

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

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

August 30, 2016
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

Agenda

Time	#	Item	Exhibits	Contact
8:30	I	CALL TO ORDER		E. Taglieri
8:35	II	APPROVAL OF AGENDA <ul style="list-style-type: none"> • Introductions : Daniel Nova-Estepan, Intern 		
8:40	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none"> • Draft of August 2, 2016 Regular Session Minutes 		
8:45	IV	APPLICATIONS <ul style="list-style-type: none"> • Village Fertility Pharmacy –Transfer of Ownership • Special Care, LLC – Transfer of Ownership • US PharmaTrade, LLC – Wholesale Distributor • New England Home Therapies, Inc.-Transfer of Ownership (Falmouth and Canton) • Amherst Pharmacy LLC- Relocation • Apothecary of Cape Cod – Relocation • Health Care Family Pharmacy- New Community Pharm • Phoenix Pharmacy, LLC – New community pharmacy • Cardinal Health 414, LLC – Renovation/Expansion 		

10:00	V	REPORTS <ul style="list-style-type: none"> • Applications approved pursuant to Licensure Policies 13-01 & 16-01 • Monthly Report from Probation • Board Delegated Complaint Review pursuant to Licensure Policy 14-02 	Reports	R. Harris K. Fishman
10:10	VI	POLICIES <ul style="list-style-type: none"> • Amendments to Policy 14-01 • Public Hearing, September 19, 2016 • Policy. 2016-03: <u>An Introduction and Guide to the Practice and Implementation of Lean Concepts in a Pharmacy Setting</u> 		M. Chan
10:30	VII	REGULATORY REVIEW <ul style="list-style-type: none"> • 247 CMR 4.00: Personal Registration Renewal; Continuing Education Requirement • 247 CMR 6.00: Registration, Management and Operation of a Pharmacy or Pharmacy Department, • Budget bill changes to M.G.L. 		
11:30	IX	PETITION FOR REINSTATEMENT <ul style="list-style-type: none"> • Christopher Rizzo, PHA-2013-0001, PH19665 		T. Westgate
12:00	X	FLEX SESSION <ul style="list-style-type: none"> • Pilot re: Holding sanction hearings before full board • Advisory on new managers of record • Proposed Board calendar for 2017 • Update on Board Staff Response to Public Inquiries • Advisory on staff ratios, dedicated training personnel and pharmacy intern direct supervision 		V. Berg V. Thaker M. Chan
12:30		LUNCH BREAK		

1:30	XI	FILE REVIEW	
		1	SA-INV-7142, Apothecare Pharmacy, DS89820
		2	SA-INV-9409, Rite Aid, DS2577
		3	SA-INV-9330, Rite-Aid #10063, DS3009
		4	SA-INV-8725, Rite Aid #10099, DS3301
		5	PHA-2016-0027, Walgreens #10128, DS3472
		6	PHA-2016-0069, Cure-Aid Pharmacy, DS90028
		7	SA-INV-9333, Pharmacy Corp. of America, DS3599
		8	SA-INV-9420, Village Fertility Pharmacy, DS89658
		9	SA-INV-9625, Home Infusions Solutions, DS3592
		10	SA-INV-9327, Johnsons Compounding & Wellness Center, DS3579
		11	SA-INV-9328, Pentec Health, Inc., DS89913
		12	SA-INV-9534, Omnicare of Northern MA, DS89931
		13	PHA- 2016-0039, CVS Pharmacy #8972, DS89677
		14	PHA-2015-0150, CVS #447, DS3251
		15	SA-INV-8992, CVS #1031, DS89682
		16	SA-INV-9733, CVS #938, DS1505
		17	SA-INV-9425, CVS #920, DS89649
		18	SA-INV-9407, CVS #2098, DS2768
		19	SA-INV-9726. CVS #1866, DS2956
		20	SA-INV-9732, CVS #5402, DS89635

2:30	XII	<p>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.</p> <p>Specifically, the Board will discuss and evaluate the Good Moral Character as required for registration for pending applicants and request for modification/termination of probation.</p>	CLOSED SESSION
3:30	XIII	M.G.L. c. 112, § 65C SESSION	CLOSED SESSION
5:00	XIV	ADJOURNMENT	

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

**MINUTES OF THE REGULARLY SCHEDULED MEETING
239 Causeway Street, Fourth Floor Room 417A
Boston Massachusetts, 02114**

August 30, 2016

Board Members Present

Edmund Taglieri Jr., R.Ph, MSM, NHA
President
Timothy Fensky, R.Ph, FACA
President –elect
Patrick Gannon, RPh, MS
Phillippe Bouvier, R.Ph.
Karen Conley, RN, DNP
Richard Tinsley, MBA, M.Ed. (arrived at 9:02)
Catherine Basile, Pharm D, R.Ph.
William Cox CPhT (arrived at 8:37)
Andrew Stein, Pharm D, R.Ph.
Garrett Cavanaugh, R.Ph

Board Members Not Present

Michael Godek, R.Ph, Secretary
Ali Raja, MD, M.B.A., M.P.H.
Susan Cornacchio, JD

Board Staff Present

David Sencabaugh, R.Ph., Executive Director
Monica Vasquez, CPhT, Associate Executive Director
William Frisch, Director of Pharmacy Compliance
Michelle Chan, R.Ph., Quality Assurance Pharmacist
Heather Engman, JD, MPH Board Counsel
Joanne Trifone, R.Ph., Director of Pharmacy Investigations
Richard Harris, Program Analyst
Julienne Tran, PharmD, RPh. Pharmacy Investigator
Greg Melton, JD, R.Ph., Pharmacy Investigator
Vita Palazzolo Berg, JD, Chief Board Counsel
Joe Santoro, R.Ph. Contract Investigator
Kimberly Morton, CPhT, Compliance Officer
Cheryl Lathum, PharmD, R.Ph. Senior Pharmacy Investigator
Sam Penta, R.Ph. Pharmacy Investigator
Vishal Thaker, Pharm D, R.Ph., Contract Pharmacist

TOPIC I.

CALL TO ORDER 8:30 AM

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

TOPIC II.

APPROVAL OF AGENDA

DISCUSSION: None

ACTION:

Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously to approve the agenda.

Executive Director D. SENCABAUGH introduced APPE student D. NOVA-ESTAPAN from MCPHS University. President Taglieri asked other interns in the room to introduce themselves.

TOPIC III.

APPROVAL OF BOARD MINUTES

1. Draft August 2, 2016, Regular Session Minutes

DISCUSSION: None

ACTION:

Motion by R. TINSLEY, seconded by A. STEIN, and voted unanimously to approve the minutes of the Regular Session from August 2, 2016 (P. GANNON and G. CAVANAUGH abstained, since they were not present on August 2nd).

TOPIC IV:

APPLICATIONS

TIME: 8:40-10:22 am

**1. Village Fertility Pharmacy – Transfer of Ownership
Special Care, LLC – Transfer of Ownership**

RECUSAL: none

DISCUSSION: Representatives for the buyer were available by phone, however it was not necessary to call them, since the Board members were satisfied with the documents covering the transfer of ownership for the two entities which are located in Waltham, Massachusetts.

ACTION: Motion by A. STEIN, seconded by, C. BASILE, and voted unanimously in the affirmative to approve the application for transfer of ownership of Village Fertility Pharmacy to ABD Group, Inc. There was no change in MOR.

ACTION: Motion by A. STEIN, seconded by, C. BASILE, and voted unanimously in the affirmative to approve the application for transfer of ownership of Special Care, LLC to ABD Group, Inc., with waivers already in place. There was no change in MOR.

2. US PHARMATRADE

Wholesale Distributor

RECUSAL: None

DISCUSSION: US Pharmatrade, located in Burlington, MA, was represented by owner, Jalal Abbaspour. This is a start-up business with no existing clients, planning to export drugs from the United States to other countries, processed through a combination office in Burlington, MA. At the August 2nd Pharmacy Board meeting, members and Board staff were left unsure of necessary details to vote on whether to approve the license application, and asked Mr. Abbaspour to provide a more detailed business model, and the matter would be taken up at the next meeting.

Mr. Abbaspour provided the detailed description in writing prior to the August 30 meeting, and that was distributed to Board Members. Board Counsel H. ENGMAN cautioned about exporting in compliance with law. R. TINSLEY questioned Mr. Abbaspour about why it would make sense to export drugs to other countries, when it is believed that they are available less expensively outside the United States. Mr. Abbaspour responded that some are unique and not available in other countries, and that quality was an issue as well.

ACTION: Motion by P. GANNON second by P. BOUVIER, and voted in the affirmative, 9 – 1 to approve USPharmatrade’s application as a Wholesale Distributor, pending a successful inspection. R. TINSLEY voted in the Negative.

3. NEW ENGLAND HOME THERAPIES

Transfer of Ownership

RECUSAL: None

DISCUSSION: Home Solutions in Falmouth, MA and Canton, MA are transferring ownership to New England Home Therapies, a subsidiary of Bioscrip. Bioscrip was represented by Michael Carroll from their Corporate Clinical Team. Discussion centered around making sure new ownership understands upcoming proposed changes to steril compounding regulations. Other questions were answered to the Board’s satisfaction.

ACTION: Motion by P. BOUVIER, seconded by, K. CONLEY, and voted unanimously in the affirmative to approve the application for transfer of ownership of Home Solutions in Falmouth, MA, to NEHT, followed up by an inspection.

ACTION: Motion by P. GANNON, seconded by, G. CAVANAUGH, and voted unanimously in the affirmative to approve the application for transfer of ownership of Home Solutions in Canton, MA, to NEHT, followed up by an inspection.

4. AMHERST PHARMACY, LLC Relocation

RECUSAL: None

DISCUSSION: Amherst Pharmacy was represented (by phone), by Ioannis “John” Nikitas, Owner and MOR. THE Pharmacy is relocating within the same town (Amherst, MA), and will basically quadruple its front store space. Operating hours will remain the same.

ACTION: Motion by P. GANNON second by C. BASILE, and voted unanimously by those present to approve Amherst Pharmacy’s application for relocation, pending a successful inspection and review of their 795 attestation.

5. APOTHECARY of CAPE COD Relocation

RECUSAL: None

DISCUSSION: Apothecary of Cape Cod was represented by Nagy Wassef, Owner (and a pharmacist licensed in the State of Connecticut), and Ping Zou, MOR. The stated reason for the relocation is that they need more space in which to operate. Their intent is to offer the same service and keep the same hours of operation.

ACTION: Motion by P. GANNON second by C. BASILE, and voted unanimously by those present to approve Apothecary of Cape Cod’s application for relocation, pending a successful inspection.

6. HEALTH CARE FAMILY PHARMACY New Community Pharmacy

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

DISCUSSION: Health Care Family Pharmacy (HCFP), locating in Dracut, MA, was represented by Attorney Paul Garbarini, and proposed MOR, Soterius Hantzis. HCFP believes that there is a gap in coverage and pharmacy services in the area, and that they can do a better job delivering pharmacy services to customers. Representatives satisfactorily answered questions from Board Members.

ACTION: Motion by P. GANNON second by C. BASILE, and voted unanimously by those present to approve Health Care Family Pharmacy’s application as a new community pharmacy, pending a successful inspection, and after correcting #4 on their attestation, since they do not have a DCP license pending.

7. PHOENIX PHARMACY New Community Pharmacy

RECUSAL: None

DISCUSSION: Phoenix Pharmacy, to be located in Dorchester, MA, was represented by Marjan Mottaghi, proposed MOR, and Pharmacist Mohsen Alirezai. The pair answered the Board Members' questions about PMP, immunizing, self-inspection, compounding, and other items satisfactorily.

ACTION: Motion by T. FENSKY second by P. GANNON, and voted unanimously by those present to approve Phoenix Pharmacy's application as a new community pharmacy, pending a successful inspection, and changing their attestation to reflect moderate level of Non-Sterile compounding.

8. CARDINAL HEALTH Renovation and Expansion

RECUSAL: None

DISCUSSION: Cardinal Health was represented by Jay Mattson from Corporate Real Estate, in charge of construction, Sr. Zone Operations Manager Dan Palmquist, and MOR David Lamont.

Board staff has been working with Cardinal, since the recent NABP-contracted inspection turned up many areas of concern requiring remediation. In addition to the inspection results, Cardinal came into the meeting having had two consecutive above-action level results from environmental monitoring, and had conducted a third.

It was agreed between Board Staff/Members and Cardinal, that if the third EM testing results (pending at the time of the meeting) came back with above action level results, Cardinal would voluntarily cease compounding activity until remediated. Cardinal representatives stated that they had a continuity of care plan prepared for the time during the renovation period, and it would be implemented sooner, if EM testing results warranted. The plan would redirect patient care to the Cardinal facilities in Providence, RI, and Stamford, CT.

ACTION: Motion by K. CONLEY, second by A. STEIN, and voted unanimously to approve Cardinal's application for renovation.

TOPIC V.

REPORTS

Applications Approved Pursuant to Licensure Policy 13-01, 16-01 10:22 am

DISCUSSION: R. HARRIS noted that during the past month there have been eighteen (18) change-of-managers, one (1) new Community Pharmacy, five (5) transfers of ownership, and eleven (11) registered non-resident Outsourcing Facilities).

Board Delegated Review Pursuant to BDCR Policy

There were 8 Board Delegated Review cases heard on August 25, 2016 involving self-reports of CE deficiencies. All had been satisfactorily remediated and the files were closed/dismissed with no discipline warranted. The Board Delegated Review session was attended by E. TAGLIERI as the Board Member, H. ENGMAN as Board Counsel, M. CHAN (designated by W. FRISCH, Director of Pharmacy Compliance), and Executive Director D. SENCABAUGH.

ACTION: So noted

Report of activities Probation Monitor

DISCUSSION: K. FISHMAN provided the July 26, 2016 – August 18, 2016, Board of Pharmacy Statistics Report for the Probation monitor, which noted that: there are forty-nine (49) licensees on probation, twenty-seven (27) satisfactorily completed probation, three (3) licensee did not cure within 30 days, seven (7) given the opportunity to cure, and two (2) notices of further discipline.

ACTION: So noted

TOPIC VI

POLICIES

Time: 10:25 am

Amendments to Policy 14-01

DISCUSSION: To handle Good Moral Character cases, such as OUIs that are 3-5 years old. Criminal history, limited to a single event involving alcohol, occurring no less than 1 year ago, and no longer pending. If concerns arise, or less than 1 year has elapsed since resolution, the matter will be brought to the Board's attention. Note typographical error on #3a, #4 should be removed.

ACTION: Motion by P. GANNON, seconded by T.FENSKY, and voted unanimously to approve amendments to Policy 14-01 with condition of: Typographical changes.

Page 10 of 32

Minutes of the Regularly Scheduled Meeting held on August 30, 2016, approved on October 6, 2016

Notice of Public Hearing (Date: 9/19/2016)

Time: 10:30 am

247 CMR sections 3, 8, 10, and 16

DISCUSSION: Request for 1 Board member to assist on said date.

ACTION: C. BASILE to assist.

So noted

Policy 2016-03 An Introduction and Guide to the Practice and Implementation of Lean Concepts in a Pharmacy Setting: **Time: 10:31 am**

DISCUSSION: Presented by M. CHAN. Guidance in accordance with chapter 159 of the Acts of 2014. Certified LEAN concepts training guidance for efficiency and consistency within pharmacies. P.GANNON inquired into the need for regulation. H. ENGMAN noted guidance is sufficient and no corresponding regulation required, policy and M.G.L. ch.112 §39G,H,I are sufficient. R. TINSLEY raised point of patient care quality and efficiency being sufficient without need for concerns regarding waste. Proposed policy provides guidance for compounding pharmacies to develop and implement LEAN concepts (ex. Waste (medication errors)).

ACTION: Motion by P. GANNON, seconded by C. BASILE, and voted unanimously to approve Policy 2016-03, Lean Concepts in a Pharmacy Setting.

TOPIC VII:
REGULATORY REVIEW

Time: 10:36am

Regulatory Review:

247 CMR 4.00: Personal Registration Renewal; Continuing Education Requirement

DISCUSSION: V. BERG presented to the Board an update of 247 CMR 4.00. No new language contained therein. In May, CE requirements for vaccine administration were reviewed. No statute enforcing said requirement at present. Awaiting approval by Commissioner.

ACTION: None Taken. The section discussion will continue during the next meeting.

247 CMR 6.00: Registration, Management and Operation of a Pharmacy or Pharmacy Department **Time: 10:38 am**

DISCUSSION: V. Berg presented proposed changes to 247 CMR 6.00. Involves the provision of a notice to patients, prior to pharmacy closure. Edits incorporated. Language in section 6.13 with reference to providing a notice to patients when a pharmacy is set to close was discussed with the Board. Concerns were raised regarding ambiguity on length of time between notice and closure. K.CONLEY noted a need for a change to #3 "by

Page 11 of 32

Minutes of the Regularly Scheduled Meeting held on August 30, 2016, approved on October 6, 2016

mail” specify electronic versus postal. Perhaps Board can submit guidance for when electronic submission acceptable. Current regulations have no requirement noted. Change language from mail to postal mail. P. GANNON inquired as to pharmacy’s ability to fill a new prescription in the 14 days preceding closure. Language change: Upon patient request, within 3 business days of the request (Remove language before closure) change to transfer in a timely manner to meet patient needs.

ACTION: Approved with noted changes. Motion by P. GANNON with condition of noted changes, seconded by C. BASILE, and voted unanimously.

Budget Bill changes to M.G.L.

Time: 10:47 am

DISCUSSION: V. BERG presented proposed changes to M.G.L.

Section 64 amends M.G.L. c 94c section 7(a) to authorize the Board to require that outsourcing facilities who apply for an MCSR submit payment for a fee comparable as it currently does for pharmacies and wholesalers. Section 77 amends the definition for “Interchangeable biological product” in M.G.L. c. 112 section 12EE by changing FDA determination that the product is “biosimilar and interchangeable with” to “FDA determination that the product is “therapeutically equivalent to” Additional statutes to veterinary medicine regarding compounding: there is a concern among veterinarians, with regards to ability to obtain non-sterile compounds for emergency purposes if commercially available products are not appropriate for size, etc. of animal to be treated. There currently is no law allowing the distribution of these compounds by pharmacists. Understand veterinarians may have this expectation but pharmacists are not allowed to distribute compounds for office use. This may be a problem in the foreseeable future.

TOPIC VIII: Petition for Reinstatement

Christopher Rizzo, PHA-2013-0001, PH19665

Presented by H. Engman

11:05 am

RECUSAL: E. TAGLIERI recused himself and was not present for the discussion or vote.

DISCUSSION: T.FENSKY chaired this item due to E.TAGLIERI’s recusal.

Mr. Rizzo was present for the discussion and spoke on his own behalf. H. ENGMAN began the conversation by indicating Mr. Rizzo has filed a petition for reinstatement of his Massachusetts Pharmacist License. Mr. Rizzo’s MA RPH license was suspended on April of 2016, due to discipline in another jurisdiction. H. ENGMAN indicated that Mr. Rizzo submitted documentation showing that his RI RPH license was reinstated on March 17, 2016 with conditions that Mr. Rizzo does not serve as pharmacy manager for one year. He also provided documentation that his Virginia RPH license is current with no restrictions.

Mr. Rizzo indicated he was remorseful and always tries to do the right thing but was put in unfortunate situations. He indicated he was following SOP of the pharmacy. K. CONLEY asked why he didn't stand up to the company he was working for. Mr. Rizzo indicated he did not think the pharmacy was not compliant but things could have been done better. He indicated he attempted to revise SOPs and added double checks. K. CONLEY added that the role of a Pharmacist is to understand policy and procedures and apply to SOPs. Mr. Rizzo responded that he attempted to resolve the issues with the supervisors but was not successful

ACTION: At 12:07pm a motion by R.TINSLEY and seconded by P.BOUVIER to reinstate Christopher Rizzo's pharmacist license conditioned upon passing the MPJE and probation until April 2019. Additionally he shall not serve as a manager of record until 2019 and participate in an advocacy program once a year.

T.FENSKY: yes, R.TINSLEY: yes, S. CORNACCHIO: yes, P.BOUVIER: yes, A. STEIN: yes, C. BASILE: yes, K. CONELY: nay, W. COX: yes, P. GANNON: yes, G. CAVANAUGH: yes

TOPIC IX

FLEX SESSION

Time: 10:54am

Pilot: Holding sanctions hearings before the full Board

Presented by: Vita Berg

It was recommended that the Board initiate a pilot of scheduling hearings on sanctions during regularly scheduled board meetings for those cases where the licensee stipulates that he or she has engaged in conduct that is grounds for discipline and in cases where the board enters a summary decision. It was further recommended that after one year, the Board evaluate the success of the pilot in reducing time to complaint resolution and the burden on the board's ability to conduct other business during regularly scheduled board meetings.

ACTION: Motion by T. FENSKY, seconded by P. GANNON, and voted unanimously to approve a pilot to hold sanctions before the full Board.

TOPIC IX

FLEX SESSION

Time: 12:14pm

Advisory on New Managers of Record

Presented by: Michelle Chan

Discussion:

Board Quality Assurance Pharmacist Michelle Chan presented an overview of The Board of Registration in Pharmacy Advisory on New Managers of Record. The advisory is a reminder to new Managers of Record of some of the responsibilities that are required of them, when assuming the MOR position. Regulations, policies and a link to the Retail Compliance Inspection Tool can be found on the Advisory which will be posted on the Board's website.

ACTION: Motion by P. GANNON, seconded by K. CONLEY, and voted unanimously to approve the Advisory on New Managers of Record.

TOPIC IX

FLEX SESSION

Time: 12:13pm

Proposed Board Calendar for 2017

Presented by: Rick Harris

Discussion:

Meeting days will be changed from Tuesdays to Thursdays beginning next year.

ACTION: Motion by R. TINSLEY, seconded by C. BASILE, and voted unanimously to approve the Board Calendar for 2017.

TOPIC IX

FLEX SESSION

Time: 12:16pm

Update on Board Staff Response to Public Inquiries

Presented by: Vishal Thaker

Board staff logged a total of 574 inquiries from the public during FY2016. The top 3 categories of inquiries dealt with licensing, continuing education, and miscellaneous questions. Going forward, clarification keywords have been added to help categorize further the miscellaneous questions. Board staff has started recording "Time to Response" for each inquiry to help maintain accountability and provide a timely response.

So Noted

Advisory on Staff Ratios, dedicated training personnel, and pharmacy intern direct supervision.

Presented by: Vishal Thaker

Board Pharmacist Vishal Thaker presented an overview of The Board of Registration in Pharmacy Advisory on Staff Ratios, Dedicated Training Personnel and Pharmacy Intern Direct Supervision. The advisory is a reminder to licensees of the regulations regarding staff ratios and direct supervision of pharmacy interns while providing guidance on the calculation of supervisory ratios using dedicated training personnel. The Advisory will be posted on the Board's website.

ACTION: Motion by P. GANNON, seconded by K. CONLEY, and voted unanimously to approve the **Advisory on Staff Ratios, Dedicated Training Personnel, and Pharmacy Intern Direct Supervision**.

TOPIC: X

I. Open File Review Cases 1-10

I. Open File Review

1. SA-INV-7142 Apothecare Pharmacy, DS89820 TIME: 1:33 pm

RECUSAL: C. BASILE and W. COX recused and were not present for the discussion or vote on this matter.

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

- Allegation the owner of Apothecare of South Shore instructed pharmacy interns to introduce themselves as pharmacists to patients on the phone, conduct comprehensive medication reviews and to submit false claims to the MTM vendor for services that were not provided.
- MOR Peterson stated, "When pharmacy interns are in a long term setting they are monitored by a pharmacist via use of an ipad (Skype) at all times" and reiterated when a pharmacy intern is working at a remote location, "the intern is in constant communication with a supervising pharmacist via an ipad (Skype)". Students are not allowed to bill for their services at Apothecare and "a pharmacist is always involved". According to MOR Peterson, "No one, student or other, was instructed to submit false claims at any time".
- According to the Complainant, Senior Whole Health has "not been able to substantiate any of the allegations" and the MTM vendor "could not find any irregularity in the claims that were submitted for MTM services by Apothecare".

ACTION: Motion by P. GANNON, seconded by A. STEIN, and voted unanimously by those present, to CLOSE SA-INV-7142, with the issuance of a Board approved advisory letter.

Case #2

SA-INV-9409

Rite Aid #10204, DS2577

TIME: 1:36 pm

RECUSAL: W. COX, and G. CAVANAUGH recused and were not present for the discussion or vote on this matter.

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

- The Office of Public Protection received a report of an unknown loss of #100 Methylphenidate ER10mg tablets.
- A staff Pharmacist discovered the loss during weekly reconciliation of CII perpetual inventory and indicated that she filled the last prescription before the loss.
- The MOR conducted an internal investigation with the Pharmacy District Manager (PDM) and was able to rule out active loss or diversion by current pharmacy team members and conclude that the bottle was accidentally thrown out.
- PDM met with staff to review loss prevention strategies and reinforce company protocol. Note: Store does not have cameras.
- Plan of correction indicated that pharmacists will back count full and partial bottles. Only a pharmacist will handle CII and be responsible for returning CII bottles to safe as soon as possible.

ACTION: Motion by K. CONLEY, seconded by C. BASILE, and voted unanimously by those present, to CLOSE SA-INV-9409, with insufficient evidence.

Case #3

SA-INV-9330

Rite Aid #10063, DS3009

TIME: 1:39 pm

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

DISCUSSION: J. TRAN presented and summarized the investigation report pertaining to these matters.

- On Dec 29, 2015, Rite Aid Pharmacy #10063 located in Springfield, MA had a loss of #427 alprazolam 2mg tablets with submission to the Board on Feb. 2, 2016.
- MOR indicated that they had ordered 3 x100ct bottles but was substituted with 3x500ct bottles.
- Rite Aid conducted a full investigation and monitored the supply of the medication for several months. Additionally, they reviewed all paperwork and audits of prescriptions.

- There are no security cameras in the pharmacy so there is no camera footage.
- As a corrective action, all strengths of alprazolam were moved into a more visual area, & controlled substance policies were reviewed with all employees. The quantity on the invoice is circled by the Pharmacist as an additional check. If there had been further discrepancies it was discussed a camera would be added in the pharmacy.
- Investigator Brosnan completed a retail inspection (ISP-5513) on July 7, 2016 with no deficiencies noted.

ACTION: Motion by P. GANNON, seconded by C. BASILE and voted unanimously by those present, to convert SA-INV-9330 to a COMPLAINT.

Case #4

SA-INV-8725

Rite Aid #10099, DS3301

TIME: 1:46 pm

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

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

- Office of Public Protection received a DEA 106 form submission of #271 tramadol 50mg tablets at Rite Aid Pharmacy #10099 on or about September 3, 2015.
- Tramadol loss discovered upon return from maternity leave. The store's DVR system was analyzed and available pertinent footage was reviewed. The tramadol loss may have been caused by inaccurate dispensing due to miscounts and/or improper processing of returns.
- Covert cameras installed and monitored for 3 months with additional counts completed during that time with no additional loss revealed.
- A Retail Compliance (ISP-4830) inspection at Rite Aid Pharmacy #10099 was completed by Investigator John Murray on March 3, 2016 with a deficiency observed including expired Pneumovax vaccine found in the refrigerator but not administered.
- MOR reinforced policies and procedures of handling control substances to prevent miscounts including double counting all controls prior to dispensing.

ACTION: Motion by A. STEIN, seconded by T. FENSKY and voted by the majority of those present, to CLOSE SA-INV-8725, with insufficient evidence. P. GANNON voted against this action.

Case #5

PHA-2016-0027

Walgreens Pharmacy #10128, DS3472

TIME: 1:52 pm

RECUSAL: N/A

DISCUSSION: G. MELTON presented and summarized the investigation report that

Page 17 of 32

Minutes of the Regularly Scheduled Meeting held on August 30, 2016, approved on October 6, 2016

pertained to these matters.

- Office of Public Protection (OPP) opened Complaint against Walgreens Pharmacy #10128 located in Ware, MA based on an untimely Report of Loss of Controlled Substance (RLCS) submitted on December 23, 2015:
December 23, 2016:
- MOR Christopher J. Waldron submitted an untimely RLCS for “an unexplained loss” of 100 tablets of oxycodone 30mg immediate release discovered on November 20, 2015.
- MOR chose to delay reporting loss 3 weeks because he believed that “the missing drugs would eventually turn up” as the pharmacy had no history of diversion from the CII cabinet and “if something was off on the count it was always discovered because someone forgot to write in an invoice or sale.”
- MOR Waldron was issued a written warning by Walgreens for failing to report the loss in a timely manner and the result of the internal investigation reported that MOR Waldron was grossly negligent in the handling of the loss. Significantly, the internal investigation found no evidence of theft or fraud by MOR Waldron.
- MOR Waldron believed that the bottle was likely thrown out.
- MOR Waldron described the plan of correction. He stated, “Corrective action includes [sic] back counting of all CII prescriptions and verifying inventory with each prescription. Double counting of all CII prescriptions.”

Of Note:

- A Retail Compliance Inspection (ISP-4141) on November 24, 2015. OPP Inspectors observed a deficiency involving no weights and measures seal on a recently acquired scale. A plan of correction (POC) and an ongoing compliance plan were submitted to remediate the observed deficiencies.

ACTION: Motion by C. BASILE, seconded by P. GANNON, and voted unanimously by those present, to DISMISS PHA-2016-0027, with no discipline warranted.

ACTION: Motion by C. BASILE, seconded by G. CAVANAUGH, and voted unanimously by those present, to open a COMPLAINT on MOR Waldron.

Case #6

PHA-2016-0069

Cure Aid Pharmacy, DS90028

TIME: 1:55 pm

RECUSAL: N/A

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

- Office of Public Protection (OPP) opened a complaint against Cure-Aid Pharmacy located in Lawrence, MA based on inspectional deficiencies observed on May 27, 2016 and August 1, 2016. Specifically, the pharmacy was observed to be closed during normal operating hours on both inspections:

January 27, 2016:

- Cure-Aid pharmacy was issued a pharmacy license after a New Pharmacy Inspection (ISP-2697) was completed and deemed satisfactory.

May 27, 2016:

- OPP Inspectors attempted to perform a routine Retail Compliance Inspection (ISP-5353) at Cure-Aid Pharmacy. OPP Inspectors arrived at approximately 10:00am and observed that the pharmacy was “closed and locked” and “the front store was empty.” The Retail Compliance Inspection was called off at that time.

July 15, 2016:

- Cure-Aid Pharmacy’s attorney wrote that the opening has been slowed by internal business issues. The issues included administrative errors when filing the MassHealth application, MOR Grokhotov decided to leave the company, and credit with wholesalers has been unable to be obtained due to MOR Grokhotov’s departure.
- The attorney also wrote that a new MOR had been found, a change in MOR would be filed, the articles of organization would be amended, and a corrected MassHealth application would be submitted.
- The attorney further indicated in follow up correspondence that the store would be opened by August.

August 1, 2016:

- OPP Inspectors returned for a Retail Compliance Inspection (ISP-5724). Again, Cure-Aid Pharmacy was found closed during normal operating hours. However, OPP Inspectors were let inside the pharmacy by a construction worker.
- OPP Inspectors also observed “a leak observed in the ceiling and the construction worker said they were waiting for the landowner to fix it”
- The construction worker further stated that “the Pharmacy should open in September.”

Of Note:

- On August 23, 2016, Record checks showed that the Board had not received an application for a change in MOR, the Secretary of the Commonwealth’s Office showed that Cure-Aid Pharmacy corporate officers and directors remain unchanged, and the pending MassHealth application has not been approved according to MassHealth.

ACTION: Motion by P. GANNON, seconded by G. CAVANAUGH, and voted unanimously by those present, to DISMISS PHA-2016-0069, pursuant to DS90028 opening by September 30, 2016, and a successful inspection. If the pharmacy does not open by this date (9/30/16), the Board voted to request the pharmacy close in accordance with 247 CMR 6.00 and to refer the matter to prosecution if the pharmacy does not close voluntarily.

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

- Office of Public Protection (OPP) recieved a copy of a DEA 106 report with a loss of #4 oxycodone 5mg tablets and #4 oxycodone/apap 5mg/325mg tablets at Pharmacy Corporation of America on or about January 6, 2016 due to loss from the emergency kit.
- MOR Lynch indicated that the loss was discovered when pharmacy control room technician indicated that the missing tablets were not documented on the return manifest or the usage form in addition to 1 tab of lorazepam 0.5mg.
- Policy is to document removal from the kit with a copy faxed to the pharmacy with an order and placed in the kit until exchange. Before reporting off duty, the charge nurse indicates open or sealed status at the shift change & transfers the new med order to the oncoming staff.
- MOR stated that the loss occurred during the exchange at the nursing facility and courier service and one of the contributing factors in this case was that the inventory was not verified by the nurse on the return manifest upon the exchange.
- There are 4 cameras in the control room which were reviewed to confirm statements from pharmacy and courier staff; the camera in the transportation area was inconclusive.
- The Director of Nursing indicated that the kit was limited to the removal of 1 lorazepam 0.5mg tablet for a patient and not used so it was destroyed at the facility. She further noted that the nurse exchanging with the driver was new and not aware of the exchange process and the kit given back to the driver unsealed with a count verified 10 min prior to the exchange. The courier driver noted that the nurse counted and sealed the kit. The driver took a drug test and it was negative.
- The MOR provided a comprehensive investigation to the incident and concluded that the exact explanation for the loss could not be determined.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present, to CLOSE SA-INV-9333, with insufficient evidence, and to refer this matter to the Drug Control Program.

Case #8

SA-INV-9420

Village Fertility Pharmacy, DS89658

TIME: 2:13 pm

RECUSAL: N/A

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

- Board received notification on March 21, 2016 of 1 cfu/m³ Soprobioc contaminant-*Altemana* spp. (mold) (surface sample –ISO 8) non-pathogenic.
- Proper remediation completed.
- Re-sample date March, 21, 2016: Facility met the acceptance criteria: No growth and resumed USP <797> sterile compounding
- Potential Root Causes: There is a possibility that the mold might have come from the storage area where the cleaning agents are stored and hence transferred to the clean room
- Prevention: An inclusion of scrubs to be worn in clean room which will be cleaned by a professional service. Designated shoes to be used in the clean room will be distributed to all clean room personnel. Monthly cleaning of storage area added to cleaning schedule using Bleach.

ACTION: Motion by K. CONLEY, seconded by C. BASILE, and voted unanimously by those present, to CLOSE SA-INV-9420, no violation.

Case #9

SA-INV-9625

Home Infusion Solutions, DS3592

TIME: 2:15 pm

RECUSAL: N/A

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

- Board received notification on June 14, 2016 of 1 cfu/m³ -*Aspergillus niger/brasiliensis* (mold) (surface sample –ISO 8) ante room table; 1 cfu/m³ Coag. Negative *Staphylococcus* (air sample of A4 buffer room-ISO-7); 1-*Trichophyton* spp.
- Proper remediation completed
- Continued to compound low and medium risk CSP's with a BUD of 24 hours at room temperature and 3 days refrigerated following the guidelines of draft regulations 247 CMR 17 (specifically, 17.27 & 17.28)
- Re-Sample date June 17, 2016: Facility met the acceptance criteria with no growth and resumed USP <797> sterile compounding.
- Potential Root Causes: No root cause found but highly suspect positive results from an equipment box brought into the buffer area that was not cleaned properly.
- The plan of correction included the purchases of bunny suits and that the testing technicians will be required to wear them prior to entering sterile rooms. They will also require that their equipment be wiped down with sterile alcohol prior to entering sterile rooms.

Page 21 of 32

Minutes of the Regularly Scheduled Meeting held on August 30, 2016, approved on October 6, 2016

ACTION: Motion by P. GANNON, seconded by K. CONLEY, and voted unanimously by those present, to CLOSE SA-INV-9625, no violation.

Case #10

SA-INV-9327 Johnsons Compounding & Wellness Center, DS3579 TIME: 2:17 pm
RECUSAL: A. STEIN recused and was not present for the discussion or vote on this matter.

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

- Office of Public Protection opened an investigation concerning Johnsons Compounding & Wellness Center located in Waltham, MA based on a timely self-disclosure of an abnormal result.

March 31, 2016:

- Proper disclosure of abnormal results in (-) pressure cleanroom after receipt of Environmental Monitoring (EM) on March 23, 2016.
- Compounding ceased and Proper Remediation completed including EM retest.

April 11, 2016:

- Results of EM within USP action limits and compounding was resumed.

Of Note:

- The most recent USP <797> Inspection (ISP-4808) was completed on March 8, 2016 and was deemed satisfactory.

ACTION: Motion by P. GANNON, seconded by C. BASILE, and voted unanimously by those present, to CLOSE SA-INV-9327, no violation.

TOPIC: X

I. Open File Review Cases 11-20

Case #11

SA-INV-9328

Pentec Health, Inc., DS89913

TIME: 2:19 PM

RECUSAL: N/A

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

- On February 24, 2016, Board received a self-report of hits: Actionable: 1cfu/m3 Alternaria (mold) (surface sample – ISO 8), 1 cfu/m3 Staph like growth (surface sample – ISO 8)
- BUD reduced to 3 days

Page 22 of 32

Minutes of the Regularly Scheduled Meeting held on August 30, 2016, approved on October 6, 2016

- **Remediation:** installed waterless hand sanitizing dispenser outside of the anteroom, purchased dedicated shoes for testing personnel, and full remedial cleaning.
- **Root Cause:** Testing personnel most likely touched his shoes and transferred the mold from his shoes to his hands then finally to the cart.
- Follow-up EM sample date March 3, 2016 with reported date of March 14, 2016 within action limits

ACTION: Motion by C. BASILE, seconded by P. GANNON, and voted unanimously by those present, to close SA-INV-9328, no violation.

Case #12

SA-INV-9543

Omnicare of Northern MA, DS89931

TIME: 2:22

PM

RECUSAL: N/A

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

- During a routine USP <797> compliance inspection (ISP-5045) conducted on April 21, 2016, Pharmacy Investigators Seed, Murray, McKenna and Tran cited deficiencies including, but not limited to: observation of a piece of wood up against the ante room wall, a bubble in the ante room floor and it was observed that the vinyl floor lifting from the sub floor with two small cracks in the seam between the vinyl flooring sections in the same area.
- Beyond use dates (BUDs) reduced to three days with a proper remediation plan.
- Work Plan: existing flooring to be removed and cut flush with existing frames, damaged plexi glass where the sink was attached will be replaced and the sink remounted, thorough monthly type clean will be done on both rooms.
- On May 27, 2016, the Board received a self report of 1 cfu/m³ (yeast) (surface sample stainless steel cart – ISO 7) with compounding activity suspended once the results were reviewed, cleaning completed, and reinforcement of proper gowning and cleaning technique. Cleanroom shut down on 5/27/16 due to the hit. Continuity of care with compounding completed at Omnicare NH.
- EM completed June 16, 2016 with 2 non-actionable results.
- USP <797> Compliance Inspection (ISP pending) conducted by Investigators Murray, VanAllen and McKenna on June 27, 2016 with no deficiencies noted.

ACTION: Motion by K. CONLEY, seconded by C. BASILE, and voted unanimously by those present, to close SA-INV-9534, no violation.

Case #13
PHA-2016-0039
PM
RECUSAL: N/A

CVS Pharmacy #8972, DS89677

TIME: 2:24

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

- Inspectional deficiencies related to refrigeration noted on 3 inspections.
- ISP-2976 on 3/30/15 MOR Mach: not logging temperatures on 200+ occasions with most recorded less than 35°F; action indicated 4 times; 9/22/14 & 3/5/15 notation inventory damaged out of the freezer.
- CA: refrigerators were serviced; replaced old and broken thermometers; RPh on duty only is responsible for recording temps; reviewed vaccine administered during time period, contacted manufacturers to determine integrity of products, contacted MDs/patients,
- ISP-4371 on 8/11/15 MOR Reis: no action policy available for review.
- CA: submitted all P&P related to temperature monitoring and vaccine storage with staff attestations.
- ISP-5464 on 6/9/16 MOR Lai-Tran small fridge out of range 23 occasions 1/3/16 to 4/14/16 with no action documented or inadequate documentation.
- CA: New fridge purchased; revised temperature log to include time temperature noted out of range, action taken and how long it took to return in range; reviewed with all staff

ACTION: Motion by E. TAGLIERI, seconded by K. CONLEY, and voted unanimously by those present, to refer PHA-2016-0039 to the Office of Prosecution, for order to show cause and authorize to enter consent agreement for probation for a period of 1 year during which the licensee will be required to read Board Policy on refrigeration and conduct quarterly self-inspections.

Case #14
PHA-2015-0150
RECUSAL: N/A

CVS #447, DS3251

TIME: 2:28 PM

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

OPP opened a complaint against CVS Pharmacy #447 located in Northampton, MA based on the findings of two separate investigations (SA-INV-7084 & SA-INV-7677) of self-reported losses of controlled substance (RLCS) medications:

September 3, 2014

- According to the report, 112 tablets of oxycodone/acetaminophen 10/325mg were lost on August 26, 2014
- The patient called to ask if her prescription was ready for pick. The prescription was listed as verified and in waiting bin for pick up. However, the prescription was unable to be found. A label was reprinted and the prescription was dispensed at to patient at that time. Later, a review of surveillance video was performed. The video revealed that the patient had previously picked up the prescription but the transaction did not register correctly through point of sale (POS). Patient denied picking up two prescriptions when contacted.
- MOR Wheeler stated, "Since our belief is that it was not correctly rung through POS, I reviewed all the steps required during each transaction at the register with each employee."

May 7, 2015

- According to the report, 2,650 tablets of alprazolam 2mg were discovered lost on April 19, 2015.
- LPM team conducted investigation including cycle counts, covert surveillance, enhanced electronic inventory monitoring, and interviews with pharmacy staff. No evidence of diversion or policy violations.

June 2, 2016

- CVS Pharmacy #447 declined the opportunity to provide additional information after being notified of this complaint.

Of Note:

- The most recent Retail Compliance Inspection (ISP-5367) was completed at CVS Pharmacy #447 on June 1, 2016. OPP Inspectors observed deficiencies involving Licensure and Registration of Pharmacy Staff (records not easily retrievable), Pharmacy Interns and Technicians (excess trainee hours), Controlled Substances Records (CII returns), Equipment, Facility and Drug Storage (expired drugs), and Immunizations (proof of CPR). A plan of correction (POC) and an ongoing compliance plan were submitted to remediate the observed deficiencies.

ACTION: Motion by T. FENSKY, seconded by A. STEIN, and voted unanimously by those present, to refer PHA-2015-0150 to the Office of Prosecution, for order to show cause and authorize to enter consent agreement for reprimand.

Case #15

SA-INV-8992

CVS #1031, DS89682

TIME: 2:32 PM

RECUSAL: N/A

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

On December 7, 2015

- CVS Pharmacy #1031 submitted a RLCS for an unknown loss of 90 tablets of amphetamine salts combo 20mg discovered lost on November 22, 2015.
- MOR Mwangi stated, “The loss of amphetamine salts 20mg was identified during a routine reconciliation of the medication. The reason for the loss could not be conclusively confirmed. It appears that prescription number [redacted] (originally written for 120 tablets and edited to a quantity of 30 tablets due to third party insurance plan limitations) may have been dispensed for 120 instead of 30 tablets, resulting in the loss. We attempted to contact the customer to confirm but were unsuccessful in reaching them.”
- MOR Mwangi described the POC for CVS Pharmacy #1031. She stated, “Controlled substance and loss prevention polices were reviewed with pharmacy staff, which included double counting of controlled substances and smock/bag checks.”

Of Note:

- A Retail Compliance Inspection (ISP-4494) at CVS Pharmacy #1031 was completed on January 13, 2016. OPP Investigators observed deficiencies involving refrigeration and display signs. CVS Pharmacy #1031 submitted a Plan of Correction (POC) and an Ongoing Compliance Plan for remediation

ACTION: Motion by A. STEIN, seconded by C. BASILE, and voted unanimously by those present, to close SA-INV-8992 due to insufficient evidence.

Case #16

SA-INV-9733

CVS Pharmacy #938, DS1505

TIME: 2:35

PM

RECUSAL: N/A

DISCUSSION: J. TRIFONE presented and summarized the investigation report that pertained to these matters.

- OPP received notification of a loss of #252 Tramadol 50mg tablets. The loss was identified during corporate controlled substance monitoring.
- The CVS Loss Prevention Team opened an investigation and the drug was counted daily and reconciled weekly for a period of 4 weeks.
- During that time the store did not have a single variance. Video footage was not used as it was determined that this was not an active loss- An explanation of the loss was not uncovered
- The plan of corrective action indicated that the staff is now required to double count all controlled medications prior to dispensing to prevent miscounts- In addition during inventories the pharmacist will be required to double check controlled substances most commonly dispensed and prescriptions in the waiting bins to accurately count all medications- All technician that handle damage drugs

Page 26 of 32

Minutes of the Regularly Scheduled Meeting held on August 30, 2016, approved on October 6, 2016

or outdates were retrained to review proper procedures to prevent inaccuracies- MOR has reviewed all baseline loss prevention procedures with the staff, especially those that prevent drug diversion

ACTION: Motion by E. TAGLIERI, seconded by K. CONLEY, and voted unanimously by those present, to close SA-INV-9733 due to insufficient evidence.

Case #17

SA-INV-9425

CVS #920, DS89649

TIME: 2:35

PM

RECUSAL: N/A

DISCUSSION: J. TRIFONE presented and summarized the investigation report that pertained to these matters.

April 22, 2016 (amended from February 19, 2016)

- CVS submitted a RLCS for an unknown loss of 741 tablets of tramadol 50mg
- An internal investigation by CVS LPM including covert surveillance, cycle counts, and monitoring & review of inventory management was performed for a month.
- LPM reported that “this review did not reveal any evidence of diversion or gross violation of current policy. At that time the loss prevention team was able to rule out active losses or diversion by current pharmacy team members but did not uncover an explanation for the loss.”
- MOR Kilcoyne described the POC. She stated, “The loss may be attributed to inaccurate dispensing (miscounts) and improper handling/processing of returns (outdates) or StrongPak (damages) over the two year period of the reconciliation. I have reminded my team to double count all controlled medication prior to dispensing to reduce any miscounts. We have also re-trained the technicians responsible for handling damages/outdates on proper procedures to prevent inaccuracies. Finally, I have reviewed all baseline loss prevention procedures with the staff, specifically those that prevent drug diversion.”

Of Note

- The most recent Retail Compliance (ISP-4517) inspection at CVS Pharmacy #920 was completed on January 19, 2016 and was deemed satisfactory.

ACTION: Motion by E.TAGLIERI, seconded by K. CONLEY, and voted unanimously by those present, to close SA-INV-9425 due to insufficient evidence.

Case #18
SA-INV-9407
PM
RECUSAL: N/A

CVS Pharmacy #2098, DS2768

TIME: 2:36

DISCUSSION: J. TRIFONE presented and summarized the investigation report that pertained to these matters.

June 24, 2016 (amended from May 14, 2016)

- CVS submitted a RLCS for an unknown loss of 890 tablets of tramadol 50mg
- An internal investigation by CVS LPM including covert surveillance, cycle counts, and monitoring & review of inventory management was performed for a month.
- LPM reported that “this review did not reveal any evidence of diversion or gross violation of current policy. At that time the loss prevention team was able to rule out active losses or diversion by current pharmacy team members but did not uncover an explanation for the loss.”
- MOR Alexander described the POC. She stated, “Going forward, our store will review BOH modification reports, ordering, and cycle count activity in sufficient detail to quickly identify and prevent drug count discrepancies and diversion. I have also reminded my team to double count all controlled medication prior to dispensing to reduce any miscounts. In addition, during all inventories the pharmacist on duty will double check all controlled substances most commonly dispensed and prescriptions in the waiting bin to accurately count all medications. We have also retrained the technicians responsible to [sic] handling damages/outdates on proper procedures to prevent inaccuracies. Finally, I have reviewed all baseline loss prevention procedures with the staff, specifically those that prevent drug diversion.”

Of Note:

- The most recent Retail Compliance (ISP-4819) inspection at CVS Pharmacy #2098 was completed on April 19, 2016. OPP Investigators observed deficiencies involving lack of nametags for pharmacy technician and pharmacy technician trainee as well as beyond use dates (BUD) on non-sterile compounded preparations in excess of USP <795> limits. CVS Pharmacy #2098 submitted a plan of correction (POC) and an ongoing complaint plan to remediate the observed deficiencies.

ACTION: Motion by E.TAGLIERI, seconded by K. CONLEY, and voted unanimously by those present, to close SA-INV-9407 due to insufficient evidence.

Case #19
SA-INV-9726
PM
RECUSAL: N/A

CVS Pharmacy #1866, DS2956

TIME: 2:37

DISCUSSION: J. TRIFONE presented and summarized the investigation report that pertained to these matters.

- The OPP received notification of a loss of #829 Zolpidem 5mg tablets on or about April 20, 2016- The loss was from the time period of the biennial inventory 5/1/2015 thru 4/13/2016
- MOR indicated that the store received a bottle of 500 tablets in that delivery of the biennial inventory night which may not have been included in the biennial count depending on timing of the delivery and when it was actually put away.
- The CVS Loss Prevention Team opened an investigation into the matter and performed a final reconciliation, which was performed from the same time range. A copy of the CVS Inventory and Invoice Management Report was submitted to the OPP Investigator- The report indicated that the loss was significantly less at -244 tablets. This variance was based on the amount of tablets shipped and the amount of tablets dispensed during the same time period. A full investigation did not reveal any evidence of diversion or gross violations of current policy- OPP Investigator received an amended DEA 106 for -244 tablets
 - Plan of Corrective action indicated inventory reconciliation will be performed on night, medication received will be immediately included in to the inventory and all strengths of Zolpidem counted monthly-MOR has reviewed all baseline loss prevention procedures with the staff, specifically those that prevent drug diversion.

ACTION: Motion by E.TAGLIERI, seconded by K. CONLEY, and voted unanimously by those present, to close SA-INV-9726 due to insufficient evidence.

Case #20

SA-INV-9732

CVS Pharmacy #5402, DS89635

TIME: 2:38 PM

RECUSAL: N/A

DISCUSSION: J. TRIFONE presented and summarized the investigation report that pertained to these matters.

- On June 3, 2016, OPP recieved a copy of a DEA 106 report with an unknown loss of #552 Tramadol 50mg tablets.
- Loss Prevention team opened up an investigation, and were able to rule out active losses or diversion, but the cause of the previous loss remains unknown. They reviewed cycle counts, biennial inventories, staffing schedules, and inventory reports for the applicable time period and were unable to identify the reason for the loss
- Remediation- review BOH modification reports, ordering, and cycle count activity in sufficient detail to quickly identify and prevent drug count discrepancies or diversion. Will double count all controlled medication prior to dispensing to reduce any miscounts. During all inventories only the pharmacist on duty will double check all controlled

Page 29 of 32

Minutes of the Regularly Scheduled Meeting held on August 30, 2016, approved on October 6, 2016

substances most commonly dispensed and prescriptions in the waiting bin to accurately count all medications & reviewed all baseline loss prevention procedures with the staff, specifically those that prevent drug diversion

- A Retail Compliance (ISP-4624) inspection at CVS Pharmacy #5402 was completed by Investigator Rick Geaney on January 28, 2016 with one deficiency noted: Expired medications were not included in perpetual inventory counts until returned to a reverse distributor.

ACTION: Motion by E.TAGLIERI, seconded by C. BASILE, and voted unanimously by those present, to close SA-INV-9732 due to insufficient evidence.

TOPIC XI

EXECUTIVE SESSION

DISCUSSION: None

ACTION: At 2:45 President Taglieri called for a motion to enter Executive Session: Motion by W. COX seconded by P. GANNON and voted unanimously by roll call to enter into Executive Session. E. TAGLIERI; yes, T. FENSKY; yes, P. BOUVIER; yes, C. BASILE; yes, P.GANNON; yes, W. COX; yes, R. TINSLEY; yes. K. CONLEY; yes, A. STEIN: yes G. CAVANAUGH: yes

At 3:58 pm motion by P. GANNON seconded by T. FENSKY, and voted unanimously by roll call to adjourn Executive session. E. TAGLIERI; yes, T. FENSKY; yes, P. BOUVIER; yes, C. BASILE; yes, P.GANNON; yes, W. COX; yes, R. TINSLEY; yes. K. CONLEY; yes, A. STEIN: yes G. CAVANAUGH: yes

TOPIC XII.

M.G.L. c. 65C Session

DISCUSSION: None

ACTION: At 4:04 pm motion by K. CONLEY, seconded by P. GANNON and voted unanimously to enter into M.G.L. c. 65C Session. E. TAGLIERI; yes, T. FENSKY; yes, P. BOUVIER; yes, C. BASILE; yes, P.GANNON; yes, W. COX; yes, R. TINSLEY; yes. K. CONLEY; yes, A. STEIN: yes G. CAVANAUGH: yes

ACTION: At 4:59 pm motion by P. GANNON, seconded by C. BASILE and voted unanimously to voted unanimously to adjourn M.G.L. 65 C.

TOPIC XIII.

ADJOURNMENT OF MEETING

DISCUSSION: NONE

ACTION: At 5:00 pm motion by P. BOUVIER, seconded by C. BASILE, and voted unanimously to adjourn the meeting.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda for the August 30, 2016, regularly scheduled meeting of the Board of Registration in Pharmacy.
2. Draft August 2, 2016 Open Session Minutes.
3. Application for Transfer of Ownership Village Fertility Pharmacy
4. Application for Transfer of Ownership Special Care, LLC
5. Application for Transfer of Ownership Amherst Pharmacy
6. Application for Transfer of Ownership Home Infusion Solutions, Falmouth, MA
7. Application for Transfer of Ownership Home Infusion Solutions, Canton, MA
8. Application for Relocation Apothecary of Cape Cod
9. Application for New Community Pharmacy Health Care Family Pharmacy
10. Application for New Community Pharmacy Phoenix Pharmacy
11. Application for renovation and expansion Cardinal Health
12. Report of Applications approved pursuant to licensure policy 13-01
13. Report of Application information pursuant to licensure policy 16-01
14. Report from Probation Monitor 7/26/2016 – 8/18/2016
15. Board Delegated Compliant Review report 8/25/2016
16. Proposed Amendment to Licensure Policy 14-01
17. Draft Board Policy “An Introduction and Guide to the Practice and Implementation of Lean Concepts in a Pharmacy Setting”
18. Draft proposed changes to regulation 247 CMR 16.00: Collaborative Practice
19. Memo from Board Counsel on Budget Bill Outside Sections impacting pharmacy practice
20. Petition for Reinstatement PHA-2013-0001 Christopher Rizzo
21. Memo from Board Counsel on Pilot for Hearings on Sanction Before the Board
22. Draft Advisory on New Managers of Record
23. Draft Advisory on Staff Ratios, Dedicated Training Personnel, and Pharmacy Intern Direct Supervision
24. Memorandum Update on Board Staff Response to Public Inquiries
25. Investigation report in the matter of Apothecare Pharmacy, DS89820, SA-INV-7142
26. Investigation report in the matter of Rite Aid #10204, DS2577, SA-INV-9409
27. Investigation report in the matter of Rite Aid #10063, DS3009, SA-INV-9330
28. Investigation report in the matter of Rite Aid #10099, DS3301, SA-INV-8725
29. Investigation report in the matter of Walgreens Pharmacy10128, DS3472, PHA-2016-0027
30. Investigation report in the matter of Cure Aid Pharmacy, DS90028, PHA-2016-0069
31. Investigation report in the matter of Pharmacy Corporation of America, DS3599, SA-INV-9333
32. Investigation report in the matter of Village Fertility Pharmacy, DS89658, SA-INV-9420
33. Investigation report in the matter of Home Infusion Solutions, DS3592, SA-INV-9625

34. Investigation report in the matter of Johnson's Compounding and Wellness Center, DS3579, SA-INV-9327
35. Investigation report in the matter of Pentec Health, DS89913, SA-INV-9328
36. Investigation report in the matter of Omnicare of Northern MA, DS89931, SA-INV-9543
37. Investigation report in the matter of CVS #8972, DS89677, PHA-2016-0039
38. Investigation report in the matter of CVS #447, DS3251, PHA-2015-0150
39. Investigation report in the matter of CVS #1031, DS89682, SA-INV-8992
40. Investigation report in the matter of CVS #938, DS1505, SA-INV-9733
41. Investigation report in the matter of CVS #920, DS89649, SA-INV-9425
42. Investigation report in the matter of CVS #2098, DS2768, SA-INV-9407
43. Investigation report in the matter of CVS # 1866, DS2956, SA-INV-9726
44. Investigation report in the matter of CVS #5402, DS89635, SA-INV-9732

Respectfully submitted by:
M. GODEK, R.Ph.
