COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

September 7, 2017 239 Causeway Street ~ Room 417 A&B Boston, Massachusetts 02114

Agenda

Time	#	Item	Contact
8:30	I	CALL TO ORDER	T. Fensky
8:30	II	APPROVAL OF AGENDA • Introduction of Intern: Tiffany Wong	
8:35	III	 APPROVAL OF BOARD MINUTES Draft of August 3, 2017 Regular Session Minutes 	
8:40	IV	 REPORTS Applications approved pursuant to Licensure Policy 13-01 Monthly report from probation Board Delegated Complaint Review pursuant to licensure policy 14-02 Above Action Levels approved by Staff Action 16-04 	M. Botto K. Fishman V. Thaker
8:45	V	 APPLICATIONS Baxter Healthcare Corporation – Petition to Waiver Triad Isotopes (NU00019) – Transfer of Ownership Allied Pharmacy, Inc. – New Community Pharmacy Cardinal Health – Wholesale Distributor 	
9:30	VI	PILOT PROJECT • Brigham & Women's/Bay State Medical Center Technology check Technician Pilot Project	
10:00	VII	CVS HEALTH PROPOSAL FOR REMEDIATION OF UNKNOWN LOSSES	

10:30	VIII	 DETERMINATION OF COMPLIANCE Atef Ayoub, PH 233456, PHA-2017-0036 St. George Pharmacy, DS90034, PHA-2017-0035 	
10:40	IX	VIOLATION OF CONSENT AGREEMENT FOR STAYED PROBATION • CVS #433; DS89796; PHA-2016-0184	
10:50	X	 FLEX 2018 Board meeting dates PSUD Committee Pharmacy Related Outside Sections in FY18 Budget NABP District 1 & 2 meeting discussion 	
11:00	XI	 POLICIES Bureau Staff Action Policy 17-03: Petitioning for Retirement Status Enforcement Policy 17-01: Staff Action Authorization for Consent Agreements for Voluntary Surrender and Consent Agreements not to practice Retail Pharmacy Participation in Research Studies 	V. Berg M. Chan V. Thaker
11:05	XII	REGULATIONS • 247 CMR 17.00: Sterile Compounding	
		1 SA-INV-11414- Nimble RX, Inc- DS90047 Morton	
		2 PHA-2017-0075- Rite Aid #10145, DS3346 Santoro	_
		3 PHA-2017-0126- Rite Aid #10078, DS3471 Mogni	
		4 SA-INV-11043- Rite Aid #10085, DS3180 Mogni	
		5 PHA-2017-0052- Rite Aid #10091, DS2558 Seed	
		6 PHA-2017-0082- Rite Aid #10207, DS2411 Mogni	
		7 PHA-2017-0086- Bravo Pharmacy, DS89981 8 SA-INV-11229- Kevin O'Brien, PH17654	
		9 PHA-2017-0103- CVS #117, DS3207 Mogni	
		10 PHA-2017-0133- CVS #669, DS2846 Mogni	_

		File Review				
11:20	XIII	11	PHA-2017-0077- CVS #769, DS2948	Morton		
		12	PHA-2017-0068- Omnicare of Northern Mass, DS89931	Santoro		
		13	SA-INV-11236- Rite Aid #10204- DS2577	Melton		
		14	PHA-2017-0090- Walgreens #3337, DS2626	Mogni		
		15	PHA-2017-0135- Walgreens #2517, DS2106	Mogni		
		16	PHA-2017-0116- Walgreens #9011, DS3347	Santoro		
			17	PHA-2017-0047- Samuels Pharmacy, DS15095		
		18	PHA-2017-0094- Peter Lyons, PH19225	Murray		
		19	PHA-2017-0115- Custom Medicine Pharmacente DS3323	r, Mogni		
		20	PHA-2017-0145- Dan's Pharmacy, DS89748	Mogni		
		21	PHA-2017-0144- Lenox Village Pharmacy, DS33-	44 Mogni		
12:00		LUNCH BREAK				
		EXE	CUTIVE SESSION			
1:00	XIV	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, the Board will discuss and evaluate the Good Moral Character as required for registration for pending applicants.			CLOSED SESSION	
1:45	XV	ADJ	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)			
2:30	XVI	M.G.L. c. 112, § 65C SESSION			CLOSED SESSION	
5:00	XVII	ADJOURNMENT			CLOSED SESSION	

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 3, 2017

Board Members Present

Timothy Fensky, R.Ph. President
Michael Godek, R.Ph., President Elect
Susan Cornacchio, JD, RN, Secretary
Ed Taglieri Jr., R.Ph
Patrick Gannon, R.Ph
Andrew Stein, Pharm D, R.Ph.
William Cox, CPhT
Karen Conley, DNP, RN, AOCN,NEA-BC
Phillippe Bouvier, R.Ph

Board Staff Present

David Sencabaugh, R.Ph, Executive Director
Monica Botto, CPhT, Associate Executive Director
Heather Engman, JD, MPH, Pharmacy Board Counsel
Christina Mogni, R.Ph., Investigator
Michelle Chan, R.Ph. Quality Assurance Pharmacist
Michael Brosnan, PharmD, R.Ph., Investigator
Greg Melton, JD, PharmD, BCPS, R.Ph., Investigator
Joanne Trifone, R.Ph., Director of Pharmacy Investigations
Joe Santoro, R.Ph. Contract Investigator
Kimberly Morton, CPhT, Compliance Officer
Vishal Thaker, PharmD, Pharmacist
John Murray, R.Ph., Investigator
Nathan Van Allen, PharmD, R.Ph.

Board Members Not Present

Garret Cavanaugh, R.Ph. Richard Tinsley, MBA, Med, Ali Raja, MD, MBA, MPH

TOPIC I.

CALL TO ODER 8:30AM

<u>DISCUSSION</u>: A quorum of the Board was present, established by roll call. President T. FENSKY 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

<u>DISCUSSION:</u> Defer Pentec and CAP waiver and Naloxone Policy and moving INV-1141 to Closed Session

<u>ACTION:</u> Motion by P.GANNON, seconded by E.TAGLIERI, and voted affirmatively to approve the agenda, with noted changes.

- T. FENSKY introduces I.PLASARI as the new intern for the Board of Registration in Pharmacy.
- T. FENSKY asked interns in the audience to stand up and introduce themselves.

TOPIC III. APPROVAL OF BOARD MINUTES

Draft, June 29, 2017 Regular Session Minutes

DISCUSSION: None

<u>ACTION:</u> Motion by P. GANNON, seconded by E. TAGLIERI, and voted unanimously with exception to K.CONLEY and M. GODEK whom recused to approve the minute.

TOPIC IV. REPORTS

Applications approved pursuant to Licensure Policy 13-01 Presented by:

Discussion:

So noted

TOPIC IV. REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

Presented by: Dave Sencabaugh

Discussion: 6/15/20217

Tim Fensky was Board Member representative, with Michelle Chan, Heather Engman, and

Monica Botto,

One Case:

So noted

TOPIC IV

REPORTS

Above Action Levels Approved by Staff Action 16-04 Presented by: V. THAKER

Discussion:

So noted

TOPIC V

APPLICATIONS TIME 8:37 AM

- 1. Pentec, DS89913—Petition for Waiver (DEFERRED)
- 2. BioRX, DS89763 Relocation of a Community Pharmacy TIME: 8:37AM

RECUSAL: None

DISCUSSION: BioRX was represented by Gita Hosseini, Pharmacist in Charge. She plans to relocate the pharmacy into a larger space and answered the Board Member's question to their satisfaction.

- Relocating pharmacy to a larger space
- Amend application to include Schedule VI
- Discuss more information regarding their blue print
 - o Need more HVAC details
 - o May need waiver for size of pass-through
 - o Bill will continue to discuss blueprints with Gita

ACTION: Motion by A.STEIN, seconded by M. GODEK, and voted unanimously in the affirmative to approve the relocation for BioRX upon pending amendments and successful inspection.

3. Zevacor, NU00020—Transfer of Ownership of a Nuclear Pharmacy TIME: 8:43AM

RECUSAL: None

DISCUSSION: Zevacor was represented by Philip Nielson, Manager on Record and James York, Regulatory Specialist. They plan to transfer the ownership to Sophie and answered the Board Member's questions to their satisfaction.

ACTION: Motion by P. GANNON, seconded by P. BOUVIER, and voted unanimously to approve Zevacor transfer of ownership of a nuclear pharmacy to Sophie, pending amendments to their application.

- Amend Schedule VI medications only on application
- On application #9 put N/A for old MOR
 - o Ever since re-opening Phillip has been MOR

4. Cardinal Health 414

Wholesale Distributor

RECUSAL: None

DISCUSSION: Cardinal Health 414 was represented by Dave Lamont, Manager on Record. They intend to apply for a wholesale distribution license due to supplying non-patient specific cold kits, aminophylline, and lexipro.

ACTION: Motioned by P.GANNON, seconded by W. COX, and voted unanimously to approve Cardinal Health application as a wholesale distributor, pending regulation review.

- Applying for wholesale distribution license due to supplying non-patient specific cold kits, aminophylline, and lexipro
 - o All commercially available NO compounds and are not patient specific
- Inventories cannot comingle
- NABP requested wholesale license

5. Central Admixture Pharmacy, DS3312 – Petition to Waiver (DEFFERED)

TIME: 8:49AM

TIME: 8:50AM

TIME: 8:49AM

TOPIC VI. CVS WORKLOAD SHARING PRESENTATION

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

Presented By: John Rocchio and Mark

- Mike: How to ensure other RPh will help out?
 - o Part of the queue/workflow and tracked
- Mike: All stores at once will get this new system?
 - o Pilot of 10 stores first and testing in an internal setting
- Andy: How does it not reduce jobs?
 - o Increase patient care and service means an increase in business leading to increase in pharmacists
- Bill: Will other pharmacist be able to see the prescriptions?
 - o Prescription image is always there to be viewed
- Patrick: Same process for escripts?
 - o Yes
- Varying workload between PCYS depends on store volume
- Electronic tracking with store number with whoever participated
- Can do data entry and DUR
- Patients can opt out

TOPIC VII FLEX Board of Registration in Pharmacy News Letter Time: 9:45am

Discussion: V. THAKER presented the newsletter with the Board.

TOPIC VII FLEX Compounded Sterile Products Report TIME: 10:02 AM

DISCUSSSION: V. THAKER presented and summarized the investigative report that pertained to these matters.

- Online reporting portal in the pipeline
- Andy for data days supply would be useful

ACTION: No vote needed

TOPIC VII FLEX Revision of Retail, <795> and <797> inspection tools

DISCUSSSION: V. THAKER presented and summarized the investigative report that pertained to these matters.

ACTION: No votes needed, will be posted on website.

Andy: Add to Nov newsletter

TOPIC VIII POLICIES Joint Policy 2017-08: Pharmacist Administration of Vaccines **TIME: 10:15 AM**

DISCUSSSION: V. THAKER presented and summarized the investigative report that pertained to these matters.

- Immunizations other than flu must be conveyed to guardians/parents to follow up with pediatrician
- Patients 9 to 17 years old notify/convey best practice to be involved with pediatrician
- Another topic for newsletter

TF – 4C and 5C "must" resp. on Rph

Samples are concerning – no invoices etc

Be aware there are extra steps for Rph

Tips for immunizers in newsletter

ACTION: Motion by M. GODEK seconded by P. GANNON, and voted unanimously by roll call to approve the Joint Policy 2017-08: Pharmacist Administration of Vaccines.

TOPIC VIII POLICIES Policy 2017-03: Naloxone Dispensing via Standing Order (DEFFERED)

TOPIC IX File Review TIME: 10:30AM

1. PHA-2017-0084- Walgreens #1852, DS1375

RECUSAL: W. COX and M. GODEK recused and was not present for the discussion or vote on this matter.

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

- RLCS-#69 D-amphetamine XR 20mg capsules on January 9, 2017.
- Investigation was conducted and video footage reviewed showing MOR throwing out the remaining D-amphetamine bottle into the trash.
- MOR noted that he filled two prescriptions for the same patient. First filled the Damphetamine capsules and set the remaining capsules aside and then filled the second
 prescription for the patient. After he finished, he threw out the balance of Damphetamine in the trash.
- MOR implemented a change in his procedure which includes leaving the cap off and flipping any bottles to ensure they are empty prior to discarding in the trash.

ACTION: Motion by A. STEIN, seconded by P. BOUVIER, and voted unanimously by those present, to refer the matter to the office of prosecution for the issuance of an order to show cause for a consent agreement for a reprimand.

TOPIC IX File Review 2. PHA-2017-0032- Walgreens #2577, DS2117

RECUSAL: W. COX and M. GODEK recused and was not present for the discussion or vote on this matter.

TIME: 10:31AM

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

- RLCS-#100 oxycodone 10mg tablets discovered on November 26, 2016.
- Investigation failed to find cause. Investigation did not include contacting patients to confirm quantity dispensed.
- Corrective action implemented included double count of all CS during receiving, inventory, and dispensing, immediately return C-II back to safe after dispensing, immediately reconcile products in totes during receiving and secure C-II in safe.

ACTION: Motion by A. STEIN, seconded by P. BOUVIER, and voted unanimously by those present, to refer the matter to the office of prosecution for the issuance of an order to show cause for a consent agreement for a reprimand.

TOPIC IX File Review 3. PHA-2017-0102- Walgreens #2325, DS2328

RECUSAL: W. COX and M. GODEK recused and was not present for the discussion or vote on this matter.

TIME: 10:32AM

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

- RLCS-#30 oxycodone 5mg tablets allegedly due to a miscount.
- Loss discovered during a perpetual inventory on 03/04/2017.
- All transactions for oxycodone 5 mg were reviewed going back two weeks and patients
 who received the medication during the suspected period of loss were contacted but no
 one admitted to receiving 30 extra tablets.
- Video was not reviewed as pilferage was not suspected; DEA was not notified as the loss was not deemed significant.
- MOR Mowry did not submit the initial reporting within 1 business day of discovery of the loss.
- CIIs are stored in a locked cabinet and only the pharmacist has the keys; all CIIs are double counted with periodic back counts; perpetual inventory is conducted weekly.
- On 6/7/17, patient admitted to receiving 30 extra tablets; MOR Mowry had filled and verified the prescription.
- MOR Mowry submitted 2 CEs in med errors and attested to reading 247 CMR.

ACTION: Motion by P. GANNON, seconded by K. CONLEY, and voted unanimously by those present, to dismiss the complaint, no discipline warranted. The matter was remediated.

TOPIC IX File Review TIME: 10:34AM

4. SA-INV-10879- Blue Hill Pharmacy, LLC, DS89942

RECUSAL: None

DISCUSSION: S. HORN presented and summarized the investigative report that pertained to these matters.

- OPP investigators observed 5 separate occasions during the timeframe of 12/20/2016 thru 12/29/2016 that Blue Hill Pharmacy was not open during posted business hours.
- During the same timeframe OPP investigators made multiple phone calls to both Blue Hills Pharmacy and the cell phone number posted on the front door. All calls were unanswered except for one call to the cell when the person answering the phone said the pharmacy would be open in an hour.
- MOR/Owner Okeke explained that most of her business is delivery and that she is does a lot of delivery during the day and fills prescriptions when she gets back to the pharmacy.

- Dispensing reports show that Blue Hill Pharmacy filled prescriptions on all days except for Christmas Day and New Year's Day. Most prescriptions were filled between 1:00pm and 7:00pm
- Corrective action includes submitting a change of hours to BORP to change hours to 10:00am-6:00pm M-F and closed on the weekend, additionally MOR Okeke has hired a delivery driver so that the pharmacist will be on duty for all posted open hours.

ACTION: Motion by P. GANNON, seconded by M. GODEK, and voted unanimously by those present, to close staff assignment.

TIME: 10:36AM

TIME: 10:48AM

TOPIC IX File Review **5.** SA-INV-11020- CVS #140, DS2729

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

DISCUSSION: S. HORN presented and summarized the investigative report that pertained to these matters.

- RLCS-109ml of hydrocodone/chlorpheniramine ER Suspension on or about February 6, 2017 later reported by CVS that their investigation concluded there was no theft or significant loss. The loss was amended to a quantity of 97ml.
- Pharmacist McClory discovered the loss while filling a prescription.
- The perpetual count indicated the quantity on hand was 139ml but the actual quantity on hand was determined to be 30ml.
- The MOR suspects that the unknown loss was caused by an unconfirmed dispensing error or medication lost during dispensing because it is a thick suspension.
- A review of 3 months DEA 222 forms and perpetual inventory by MOR Martino did not indicate any other discrepancies.
- Corrective action included a team discussion related to the importance of quality control during the filling of controlled substances; additionally they will mark a line on the stock bottle after each dispensing indicating where medication settled to after the dispensing.
- There have been no further losses of this medication reported to the BORP.
- Thoughts to include in newsletter as best practice product is very viscous and comes up a lot

ACTION: Motion by P. GANNON, seconded by W. COX, and voted unanimously by those present, to close staff assignment upon receipt of a formal policy and procedure for reconciliation.

TOPIC IX File Review 6. SA-INV-10752, CVS #73, DS89858

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

DISCUSSION: S. HORN presented and summarized the investigative report that pertained to these matters.

- RLCS-117ml of hydrocodone/chlorpheniramine ER Suspension on or about November 23, 2016 later reported by CVS that their investigation concluded there was no theft or significant loss.
- Pharmacist Hatzis discovered the loss while filling a prescription for 70ml when it was determined there was not enough in stock to fulfill the quantity.
- The perpetual count indicated the quantity on hand was 140ml but the actual quantity on hand was determined to be 23ml (measured in a graduated cylinder). A review of the perpetual inventory logs by OPP revealed 4 separate occasions, prior to the 11/23/16 variance, in which the on-hand quantity was negatively adjusted by 10ml to reflect a "liquid estimation variance".
- Corrective action included a discussion related to the importance of quality control during the filling of controlled substances.
- There have been no further losses of this medication reported to the BORP.

ACTION: Motion by P. GANNON, seconded by A. STEIN, and voted unanimously by those present, to close staff assignment upon receipt of a formal policy and procedure for reconciliation.

TOPIC IX File Review 7. SA-INV-11032- CVS #46, DS17594

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

TIME: 10:50AM

DISCUSSION: S. HORN presented and summarized the investigative report that pertained to these

- RLCS- 105ml of hydrocodone/chlorpheniramine ER Suspension on or about January 25, 2017 later reported by CVS that their investigation concluded there was no theft or significant loss. The loss was amended to a quantity of 81ml.
- The loss was discovered during the filling of a prescription when was no product left on hand and the perpetual count indicated that the expected balance on hand should have been 105ml.
- MOR stated that the suspension is a thick, viscous liquid and consequently difficult to dispense an exact amount. She believes the loss occurred during the normal course of dispensing.
- A review of the perpetual inventory logs by OPP revealed 12 prescriptions dispensed during the 3-month period prior to the loss and the inventory was reconciled 10 times during that period with no discrepancies noted.
- Corrective action includes measuring the medication as accurately as possible, allowing time for the liquid to settle for an accurate dispensing.

ACTION: Motion by P. GANNON, seconded by P. BOUVIER, and voted unanimously by those present, to close staff assignment upon receipt of a formal policy and procedure for reconciliation.

TOPIC IX File Review 8. SA-INV-11237- CVS #1858, DS2146

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

TIME: 10:52AM

TIME: 10:54AM

DISCUSSION: S. HORN presented and summarized the investigative report that pertained to these

- RLCS- 126ml of hydrocodone/chlorpheniramine ER Suspension on or about February 12, 2017 later reported by CVS that their investigation concluded there was no theft or significant loss. The loss was amended to a quantity of 114ml (based on the amount of prescriptions dispensed for this medication).
- The loss was discovered while MOR McGrane was performing the perpetual inventory. The actual on hand quantity was 480mls when the perpetual inventory count stated the expected quantity should have be 606mls. She believes the loss occurred during the dispensing process stating the suspension is a thick, viscous liquid and consequently is difficult to dispense the exact amount of this medication.
- A review of the perpetual inventory logs by OPP revealed 2 prescriptions dispensed during the 3-month period prior to the loss and the inventory was reconciled 15 times during that period with no discrepancies noted.
- Corrective action includes measuring the medication as accurately as possible, allowing time for the liquid to settle for an accurate dispensing.

ACTION: Motion by P. GANNON, seconded by K. CONLEY, and voted unanimously by those present, to close staff assignment upon receipt of a formal policy and procedure for reconciliation.

TOPIC IX File Review 9. SA-INV-11033- CVS #1972, DS2498

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

DISCUSSION: S. HORN presented and summarized the investigation report that pertained to these matters.

- RLCS- 103ml of hydrocodone/chlorpheniramine ER Suspension on or about February 5, 2017 later reported by CVS that their investigation concluded there was no theft or significant loss.
- The loss was discovered during the filling of a prescription. MOR Connors stated that the suspension is a thick, viscous liquid and consequently difficult to dispense an exact amount. He believes the loss occurred during the normal course of dispensing.
- A review of the perpetual inventory logs by OPP revealed 7 prescriptions dispensed during the 3-month period prior to the loss and the inventory was reconciled 14 times during that period with no discrepancies noted.

• Corrective action includes measuring the medication as accurately as possible, allowing time for the liquid to settle for an accurate dispensing.

ACTION: Motion by M. GODEK, seconded by K. CONLEY, and voted unanimously by those present, to close upon receipt of formal policy and procedure for reconciliation.

TOPIC IX File Review 10. PHA-2017-0067 CVS #1972, DS2498

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

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

• RLCS-Unknown loss of 752 lorazepam 0.5mg tablets on or about 01/09/2017 reported on 01/31/2017 to BORP and DEA.

TIME: 10:55am

TIME: 10:59AM

- Loss was determined via corporate controlled substance monitoring.
- Daily counts were conducted with weekly reconciliations.
- No variances were identified and loss prevention ruled out diversion and active losses.
- Video footage was not reviewed as the timeframe of the loss could not be determined.
- CA includes monitoring reports, ordering and cycle counts; double counting all controlled substances; during all inventories, the pharmacist will double check all commonly dispensed controlled substances including prescriptions in the waiting bin to accurately count all medications; retraining staff on handling damages/outdates; review of all baseline loss prevention procedures with staff.

ACTION: Motion by A. STEIN, seconded by W. COX, and voted unanimously by those present, for stayed probation perpetual inventory on all BZDS for 6 months and exact counts on CS inventory within 60 days or submit documentation that one was conducted at last biennial.

TOPIC IX File Review 11. PHA-2017-0101- CVS #38, DS3510

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

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

- RLCS-Unknown loss of #372 tramadol 50 mg tablets and 1,219 lorazepam 0.5 mg tablets reported on 02/06/2017 with a date of loss indicated on or about 12/09/2016 (violation of the 7 day reporting requirement);
- Loss identified via corporate controlled substance monitoring and based on 5/1/15 biennial inventory compared with dispensed, acquired and returned drug; no diversion suspected;

- Video not review with no determination of loss;
- Daily counts for 8 weeks with no discrepancies;
- CA included monitoring of BOH reports, ordering, cycle counts; double count all controls; retraining of staff on handling of control outdates and damages; review of all baseline loss prevention procedures;
- Exact count of CIII-Vs conducted on last biennial inventory on 4/30/17; last inspected 4/10/17 with no deficiencies

ACTION: Motion by A. STEIN, seconded by M. GODEK, and voted unanimously by those present, for stayed probation perpetual inventory on all BZDS and tramadol for 6 month and exact counts on CS inventory within 60 days or submit documentation that one was conducted at last biennial.

TOPIC IX File Review TIME: 11:00am 12. PHA-2017-0089- CVS #1204, DS2239

RECUSAL: S. CORNACCHIO 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.

- RLCS-Submitted report of unknown losses of 360 tablets of lorazepam 0.5mg, 3221mL of codeine-guaifenesin 10-100mg/5mL oral liquid, and 1447 tablets of tramadol 50mg then amended report to include only 361 tablets of tramadol 50mg as a loss. Pharmacy's records showed overages rather than losses for the liquids.
- Loss Prevention and MOR investigated the matter and were unable to determine the cause of the loss but ruled out diversion.
- Corrective action implemented per CVS standard response to an unknown RLCS.

ACTION: Motion by A. STEIN, seconded by P. BOUVIER, and voted unanimously by those present, for stayed probation perpetual inventory on all BZDS and tramadol for 6 month and exact counts on CS inventory within 60 days or submit documentation that one was conducted at last biennial.

TOPIC IX File Review TIME: 11:05am 13. PHA-2017-0111- CVS #321, DS2989

RECUSAL: S. CORNACCHIO 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.

- RLCS-Submitted report of unknown loss of 603 tablets of lorazepam 1mg. After an internal investigation, the quantity of lorazepam 1mg tablets was amended to 814 on April 26, 2017.
- MOR attributed cause to inaccurate 2015 biennial inventory resulting in the exact count of the change in MOR inventory to result in a discrepancy.
- Corrective action implemented per CVS standard policy for response to unknown RLCS.

Add newsletter or advisory of exact counts/perpetual inventory

ACTION: Motion by A. STEIN, seconded by M. GODEK, and voted unanimously by those present, for stayed probation perpetual inventory on all BZDS for 6 month

TOPIC IX File Review TIME: 11:07 AM 14. PHA-2017-0076- CVS #1132, DS1734

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

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

- RLCS-#413 tramadol 50mg tablets discovered on or about February 15, 2017, during corporate reporting of tramadol 50mg tablets. The reason for the loss is unknown
- MOR submitted a signed attestation that there was a review of cycle counts, biennial
 inventories, staffing schedules and inventory reports for the applicable time and were
 unable to identify the reason for the loss. He indicates that all policy and procedures
 pertaining to controlled substance ordering, receiving, accountability and management
 were followed.
- MOR noted that the store has five cameras in the pharmacy but the video was not reviewed because there is a lack of coverage in the bay or production area and no active loss or specific time to review since the change in manager on December 29, 2016
- MOR indicated that all Loss Prevention policy and procedures were reviewed with the staff, additional cycle counts will be done on a regular basis. Also, the medication was relocated to an area with improved camera coverage.

ACTION: Motion by A. STEIN, seconded by P. BPUVIER, and voted unanimously by those present, for stayed probation perpetual inventory on all BZDS and tramadol for 6 month and

exact counts on CS inventory within 60 days or submit documentation that one was conducted at last biennial.

TOPIC IX File Review
15. PHA-2017-0038- CVS #746, DS2818

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

TIME: 11:09AM

TIME: 11:09AM

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

- During ISP, Technician Lee license was found to have expired on 11-27-2010 and was never reviewed.
- MOR Luong explained that the technician was hired as a technician in training and never divulged she had previously been licensed as a technician. She now has a local policy to vet all new hires against the public verify a license database.
- Technician Lee was notified on multiple occasions and failed to respond. Her license remains expired.

ACTION: Motion by P. GANNON, seconded by M. GODEK, and voted unanimously by those present, to reprimand CVS #746.

TOPIC IX File Review
16. PHA-2017-0037- Linda Luong, PH232577

RECUSAL: S. CORNACCHIO and M. BOTTO 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.

- During ISP, Technician Lee license was found to have expired on 11-27-2010 and was never reviewed.
- MOR Luong explained that the technician was hired as a technician in training and never divulged she had previously been licensed as a technician. She now has a local policy to vet all new hires against the public verify a license database.
- Technician Lee was notified on multiple occasions and failed to respond. Her license remains expired.

ACTION: Motion by P. GANNON, seconded by M. GODEK, and voted unanimously by those present, to dismiss, discipline not warranted remediation complete.

TOPIC IX File Review 17. PHA-2017-0040- Deborah Lee, PT10339

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

TIME: 11:09AM

TIME: 11:20 AM

TIME: 11:22AM

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

- During ISP, Technician Lee license was found to have expired on 11-27-2010 and was never reviewed.
- MOR Luong explained that the technician was hired as a technician in training and never divulged she had previously been licensed as a technician. She now has a local policy to vet all new hires against the public verify a license database.
- Technician Lee was notified on multiple occasions and failed to respond. Her license remains expired.

ACTION: Motion by P. GANNON, seconded by K. CONLEY, and voted unanimously by those present, to dismiss, discipline not warranted. A letter will be sent to Technician Lee to renew her license.

TOPIC IX File Review
18. PHA-2017-0041- Rite Aid #10172, DS2405

RECUSAL: R. LO 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.

- RLCS-Submitted report of unknown loss of 40 tablets of hydromorphone 4mg discovered on April 11, 2016.
- Investigation with Loss Prevention failed to uncover a cause but diversion was ruled out.
- Former MOR attributed loss to excess quantity dispensed though patients were contacted and denied receiving extra tablets.
- The RLCS was not reported to the BORP in a timely manner (at least 4 weeks from the time of initial discovery)

ACTION: Motion by M. GODEK, seconded by P. GANNON, and voted unanimously by those present, to reprimand Rite Aid #10172.

TOPIC IX File Review
19. PHA-2017-0109- Rite Aid #10132, DS2999

RECUSAL: R. LO 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.

- OPP received notice from the Professional Credential Service (PCS) on April 17, 2017 that Technician Trainee Redona Hyso submitted a pharmacy technician application with 1,818 hours worked.
- MOR Hamoud indicated that the trainee was hired in September 2015 prior to the implementation of the RA Pharmacy Technician University Training program which tracks training and hours worked.
- MOR indicated she was newly promoted to MOR and was not aware that Trainee Hyso exceeded trainee hours but took steps to complete the technician paperwork.
- MOR Hamoud apologized for the incident and says that the pharmacists are trained to manage and track tech trainee hours in the Pharmacy Technician University Program.
- Retail compliance inspection was completed on February 1, 2017 with no deficiencies noted.

ACTION: Motion by W. COX, seconded by K. CONLEY, and voted unanimously by those present, to dismiss, discipline not warranted remediation complete.

TOPIC IX File Review 20. SA-INV-10899- Nancy Leach, PH232392

RECUSAL: R. LO 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.

TIME: 11:23 AM

- Rite Aid Pharmacy #10189 reported two unknown losses of C-II on separate occasions while Pharmacist Leach served as MOR.
- Pharmacist Leach retired prior to the response being submitted by Rite Aid 10189.
- A statement from her was not included in the response. The BORP requested that she submit a response addressing the second loss.
- Pharmacist Leach described that she completed an investigation of the matter and failed to find a cause. She opined that the error occurred when a new pharmacist floater failed to properly receive a shipment.
- She also explained that she was asked in emergency to serve as MOR until a replacement was found. She ended up serving as MOR for a year. She stuck with the pharmacy despite repeated requests for support in the form of permanent staff and remodeling were turned down despite the DM acknowledging the requests were needed.
- Pharmacist Leach stuck with the pharmacy rather than quit because she felt that she was able to implement changes that made the pharmacy safer and more efficient for patients. She explained that she was unable to fully implement her local policies due lack of support from corporate and pressure from corporate to produce prescriptions as fast as possible. She also provided a thank you email from her DM when she retired noting she did an excellent job in a tough pharmacy.

ACTION: Motion by P. GANNON, seconded by A. STEIN, and voted unanimously by those present, to close, discipline not warranted.

TOPIC IX	File Review		
21. SA-INV-10454- I	Bouvier Pharmacy, DS9725	TIME:	11:24am

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

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

- During an ISP on February 16, 2016, the temperature of the refrigerator was out of range (50°C) and the logs for the refrigerator and freezer were not documented on 2-13-16 and 2-14-16.
- Bouvier Pharmacy properly remediated by upgrading the refrigerator, contacting mfg's of products potentially affected, and notifying patients and providers of the potential for decrease potency or drugs. No problems with potency were reported to the pharmacy.
- Of note, the ownership of the pharmacy was transferred and Bouvier Pharmacy has closed.

ACTION: Motion by P. GANNON, seconded by K. CONLEY, and voted unanimously to close staff assignment with discipline not warranted and remediation complete.

TOPIC IX File Review
22. SA-INV-11502- Donald Hastings, PH15709

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

- Self-report of an expired pharmacist license for the 2016 renewal cycle. Licensee discovered the lapse on May 11, 2017 during a routine audit from his employer.
- He indicated the lapse of renewal was not intentional but he moved and did not update his address with the Board.

TIME: 11:25am

• He submitted 4 CEUs of law as remediation which will be above and beyond the 20 CEs for 2017.

ACTION: Motion by K. CONLEY, second by P. GANNON, and voted unanimously to close staff assignment.

TOPIC IX File Review
23. PHA-2017-0021- Worcester Family Pharmacy, DS89703

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

- RLCS-#6 oxycodone 10mg tablets were discovered lost on September 7, 2016 and #10 methylphenidate 20mg tablets on October 27, 2016 due to prescription miscount.
- Worcester Family Pharmacy conducted a full investigation for both losses. In both cases, the pharmacist did not double-count the medication.
- No video footage was reviewed.
- Both losses were discovered when the pharmacist logged the prescription.
- Policies and procedures related to controlled substance accountability were reviewed with staff.
- MOR Lebowitz completed 2 contact hours in patient safety and attested to 247 CMR 15, CQI Program and will double-count and back-count all CII prescriptions.
- Retail compliance inspection conducted on June 6, 2017 with deficiencies noted: refrigerator temp issues and cleanliness of blister packaging.

ACTION: Motion by M. GODEK, seconded by P. GANNON, and voted unanimously by all who were present to dismiss with discipline not warranted.

TOPIC IX File Review 24. PHA-2017-0022- Caitlin Lebowitz, PH233515

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

- RLCS-#6 oxycodone 10mg tablets were discovered lost on September 7, 2016 and #10 methylphenidate 20mg tablets on October 27, 2016 due to prescription miscount.
- Worcester Family Pharmacy conducted a full investigation for both losses. In both cases, the pharmacist did not double-count the medication.
- No video footage was reviewed.
- Both losses were discovered when the pharmacist logged the prescription.
- Policies and procedures related to controlled substance accountability were reviewed with staff.
- MOR Lebowitz completed 2 contact hours in patient safety and attested to 247 CMR 15, CQI Program and will double-count and back-count all CII prescriptions.
- Retail compliance inspection conducted on June 6, 2017 with deficiencies noted: refrigerator temp issues and cleanliness of blister packaging.

ACTION: Motion by M. GODEK, seconded by P. GANNON, and voted unanimously by all who were present to dismiss with discipline not warranted and remediation complete.

TOPIC IX	File Review					
25. SA-INV-11421 – Cardinal Health 414, NU11 (WILL BE HEARD AFTER						
APPLICATION	(\mathbf{S})	TIME:	9:01am			

DISCUSSION: N. VAN ALLEN presented and summarized the investigation that pertained to this matter.

On March 21st, 2017, an inspection conducted by NABP identified that Cardinal Health 414 Nuclear Pharmacy was distributing pharmaceuticals without prescriptions or an active wholesale distributor license. The drugs provided are interventional agents and commonly used in nuclear medicine. It was thought that this process was covered by a FDA "5% rule" when compared to the total number of doses distributed. MA does not recognize a 5% rule and thus a prescription or licenses would be required. On June 12th, 2017, Cardinal Health 414 Nuclear Pharmacy submitted an application for a Wholesale Distributor license.

Action: Motion by M. GODEK, seconded by K. CONLEY, and voted unanimously by those who were present to close with discipline not warranted