from within the compounding room through a bathroom corner on the floor above CVS Pharmacy #02162, and finally onto the roof for external ventilation purposes. In addition, noise stabilizers will be utilized to ensure no negative impact on the hospital patients, pressure balancing will be addressed if unable to address in a temporary fix and engineering documents will be submitted to the Board by April 4, 2019 for review upon receipt.

ACTION: Motion by S. HAMILTON, seconded by K. TANZER, and voted unanimously by those present, to DISMISS the matter (PHA-2018-0086), No Discipline Warranted, Remediation Complete.

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**Topic X** **EXECUTIVE SESSION** **Time: 11:49 AM**  
**Read by A. Stein**

DISCUSSION:

ACTION: At 11:50 AM President A. Stein read the statement on reasons for Executive Session.

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**Topic X:** **Executive Session Call to Order:** **Time: 11:52 AM**  
**By: A. Stein**

ACTION: Motion by M. Godek, seconded by L. Giambarresi, and voted unanimously by roll call to call the May 2, 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; T. Fensky, yes; L. Giambarresi, yes.



18. PHA-2018-0077 Injured Workers Pharmacy-DS89727
19. PHA-2018-0087 Metrowest Pharmacy-DS90075
20. SA-INV-14346 V-Care Pharmacy and Surgical Supplies-DS89813
21. PHA-2019-0017 Rite Aid #10115-DS90151
22. PHA-2019-0014 Maryesther Fournier-PH16359
23. PHA-2019-0008 CVS #7530-DS3564
24. PHA-2019-0016 CVS #861-DS3550
25. PHA-2019-0003 CVS #2500-DS3606
26. PHA-2018-0044 CVS #2071-DS3589
27. PHA-2018-0086 CVS #2162-DS2687

Respectfully Submitted,  
Julie Lanza, CPhT, Secretary