

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

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

May 4, 2017  
239 Causeway Street ~ Room 417 A&B  
Boston, Massachusetts 02114

**Agenda**

<b>Time</b>	<b>#</b>	<b>Item</b>	<b>Contact</b>
<b>8:30</b>	<b>I</b>	<b>CALL TO ORDER</b>	T. Fensky
<b>8:35</b>	<b>II</b>	<b>APPROVAL OF BOARD MINUTES</b> <ul style="list-style-type: none"> <li>• Draft of April 6, 2017 Regular Session Minutes</li> </ul>	Sencabaugh
<b>8:45</b>	<b>III</b>	<b>Sanction Hearing</b> <ul style="list-style-type: none"> <li>• Bhuren Patel-PH21347, PHA-2011-0211, PHA-2010-0195, PHA-2011-0212</li> </ul>	R. Banks
<b>9:15</b>	<b>IV</b>	<b>ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)</b>	<b>CLOSED SESSION</b>
<b>9:45</b>	<b>V</b>	<b>Applications</b> <ul style="list-style-type: none"> <li>• Baystate Pharmacy (DS89827)Springfield-renovation/expansion</li> <li>• Eaton Apothecary, Boston-New Community Pharmacy</li> <li>• Theragnostics, Boston-Wholesale Distributor</li> <li>• Cornerstone Health Solution, Randolph-New Community Pharmacy</li> </ul>	
<b>10:15</b>	<b>VI</b>	<b>Notice of Violation of Probation</b> <ul style="list-style-type: none"> <li>• Mark Hatfield, PT15445, PHA-2015-0107</li> </ul>	K. Fishman
<b>10:45</b>	<b>VII</b>	<b>REPORTS</b> <ul style="list-style-type: none"> <li>• Applications approved pursuant to Licensure Policy 13-01</li> <li>• Monthly report from probation</li> <li>• Board Delegated Complaint Review pursuant to licensure policy 14-02</li> <li>• Above Action Levels approved by Staff Action 16-04</li> </ul>	M. Botto K. Fishman V. Thaker

<b>11:00</b>	<b>VIII</b>	<b>FLEX</b> <ul style="list-style-type: none"> <li>• CVS Health Coram Pilot-Closed Circuit Cleanroom Monitoring</li> <li>• Exact Count Biennial Inventory Letter</li> <li>• Discussion of non-resident outsourcing recalls-Isomeric Recall</li> </ul>	D. Sencabaugh W. Frisch
<b>11:30</b>	<b>IX</b>	<b>ADVISORY</b> <ul style="list-style-type: none"> <li>• Reporting Defective Compounds advisory</li> <li>• Defective Drug Preparation Reporting Form</li> </ul>	M. Chan W. Frisch
<b>11:45</b>	<b>X</b>	<b>POLICIES</b> <ul style="list-style-type: none"> <li>• Pharmacy Report of Serious Adverse Drug Event or Improper Drug Dispensing</li> </ul>	M. Chan W. Frisch V. Thaker
<b>12:00</b>	<b>XI</b>	<b>File Review</b> <ol style="list-style-type: none"> <li>1 PHA-2016-0113- Conley's Drug Store Inc.- DS89731</li> <li>2 PHA-2017-0016- Alexander Doyle- PH26776</li> <li>3 SA-INV-10404- Conley's Drug Store Inc.- DS89731</li> <li>4 PHA-2016-0188- Conley's Drug Store Inc. - DS2654</li> <li>5 PHA-2017-0017- Richard Doyle- PH15680</li> <li>6 SA-INV-10485- Heritage Biologics Inc- DS89956</li> <li>7 PHA-2016-0225- Walgreens #7063- DS3238</li> <li>8 PHA-2017-0028- Walgreens #10673- DS89633</li> <li>9 PHA-2016-0181- CVS #1877- DS3010</li> <li>10 PHA-2017-0045- CVS #2206- DS2762</li> <li>11 PHA-2016-0210- Rite Aid Pharmacy #10118- DS2563</li> <li>12 PHA-2016-0206- Community Care Pharmacy III, Inc.- DS89960</li> <li>13 SA-INV-10910- David Small- PH20099</li> <li>14 SA-INV-10884- Deidre Forest- PT3794</li> </ol>	J. Trifone
<b>12:30</b>		<b>LUNCH BREAK</b>	

<b>1: 30</b>	<b>XII</b>	<p><b>EXECUTIVE SESSION</b></p> <p>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 applicant, notice of a probation violation and, petition of reinstatement.</p>	<b>CLOSED SESSION</b>
<b>2:30</b>	<b>XIII</b>	<b>ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)</b>	<b>CLOSED SESSION</b>
<b>3:30</b>	<b>XIV</b>	<b>M.G.L. c. 112, § 65C SESSION</b>	<b>CLOSED SESSION</b>
<b>5:00</b>	<b>XV</b>	<b>ADJOURNMENT</b>	<b>CLOSED SESSION</b>

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

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

**May 4, 2017**

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**Board Members Present**

Timothy Fensky, R.Ph. President  
Susan Cornacchio, JD, RN, Secretary  
Patrick Gannon, R.Ph  
Catherine Basile, Pharm D, R.Ph  
Andrew Stein, Pharm D, R.Ph.  
Richard Tinsley, MBA, Med,  
Ed Taglieri Jr., R.Ph. President  
Ali Raja, MD, MBA, MPH  
Karen Conley, DNP, RN, AOCN, NEA-BC  
William Cox, CPhT  
Phillippe Bouvier, R.Ph.

**Board Members Not Present**

Michael Godek, R.Ph., President-Elect  
Garret Cavanaugh, R.Ph.

**Board Staff Present**

David Sencabaugh, R.Ph, Executive Director  
Monica Botto, CPhT, Associate Executive Director  
Heather Engman, JD, MPH, Pharmacy Board Counsel  
William E. Frisch, Jr., R.Ph., Director of Compliance  
Michelle Chan, R.Ph. Quality Assurance Pharmacist  
Michael Brosnan, PharmD, R.Ph., Investigator  
Greg Melton, JD, 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  
Rick Geaney, R.Ph., Investigator  
Nathan Van Allen, PharmD, R.Ph.  
John Murray, R.Ph., Investigator  
Paul Seed, R.Ph., Investigator  
Julienne Tran, R.Ph., Investigator

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**TOPIC I**

**CALL TO ORDER**

**TOPIC I.**

**CALL TO ORDER 8:30 AM**

**DISCUSSION:** 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**

DISCUSSION: None

ACTION:

1. Motion by P. GANNON, seconded by E. TAGLIERI, and voted unanimously to approve the agenda. T. FENSKY asked interns in the audience to stand up and introduce themselves.

2.

**TOPIC III:**

**APPROVAL OF BOARD MINUTES**

1. Draft April 6, 2017, Regular Session Minutes

DISCUSSION: Change title for Susan Cornacchio to, RN, JD, and Secretary

ACTION:

3. Motion by E. TAGLIERI, seconded by P. BOUVIER, and voted affirmatively to accept the minutes of the 4/6/2017 General Session minutes, with noted change.

**TOPIC VII:** (taken out of order)

**REPORTS**

**Applications Approved Pursuant to Licensure Policy 13-01,**

**8:34 am**

DISCUSSION: M. BOTTO noted that during the past month there have been eighteen (18) change-of-managers, eight (8) renovation/expansions, and one (1) renovation/expansion approved by staff.

So noted

**Report of activities Probation Monitor**

DISCUSSION: D. SENCABAUGH (for K.FISHMAN) reported that there were no changes in the Probation statistics to report since the last report.

ACTION: So noted

**Board Delegated Review Pursuant to BDCR Policy**

There were 6 Board Delegated Review (all Staff Assignments) cases heard on May 1, 2017. 5 of the 6 were self-reports of a CE deficiency (SA-INV-10898, SA-INV-893, SA-INV-10791, SA-INV-10909, SA-INV-10621) and all of the 5 had been successfully remediated. The 6<sup>th</sup> case was a consumer grievance SA-INV-10895, which, after investigation, was "closed- no violation."

The Board Delegated Review session was attended by T. FENSKY as the Board Member, H. ENGMAN as Board Counsel, W. FRISCH, Director of Pharmacy Compliance, and Executive Director D. SENCABAUGH.

ACTION: So noted

**REPORTS**

**Staff Action to Handle Above Action Level reports pursuant to 16-04:**

DISCUSSION: V. THAKER reported that there were four (4) above action level reports, and all had remediated and closed.

ACTION: So noted

**TOPIC VIII.**

**FLEX**

**TIME: 8:37 am**

**Exact Count Biennial Inventory Letter**

**Time: 8:37AM**

**Presented by David Sencabaugh**

DISCUSSION: D. SENCABAUGH presented the Exact Count Biennial Inventory Letter authorized on April 6, 2017 by board members. The letter recommended exact counts of all federally controlled substances for stores

to note in their records. This may reduce the number of reported losses that have previously been based on estimated drug counts.

ACTION: None Warranted

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**Discussion of non-resident outsourcing recalls- Isomeric Recall  
Presented by David Sencabaugh**

**8:35AM**

DISCUSSION: D. SENCABAUGH summarized the Isomeric Recall and the Board Staff's process for managing the recall. This was the first non-resident outsourcer recall since the licensing category was created. Board staff called all licensees who received recalled product. There were no adverse events reported.

ACTION: None Warranted

**TOPIC IX.**

**ADVISORY**

**TIME: 8:37AM**

**Reporting Defective Compounds Advisory  
Defective Drug Preparation Form**

DISCUSSION: Presented by V. THAKER. MGL 112 39D(e) calls for a pharmacy to maintain a defective drug preparation log for compounded medications dispensed or distributed in the state. A defective drug preparation is any compounded medication that does not conform to the pre-established recipe or what was prescribed. This is an advisory letter informing our licensees of the types of compounded medications that need to be maintained in such a log and what medications need to be reported to the Board, within 7 days of dispensing. The document goes on to outline the specific information, per statute, that needs to be captured in the log.

This reporting document compliments the advisory letter, above. This form was created based on research from ISMP and other State Boards of Pharmacy. Its purpose is to have the pharmacy provide us with information related to what was supposed to be dispensed against what was actually dispensed. The pharmacies must provide the specific reason for the recall of the drug, whether or not they contacted recipients of the product(s), and to provide us with a root cause explanation and what corrective action the pharmacy took.

ACTION: Motion by A. STEIN, seconded by C. BASILE and voted unanimously to approve the advisory. Motion by K. CONELY, seconded by P. BOUVIER and voted unanimously to approve the Defective Drug Preparation form with the noted changes.

**TOPIC X**

**POLICIES**

**TIM: 8:43 AM**

**Pharmacy Report of Serious Adverse Drug Event or Improper Dispensing**

DISCUSSION: Presented by V. THAKER. MGL 112 39D calls for pharmacies to report a serious adverse drug event, as defined in MGL 111 51H, within 7 business days of discovery. The statute also calls for a pharmacy to report any improper dispensing of a prescription drug that results in serious injury or death. We consolidated the reporting of these two events as they go hand in hand. A serious adverse drug event may occur even if the product was dispensed appropriately. However, any improper drug dispensing that results in serious injury or death is, by definition, a serious adverse drug event. This form was created by referencing those of pharmaceutical companies, state boards of pharmacy, and other government entities (FDA, CDC). The matter

is being deferred to the next Board meeting to allot time to make changes to the form as requested by Board Members.

ACTION: None Warranted

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**TOPIC III**

**SANCTION HEARING**

**Time: 8:57AM**

**Bhuren Patel, PH21347- PHA-2011-0211, PHA-2011-0212, PHA-2010-0195**

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

DISCUSSION: Presented by H. ENGMAN. The parties stipulated to certain facts and violations. There is no dispute regarding the underlying facts of violations in this case. During the Sanction Hearing, both parties will have an opportunity to present evidence of mitigating and/or aggravating circumstances and the board will determine the appropriate sanction.

Presented by R.BANKS. BANKS concedes that, subsequent to 2011,- Pelham Community Pharmacy has made significant strides in improving. R.BANKS indicates the previous vote by the Board of Pharmacy was for a two year probation on both Pelham Community Pharmacy and Bhuren Patel, and Bhuren Patel was no longer to serve as Manager of Record. R.BANKS believes these are appropriate recommendations.

Presented by B.PATEL. Pelham Community Pharmacy has made significant changes since 2011. Pharmacy hired a consultant and has made numerous technological advances. Pelham Community Pharmacy has had five subsequent inspections completed with no deficiencies noted.

Presented by R.FRADETTE. Licensee takes responsibility for the medication error and inspectional deficiencies. Bhuren Patel will not serve as Manager of Record. R.FRADETTE submits letters of support from clients and a letter from current Manager of Record of Pelham Community Pharmacy itemizing eighteen improvements made in the pharmacy since the adverse event. R.FRADETTE indicates Bhuren Patel has agreed to not serve as Manager of Record- but believes the two year probation should be retro-dated to show that Bhuren Patel was on probation for two years and that it was successfully completed.

**TOPIC XII**

**Adjudicatory Session**

DISCUSSION: None

ACTION: At 9:23 am, on a motion by C. BASILE, seconded by E. TAGLIERI, the members voted unanimously to enter into Adjudicatory session. A. STEIN recused.

**TOPIC V:**

**APPLICATIONS**

**TIME: 10:05 am**

**1. Baystate Pharmacy, DS89827      Renovation / Expansion**

RECUSAL: C. BASILE recused and was not present for the discussion or vote regarding this matter.

DISCUSSION: Baystate Pharmacy was represented by Gary Kerr, Director of Operations, and Nicholas Bull, R.Ph., proposed MOR. They plan to roughly double the existing space and answered the Board members' questions to their satisfaction.

4. ACTION: Motion by K. CONLEY, seconded by P. GANNON, and voted unanimously in the affirmative to approve Baystate Pharmacy to proceed with the proposed renovations to the Pharmacy in Springfield.

## **2. Eaton Apothecary – New Community Pharmacy**

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

DISCUSSION: Eaton was represented by John Lynch, Director of Pharmacy Operations, and James Pearce, R.Ph., proposed MOR. They answered the Board members’ questions to their satisfaction. They applied for a waiver to not have exterior signage.

ACTION: Motion by P. GANNON, seconded by, A STEIN, and voted unanimously in the affirmative to approve the application for the new community pharmacy Eaton, with waiver, pending successful inspection.

## **Theragnostics – Wholesale Distributor – 10:17 am**

RECUSAL: None.

DISCUSSION: Theragnostics was represented by Patrick Donahue. They intend to distribute products manufactured in Germany, to nuclear pharmacies throughout the United States. Theragnostics will take ownership of the products from point A to point B, but they will not take possession, as they will be a virtual wholesaler.

ACTION: Motion by P. GANNON, seconded by P. BOUVIER, and voted unanimously to approve Theragnostics application as a Wholesale Distributor, pending successful inspection.

## **Cornerstone Health Solutions      New Community Pharmacy      10:22 am**

RECUSAL: None

DISCUSSION: Cornerstone Health Solutions was represented by Sebastian Hamilton, R.Ph., proposed MOR. Cornerstone is planned to be a mail-order facility dedicated to filling prescriptions for Boston Medical Center patients and employees. Mr. Hamilton answered the Board members’ questions to their satisfaction. They applied for a waiver to not have exterior signage, not to have a scale, and not to compound,

ACTION: Motion by A. STEIN, seconded by C. BASILE, and voted unanimously in the affirmative to approve the application for the new community pharmacy Cornerstone Health Solutions, pending appropriate waiver requests sent to Board staff, the filing of an attestation, updated application to include non-narcotic C-IIs, and a successful inspection.

## **TOPIC VI**

## **NOTICE OF VIOLATION OF PROBATION**

**Time: 10:35AM**

### **Mark Hatfield, PT15445- PHA-2015-0107**

DISCUSSION: Presented by K. FISHMAN. Notification of Licensee’s non-compliance with the Non-Disciplinary Consent Agreement for Stayed Probation (“Agreement”) he entered into with the board, effective February 26, 2016. Specifically, Licensee did not comply with the Agreement at paragraph 4 (d), which requires him to submit two (2) contact hours of continuing education in the area of Pharmacy Law and an attestation to the Board demonstrating he has read and reviewed 247 CMR 8.00 within 90 days of the agreement. Despite several written and one verbal communication, the Licensee has not complied with the Agreement. The licensee did tell K.FISHMAN that he is no longer working as a Pharmacy Technician and currently works as a police officer.



ACTION: Motion by R.TINSLEY, seconded by P.GANNON, and voted unanimously by those present, to issue a notice of violation of probation and intent to impose further discipline.

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**TOPIC VIII**                      **FLEX SESSION**      **(resumed)**

**CVS Health- Coram Pilot**  
**Presented by John Rocchio & Shamir Patel**

**TIME: 10:44AM**

DISCUSSION: J. ROCCHIO and S. PATEL presented a program that will enable pharmacist supervision of clean room activities via an advanced, closed-circuit camera monitoring system with planned implementation at the Norwood, MA Coram location.

ACTION: None Warranted

**TOPIC XI**                      **OPEN FILE REVIEW**

**TIME: 11:14 AM**

Case #1 PHA-2016-0113      Conley's Drug Store, Inc., DS89731                      Time: 11:14 AM

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

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

- Inspection 8/10/16 & 8/11/16 with numerous deficiencies cited including expired meds in active inventory; door to pharmacy from consultation area unlocked; PT who reconciled perpetual inventory working with expired license for 7 mo.; CPhT making entries in perpetual and performing reconciliation; CS rx's that appeared to be copied (void on rx); perpetual not reconciled every 10 days; expired CII meds found in MOR's office; one CSOS key being shared; QRE reports not available.
- Total of 63 drugs in RxSafe and Script-Pro (active inventory) were expired. 716 prescriptions were identified as possibly filled with expired meds. 188 partial bottles and 589 full bottles of tabs/caps returned to vendor MOR would not notify patients who potentially received expired meds and stated this was not a QRE; not physically counting CII's in RxSafe every 10 days; perpetual inventory does not reflect RPh who verified prescription.
- All expired meds returned; new procedure for checking dates for expired meds with one quarantine area created; door will be locked at all times; PT renewed license 8/11/16; only RPh or CPhT will be allowed to make perpetual inventory adjustments; all faxes without a header or with "void" will be verified; CSOS applications filed for other RPhs; default of 1 year BUD will be manually fixed; compliance binder created for all required documents including CQI. Onboarding process for new hires created, staff retrained on adding and updating lot # and expiration date for Script-Pro. Inventory checked for expired meds monthly for return quarterly; no adverse reactions or incidents reported by patients. Retained an Attorney.

ACTION: Motion by E.TAGLIERI, seconded by P.BOUVIER, and voted unanimously by those present, to refer the matter (PHA-2016-0113) to the office of the prosecution for the issuance of an order to show cause, consolidate with SA-INV-10404, and to authorize resolution of the matter by a consent agreement for PROBATION for a period of 1 YEAR with special terms, as amended by E.TAGLIERI and seconded by P.GANNON, to include not acting as preceptor of students at the site during the probation period.

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Case #2

PHA-2017-0016

Alexander Doyle, PH26776

Time: 11:14AM

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

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

- Inspection 8/10/16 & 8/11/16 with numerous deficiencies cited including expired meds in active inventory; door to pharmacy from consultation area unlocked; PT who reconciled perpetual inventory working with expired license for 7 mo.; CPhT making entries in perpetual and performing reconciliation; CS rxs that appeared to be copied (void on rx); perpetual not reconciled every 10 days; expired CII meds found in MOR's office; one CSOS key being shared; QRE reports not available.
- Total of 63 drugs in RxSafe and Script-Pro (active inventory) were expired. 716 prescriptions were identified as possibly filled with expired meds. 188 partial bottles and 589 full bottles of tabs/caps returned to vendor MOR would not notify patients who potentially received expired meds and stated this was not a QRE; not physically counting CIIs in RxSafe every 10 days; perpetual inventory does not reflect RPh who verified prescription.
- All expired meds returned; new procedure for checking dates for expired meds with one quarantine area created; door will be locked at all times; PT renewed license 8/11/16; only RPh or CPhT will be allowed to make perpetual inventory adjustments; all faxes without a header or with "void" will be verified; CSOS applications filed for other RPhs; default of 1 year BUD will be manually fixed; compliance binder created for all required documents including CQI. Onboarding process for new hires created, staff retrained on adding and updating lot # and expiration date for Script-Pro. Inventory checked for expired meds monthly for return quarterly; no adverse reactions or incidents reported by patients.

ACTION: Motion by E.TAGLIERI, seconded by P.BOUVIER, and voted in the affirmative by all Board members present except 1 nay from A.STEIN, to refer the matter (PHA-2016-0113) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for Alexander Doyle for PROBATION for a period of 1 YEAR with special terms to include that he may not be Manger of Record (MOR) during the probation period, must read and attest to 247 CMR in its entirety, complete an additional 5 CE credits in the area of USP <795> non-sterile compounding, and not to precept pharmacy interns during the probationary period.

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Case #3

SA-INV-10404

Conley's Drug Store, Inc., DS89731

Time: 11:33 AM

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

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

Approved June 15, 2017

- Selling compounded OTC preparations including terpin hydrate preparations containing 44% alcohol (based on OPP investigator's calculations) compounded at Conley's in Ipswich.
- Claims Board never told them to stop practice prior to 10/17/2016 inspection at Conley's in Ipswich. Sale of products not tracked. Allegedly only sold terpin hydrate to patients 21 or older.
- Stopped selling compounded OTC's by voluntary agreement on 10/21/2016.

ACTION: Motion by E.TAGLIERI, seconded by P.BOUVIER, and voted unanimously by those present, to combine (SA-INV-10404) with PHA-2016-0113.

Case #4

PHA-2016-0188      Conley's Drug Store, Inc., DS2654      Time: 11:25 AM

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

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

- USP <795> inspection 10/17/16 with deficiencies of compounding including the compounding of OTC drugs sold in the front store including terpin hydrate and terpin hydrate DM with 41% alcohol content (mislabeled-contained 44% per compounding records), ibuprofen 5% cream and Migraine Relief containing ketoprofen 25mg (rx only); incomplete compounding logs with no directions, equipment and BUDs noted; missing master formulations; extended BUDs with no validation; no QA on compounding logs. Not determining BUD by expiration date of components less than master formula's BUD. Compounding preserved water for use as a component in other compounds.
- States 12/2013 attestation to the Board disclosed compounding OTCs. Repackaging Aladerm for sale OTC. Allegedly restricted sale of terpin hydrate to customers 21 or older.
- Hiring a new MOR who will be formally trained in compounding. On 10/21/2016 voluntarily ceased the sale of compounded OTCs. New P&Ps for compounding; updating master formulations, plan on additional compounding training and changing the floor in the compounding area. In process of completing a 22 CE course in veterinary compounding

ACTION: Motion by E.TAGLIERI, seconded by P.GANNON, and voted unanimously by those present, to refer the matter (PHA-2016-0188) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for PROBATION for a period of 1 YEAR, during which time the store cannot precept students.

Case #5

PHA-2017-0017      Richard Doyle, PH15680      Time: 11:25 AM

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

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

- USP <795> inspection 10/17/16 with deficiencies of compounding including the compounding of OTC drugs sold in the front store including terpin hydrate and terpin hydrate DM with 41% alcohol content (mislabeled-contained 44% per compounding records), ibuprofen 5% cream and Migraine Relief containing ketoprofen 25mg (rx only); incomplete compounding logs with no directions, equipment and BUDs noted; missing master formulations; extended BUDs with no validation; no QA on compounding logs. Not determining BUD by

expiration date of components less than master formula's BUD. Compounding preserved water for use as a component in other compounds.

- States 12/2013 attestation to the Board disclosed compounding OTCs. Repackaging Aladerm for sale OTC. Allegedly restricted sale of terpin hydrate to customers 21 or older.
- Hiring a new MOR who will be formally trained in compounding. On 10/21/2016 voluntarily ceased the sale of compounded OTCs. New P&Ps for compounding; updating master formulations, plan on additional compounding training and changing the floor in the compounding area. In process of completing a 22 CE course in veterinary compounding

ACTION: Motion by E. TAGLIERI, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2017-0017) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for PROBATION for a period of 1 YEAR with special terms to include read and attest to 247 CMR in its entirety, complete an additional 5 CE (total of 8 in 795) credits in the area of USP <795> non-sterile compounding, and not to precept pharmacy interns or be Manager of Record (MOR) during the probationary period.

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Case #6

SA-INV-10485

Heritage Biologics, Inc., DS89956

Time: 11:52 AM

RECUSAL: NONE

DISCUSSION: R. GEANEY presented and summarized the investigative report that pertained to these matters.

- On November 8, 2016, investigators went to do a retail compliance inspection but conducted a site visit (ISP-6279). There was no pharmacist on duty or any drug product at the pharmacy. There was only an administrative person at the desk in the reception area.
- November 10, 2016 OPP investigator confirmed with board staff that the MOR change had been completed. Investigators spoke with MOR Gonneville who told him that he works only 10 hours per week at Heritage Biologics, Inc and is the only pharmacist employed. He stated that they have never filled a prescription order or had any medication on site since they were licensed. They were in the process of hiring a sales person to recruit patients. MOR also stated that he is employed as a staff pharmacist elsewhere. Both PMP and ARCOS were run and showed no activity.
- On November 28, 2016, MOR Gonneville was provided with 247 CMR 6.02:(9)(a) which states that a pharmacist must always be on duty while the pharmacy is open.
- On January 20, 2017, investigators returned to the pharmacy for a follow up retail compliance inspection (ISP-6663). MOR Gonneville was present. They do not have any drug products in stock and have not yet ordered anything. They will be dealing with mostly hemophiliac patients once they begin to get referrals.
  - On March 17, 2017, investigators returned to the pharmacy for a site visit (ISP-6945). MOR Gonneville was on site and is present Monday through Friday from 9:00am to 5:00pm. They do not have any drug product in stock and do not have any active patients.
  - Pharmacy is now staffed with a full-time pharmacy manager. They have not yet ordered, stocked or dispensed any drug product since their license was issued on 3/16/15.

ACTION: Motion by P. GANNON, seconded by K. CONLEY and voted unanimously by those present, to close (SA-INV-10485) with instructions to close DS89956 in accordance with 247 CMR 6 or begin operating as a pharmacy within 60 days. If they fail to comply then a complaint will be opened on DS89956.

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Case #7

PHA-2016-0225

Walgreens #7063, DS3238

Time: 11:56 AM

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

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

- During a retail compliance inspection (ISP-6172) conducted on October 19, 2016, pharmacy investigator observed multiple CII prescriptions from a Job Corps facility that did not have signatures of the dispensing pharmacist endorsed across the face of the prescription and a prescription for a Concerta 36mg was filled and delivered prior to receiving a hard copy in violation of 247 CMR 6.07 (1) (b)
- MOR indicated that a floating pharmacist left before receiving the hard copies and the prescriptions were inadvertently filed without being endorsed/cancelled by the pharmacist.
- Plan of correction indicated that on October 29, 2016, the pharmacy immediately ceased filling and delivering CII prescriptions faxed until they received the actual prescription.

ACTION: Motion by P. GANNON, seconded by C. BASILE, and voted unanimously by those present, to refer the matter (PHA-2016-0225) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

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Case #8

PHA-2017-0028

Walgreens #10673, DS89633

TIME: 11:58AM

RECUSAL: W. COX

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

- Retail compliance inspection (ISP-6210) conducted on October 26, 2016
- Deficiencies included: unresolved discrepancies in the perpetual inventory, incomplete CSOS records, and incomplete/inaccurate compounding records
- MOR Anderson submitted a DEA 106 on November 10, 2016 for 150 methylphenidate 20mg tablets as a result of her investigation into the unresolved discrepancies in the perpetual inventory. The loss was determined to be the result of a duplicate dispensing of 90 tablets and an alleged over dispensing of 60 tablets
- MOR Anderson indicated that the incomplete CSOS e-forms were due to her not understanding how to edit the form once it timed out after 25 min
- MOR Anderson indicated that to prevent the omission of key steps, as identified on the compounding log for atenolol, a checklist was developed and posted on the front cover of the compounding binder.

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

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Case #9

PHA-2016-0181

CVS #1877, DS3010

TIME: 12:00 PM

RECUSAL: S. CORNACCHIO

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

- OPP received notification that CVS #1877 had a loss of 215 Diazepam 5mg tablets on June 22, 2016 (Previously SA-INV-10003), and an unknown loss of 60 oxycodone-acetaminophen 10/325mg tablets on September 27, 2016 (Previously SA-INV-10628).

Approved June 15, 2017

- The loss of Diazepam 5mg at was identified via corporate controlled substance monitoring. An investigation was conducted and a reason for the loss was not uncovered.
- The loss for 60 Oxycodone-Acetaminophen 10-325mg tablets was discovered after performing a back count, and the count was off by 60 tablets.
- The loss is due to a suspected prescription miscount. Calls to patients could not confirm this
- Corrective action was taken after each loss.

ACTION: Motion by C. BASILE, seconded by K. CONLEY and voted unanimously by those who were present to refer the matter to the office of prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for stayed probation with special terms to perpetual inventory of all benzodiazepine containing products for six months and to have an exact controlled substance inventory reported within 60 days.

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Case #10

PHA-2017-0045

CVS #2206, DS2762

TIME: 12:05 PM

RECUSAL: S. CORNACCHIO

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

- On September 7, 2016, CVS Pharmacy #2206 the reported an unknown loss of 538 tablets of tramadol 50mg that occurred on September 1, 2016.
- According to MOR Facchiano, a suspected loss of 538 tablets of tramadol 50mg was identified by staff from the corporate controlled substance monitoring program and reported to her on September 1, 2016.
- An internal investigation was then initiated with the assistance of the CVS Loss Prevention Team and found no evidence of active diversion but were unable to determine a cause for the loss.

2.

ACTION: Motion by P. GANNON, seconded by E. TAGLIERI and voted unanimously by those who were present to refer the matter to the office of prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for stayed probation with special terms to perpetual inventory of all tramadol containing products for six months and to have an exact controlled substance inventory reported within 60 days.

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Case #11

PHA-2016-0210

Rite Aid Pharmacy #10118, DS2563

TIME: 12:07 PM

RECUSAL: NONE

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

- On October 24, 2014, Rite Aid #10118 reported a loss of 90 tablets of oxycodone 10mg that occurred on October 8, 2014 due to a dispensing error.
- A prescription for 90 tablets of oxycodone 10mg was placed in the wrong patient's bag and dispensed. (The monographs and bottles were crisscrossed between the 2 patients.)
- The error was discovered when the second patient's caregiver came to pick up the prescription and found the bottle inside the bag was for another patient.
- The patient was contacted and admitted that he received the wrong drug. However, the patient never returned to the pharmacy despite agreeing to. He later changed his statement and said that he never received the oxycodone 10mg prescription.

ACTION: Motion by C. BASILE, seconded by A. STEIN and voted unanimously by those who were present to dismiss the complaint, no discipline warranted. The matter was remediated.

Case #12

PHA-2016-0206 Community Care Pharmacy III, Inc., DS89960

TIME: 12:09 PM

RECUSAL: NONE

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

- On March 11, 2016, retail compliance inspection was conducted at Community Care Pharmacy III, Inc.
- Multiple deficiencies were observed including outdated signage with the former MOR and no hours of operation.
- The pharmacy lacked a process for receiving Schedule III - V controlled substances. Schedule III - V controlled substances invoices were not separated from other invoices and not readily retrievable. The dates of receipt were also not recorded on the invoices.
- The refrigerator temperatures recorded in the logs were out of range on multiple occasions with 4 noted excursions lasting from 3-4 days to 2 weeks. No response to the excursions was documented despite a written policy.
- ISP conducted in April, 2017 with no deficiencies noted.

3.

ACTION: Motion by A. STEIN, seconded by W. COX and voted unanimously by those who were present to dismiss the complaint, no discipline warranted. The matter was remediated.

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Case #13

SA-INV-10910

David Small, PH20099

TIME: 12:10 PM

RECUSAL: A. RAJA 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:

- During a DEA inspection at Nantucket Cottage Hospital in December 2016, they learned that a technician is scheduled in the pharmacy for about 2 hours prior to the arrival of a pharmacist. The technician was able to swipe her card to access the pharmacy.
- The technician does paperwork but also prepares medication for the floors for the pharmacist to verify. The technician also disclosed during her interview that on occasion that she had brought medication to the floor without verification by the pharmacist.
- MOR Small indicated that he immediately took steps to correct the issue so that there is always a pharmacist on-duty when non-pharmacist personnel are in the pharmacy.
- MOR Small stated, "I understand that compliance with these and other DPH requirements are important. As the supervising pharmacist at NCH I will continue to do my part to make sure that the pharmacy follows all pharmacy laws and DPH regulations."

ACTION: Motion by A. STEIN, seconded by P. GANNON, and voted unanimously by those present, to close SA-INV-10910 with the condition that he reads and attests to 247 CMR 6.00 and 8.00.

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Case #14

SA-INV-10884

Deidre Forest, PT3794

TIME: 12:10 PM

RECUSAL: A. RAJA 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:

- During a DEA inspection at Nantucket Cottage Hospital in December 2016, they learned that a technician is scheduled in the pharmacy for about 2 hours prior to the arrival of a pharmacist. The technician was able to swipe her card to access the pharmacy.
- The technician does paperwork but also prepares medication for the floors for the pharmacist to verify. The technician also disclosed during her interview that on occasion that she had brought medication to the floor without verification by the pharmacist.
- MOR Small indicated that he immediately took steps to correct the issue so that there is always a pharmacist on-duty when non-pharmacist personnel are in the pharmacy.
- MOR Small stated, "I understand that compliance with these and other DPH requirements are important. As the supervising pharmacist at NCH I will continue to do my part to make sure that the pharmacy follows all pharmacy laws and DPH regulations."

4.

ACTION: Motion by A. STEIN, seconded by P. GANNON, and voted unanimously by those present, to close SA-INV-10910 with the condition that she reads and attests to 247 CMR 6.00 and 8.00.

#### TOPIC XI

##### **EXECUTIVE SESSION**

DISCUSSION: None

ACTION: At 10:51 pm President T. FENSKY read the statement on reasons for Executive Session. At 2:03, he called for a motion to enter Executive Session: Motion by

P. GANNON, seconded by C. BASILE and voted unanimously by roll call to enter into Executive Session. E.

TAGLIERI; yes, T. FENSKY; yes, P. BOUVIER; yes,

C. BASILE; yes, S. CORNACCHIO yes, A. STEIN: yes G. CAVANAUGH: yes;

R.TINSLEY; yes, P. GANNON; yes (M. GODEK, who attended from opening until lunch, was not present.)

#### TOPIC XII

##### **Adjudicatory Session**

DISCUSSION: None

ACTION: At 11:06 pm, on a motion by W. COX, seconded by M. GODEK, the members voted unanimously to enter into Adjudicatory session.

ACTION: At 1:35 pm, on a motion by P. GANNON, seconded by C. BASILE, the members voted unanimously again, to enter into Adjudicatory session.

#### TOPIC XIII.

##### **M.G.L. c. 65C Session**

DISCUSSION: None

ACTION: At 11:24 pm motion by E. TAGLIERI, seconded by C. BASILE and voted unanimously to enter into M.G.L. c. 65C Session.

#### TOPIC XIV.

##### **ADJOURNMENT OF MEETING**

DISCUSSION: NONE

ACTION: At 2:13 pm motion by M. GODEK, seconded by C. BASILE, and voted unanimously to adjourn the meeting. P. GANNON left meeting at 2:10 pm.

#### EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

5. Draft Agenda of the 5/4/2017 General Session
6. Draft Minutes of the 4/6/2017 Meeting
7. Letter sent by Executive Director to Licensees on Exact Count Biennials recommendation
8. Draft Advisory on Defective Compounds



9. Draft Defective Drug Preparation Form
10. Draft Pharmacy Report Form for Serious Adverse Drug Event or Improper Dispensing
11. Memo from Heather Engman to Members of the Board of Registration in Pharmacy re Bhuren Patel (for investigative conference.)
12. Application of Baystate Pharmacy, DS89827 – for Renovation/Expansion
13. Application of Eaton Apothecary as a New Community Pharmacy
14. Application of Theragnostics – as a new Wholesale Distributor
15. Application of Cornerstone Health Solutions as a New Community Pharmacy
16. Memo from Karen Fishman, Probation Monitor, on Mark Hatfield, PT15445 re: PHA-2015-0107
17. Slide presentation from CVS Health re: Coram and use of Closed Circuit Camera Technology in Clean Room.
18. Report on applications Approved Pursuant to Licensure Policy 13-01
19. Report of Board Delegated Review Session from 5/1/2017
20. Report of Above Action Level pursuant to Policy16-04
21. Investigation report in the matter of PHA-2016-0113 Conley's Drug Store, Inc. DS89731
22. Investigation report in the matter of PHA-2017-0016 Alexander Doyle, PH26776
23. Investigation report in the matter of SA-INV-10404 Conley's Drug Store, DS89731
24. Investigation report in the matter of PHA-2016-0188, Conley's Drug Store, DS2654,
25. Investigation report in the matter of PHA-2017-0017, Richard Doyle, PH15680
26. Investigation report in the matter of SA-INV-10485, Heritage Biologics, DS89956
27. Investigation report in the matter of PHA-2016-0225, Walgreens #7063
28. Investigation report in the matter of PHA-2017-0028, Walgreens, DS89633
29. Investigation report in the matter of PHA-2016-0181, CVS #1877, DS3010
30. Investigation report in the matter of PHA-2017-0045, CVS #2206, DS2762,
31. Investigation report in the matter of PHA-2016-0210, RiteAid Pharmacy#10118, DS2563
32. Investigation report in the matter of PHA-2016-0206, Community Care Pharmacy III, DS89960,
33. Investigation report in the matter of SA-INV-10910, David Small, PH20099
34. Investigation report in the matter of SA-INV-10884, Diedre Forest, PT3794

Respectfully submitted by:

S. CORNACCHIO, R.Ph.  
Secretary