

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

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

May 3, 2018
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Beth Rabasco, Phone: 617-624-5291 in advance of the meeting. While the Board will do its best to accommodate you, certain accommodations may require distinctive requests or the hiring of outside contractors and may not be available if requested immediately before the meeting.

Agenda

Time	#	Item	Page	Contact
8:30	I	CALL TO ORDER		M. Godek
	II	APPROVAL OF AGENDA • Introduction of Interns		
	III	APPROVAL OF BOARD MINUTES • Draft of April 5, 2018 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		R. Harris M. Botto E. Taglieri

8:45	V	<p>APPLICATIONS</p> <ul style="list-style-type: none"> • Pine Pharmaceutical: Petition for a waiver • Partners Pharmacy – Pilot ADM Program • Island Pharmacy (DS2953)- Transfer of Ownership • Remedium Pharmacy (DS89943) –Renovation/Expansion • Soleo Health (DS89958)- Petition for a Waiver • North Falmouth Pharmacy (DS89831) – Petition for a waiver • New England Life Care – Petition for Waiver • Walgreens 10152 - Change of Manager 	
9:45	VI	<p>FLEX</p> <ul style="list-style-type: none"> • CPE Monitor App • Atrius Health: CDTM advisory opinion • Advisory Committee Meeting – May 17, 2018- 9 a.m. – 12 noon 	
10:15	VII	<p>POLICIES</p> <ul style="list-style-type: none"> • Policy 2018-02: Continuing Education credits for Postgraduate Pharmacy Academic Courses • Staff Action Policy 17-03: Staff Action Policy for Implementation of PSUD revisions • Consent Agreement for PSUD Participants (CAPP) <ul style="list-style-type: none"> ○ CAPP Attachment A: Individualized Rehabilitation Plan (IRP) ○ CAPP Attachment B: PSUD Body Sampling Testing Protocol 	H. Engman
10:45	VIII	<p>REGULATIONS</p> <ul style="list-style-type: none"> • 247 CMR 16.00: Collaborative Drug Therapy Management • 247 CMR 22.00: Fines (proposed new regulation) 	

12:00	IX	FILE REVIEW	
		1	PHA-2018-0028- Cantrell Drug Company- NO00027
		2	PHA-2018-0004- CVS #447- DS3251
		3	PHA-2018-0006- CVS #257- DS3331
		4	PHA-2017-0219- CVS #1007- DS90074
		5	SA-INV-12422- CVS #0008- DS2926
		6	PHA-2017-0223- Rite Aid #10068- DS2369
		7	PHA-2017-0185- Rite Aid #10206- DS2412
		8	SA-INV-12601- Rite Aid #10110- DS3097
		9	PHA-2017-0217- Walgreens #2309- DS1876
		10	PHA-2017-0218- Walgreens #2861- DS2232
		11	PHA-2017-0202- Ethos Veterinary Health, LLC- DS90035
		12	SA-INV-12421- Hopinkton Drug- DS8191
		13	SA-INV-12720-Blue Hills Pharmacy- DS89900
		14	SA-INV-12085- Prescott Pharmacy- DS90051
		15	SA-INV-12779- Hamid Mohaghegh- PH17643
		16	SA-INV-12679- Seaside Pharmacy- DS89919
		17	SA-INV-12519- Denise DiCiaccio- PH21816
		18	PHA-2017-0216- Stop & Shop #402- DS2260
		19	SA-INV-12623- Baystate Pharmacy- DS89912
20	SA-INV-12424- Village Fertility Pharmacy, LLC- DS90059		

**12:30
LUNCH BREAK**

1:30	X	<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. Specifically, the Board will the review a request for the reinstatement of a license, the review of probation compliance and evaluate the Good Moral Character as required for registration for pending applicants.</p>		CLOSE D SESSIO N
2:00	XI	<p>ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)</p>		
2:50	XII	<p>M.G.L. c. 112, § 65C SESSION</p>		CLOSE D SESSIO N
5:00	XIII	<p>ADJOURNMENT</p>		CLOSE D SESSIO N

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

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

March 1, 2018

Board Members Present

Michael Godek, RPh. President
Andrew Stein, Pharm D, RPh. President Elect
Susan Cornacchio, JD, RN
Kim Tanzer, PharmD, RPh., Secretary
Stephanie Hernandez, Pharm D, BCGP, RPh
Patrick Gannon, RPh
Timothy Fensky, RPh
Carly Jean-Francois, RN, NP
Julie Lanza, CPhT
Leah Giambarresi, Pharm D, RPh
Ali Raja, MD, MBA, MPH [LEAVING 3 PM]

Board Members Not Present

Dawn Perry, JD
Phillippe Bouvier, RPh

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, CPhT, Associate Executive Director
Heather Engman, JD Chief Board Council
Michelle Chan, RPh. Quality Assurance Pharmacist
William Frisch, RPh Director of Pharmacy Compliance
Joanne Trifone, RPh., Director of Pharmacy Investigations
Kimberly Morton, CPhT, Compliance Officer
Nathan Van Allen, PharmD, RPh. Investigator
Greg Melton, JD, PharmD, BCPS, RPh, Investigator
Julienne Tran, Pharm D, RPh Investigator
Christina Mogni, RPh Investigator
Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:34 AM

A quorum of the Board was present, established by roll call. President M. Godek chaired the meeting and asked if anyone was recording hearing, no one responded. He explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: M. Godek, yes; A. Stein, yes; S. Cornacchio, yes; L. Giambarresi, yes; K. Tanzer, yes; S. Hernandez, yes; P. Gannon, yes; T. Fensky, yes; C. Jean-Francois, yes; J. Lanza, yes; A. Raja, yes.

TOPIC II.**Approval of Agenda****TIME 8:35 AM****Agenda March 1, 2018****DISCUSSION:**

No changes to the agenda.

ACTION:

Motion by P. Gannon, seconded by T. Fensky, and voted unanimously approve the agenda.

Executive Director, D. Sencabaugh, introduced 1 new Interns: Patsy Casalino, MCPHS Boston; Godek called all the other interns in attendance to stand up and introduce themselves.

Topic III**Approval of Board Minutes****TIME: 8:36 am****Minutes****Draft, February 1, 2018 Regular Session Minutes****Changes:**

None

Action:

Motion by S. HERNANDEZ, seconded by P. GANNON, and voted unanimously to approve the regular session minutes of February 1, 2018.

TOPIC IV**REPORTS****Applications approved pursuant to Licensure Policy 13-01****Time: 8:37AM**

Discussion: M. BOTTO noted that during the past month there have been forty-six (46) changes of manager on record (MOR).

So noted

TOPIC IV**REPORTS****Monthly Report from Probation****Time: 8:37AM**

Discussion: M. BOTTO provided the January 1, 2018 – February 22, 2018, Board of Pharmacy Statistics Report for the Probation monitor, which noted that there are currently sixty (60) licensees on probation, with one (1) extended and three (3) given the opportunity to cure. Seven (7) licensees satisfactorily completed probations.

So noted

TOPIC IV**REPORTS****Monthly Report from BDCR pursuant to Policy 14-02****Time: 8:37AM**

Discussion: There were seven (7) Board Delegated Review cases heard on February 27, 2018. One of the cases was a QRE (SA-INV-11818) and has been closed with insufficient evidence. The other six cases were CE deficiencies (SA-INV-12629, SA-INV-12628, SA-INV-12626, SA-INV-12710, SA-INV-12687, and SA-INV-12688) which were closed with no discipline warranted and remediation complete. The Board Delegated Review session was attended by M. GODEK as the Board Member, W. FRISCH Director of Pharmacy Compliance, H. ENGMAN as Board Counsel, and Executive Director D. SENCABAUGH.

So noted

TOPIC IV**REPORTS****Above Action Levels Approved by Staff Action 16-04****Time: 8:38AM**

Discussion: K. MORTON reported that there were three above action level reports. All reports had been successfully remediated and closed

So noted

TOPIC IV**REPORTS****PSUD Monthly Report****Time: 8:38AM**

Discussion: M. BOTTO reported that there are a total of twelve (12) participants, as well as one (1) inquiry, two (2) received applications, and three (3) admissions.

So noted

TOPIC V:

APPLICATIONS

1. Genoa Healthcare Petition for Waiver

Time: 8:39 am

RECUSAL: None

DISCUSSION: Genoa was represented by Jason Kan and Kevin O’Connell.

Genoa came before the Board of Pharmacy, petitioning for waivers, since a name change occurred, and in an effort to be consistent across all of their facilities. The waivers were for 247 CMR 6.02 (5) – Signage, 247 CMR 9.01 (15) – Limited Service, 247 CMR 6.01 (5)(a)(8) – OTC Drugs, 247 CMR 6.01(5)(a)(4) – Balance-Compounding, 247 CMR 9.01 (16) – Compounding, 247 CMR 6.02 (4) – Chemicals – Compounding.

ACTION:

For Acton facility:

Motion by A. STEIN, seconded by P. GANNON, and voted unanimously in the affirmative to approve the application for Waiver for Genoa HealthCare, Acton, DS 90081.

For Greenfield:

Motion by A. STEIN, seconded by P. GANNON, and voted unanimously in the affirmative to approve the application for Waiver for Genoa HealthCare, Greenfield, DS 89910.

For Holyoke:

Motion by A. STEIN, seconded by P. GANNON, and voted unanimously in the affirmative to approve the application for Waiver for Genoa HealthCare, Holyoke, DS 90086.

For Marlborough:

Motion by A. STEIN, seconded by P. GANNON, and voted unanimously in the affirmative to approve the application for Waiver for Genoa HealthCare, Marlborough, DS 89967.

2. Hannaford #8017, DS 3578 Change of Manager Time: 8:44 am

RECUSAL: None

DISCUSSION: Hannaford Pharmacy was represented by MOR Lauren Ries and District Manager Nathaniel Sides. Ries has served as MOR for 4 years previously. She answered all of the Board Members questions to their satisfaction. All necessary CEs were documented.

ACTION: Motion by A. STEIN, seconded by L. Giambarressi, and voted unanimously to approve Lauren Ries as MOR of Hannaford # 8017.

3. Crown Colony Pharmacy Petition to Compound Non-Sterile Complex Time 8:46 am

RECUSAL: None

DISCUSSION: Crown Colony was represented by Thuy Nguyen, MOR, and Hung Doan – Owner. Both Nguyen and Doan appeared before the Board on 2/1/18, and had received approval for a DS license, pending a successful inspection, and contingent upon agreeing not to conduct non-sterile complex compounding until issues of concern at Blue Hill Pharmacy (also owned by Doan), had been resolved, and approved by the Board. Since that time, the Board had inspected the facility successfully, and inspectional concerns at Blue Hill Pharmacy had been resolved.

ACTION: Motion by T. FENSKY, seconded by L. GIAMBARRESSI, and unanimously approved to conduct non-sterile complex compounding.

TOPIC VI

FLEX SESSION

Time: 8:55AM

**1. Sterile Compounding Tool
Presented by: Bill and Nathan
Discussion:**

N. VAN ALLEN presented the completed Sterile Compounding Tool and indicated the tool was a result of converting DRAFT 247 CMR 17 into an audit tool for future compounding licensees. N. VAN ALLEN stated the goal is to use the tool across jurisdiction, and that the Massachusetts Board of Pharmacy in Registration want to start piloting the tool. Since Section 17 is in draft form, and so detail-oriented, the tool would be available on the MABORP website so licensees could self-administer the survey. D. SENCABAUGH updated the Board Members on the status of Section 17. T. FENSKY asked if the questions on the tool were duplicative and if they called out Best Practice Recommendations. N. VAN ALLEN answered the questions were not duplicative and the Best Practice Recommendations were included on the tool but in gray scale so licensees could differentiate. M. GODEK asked what types of questions were included on the tool. N. VAN ALLEN answered the questions related to DRAFT 247 CMR 17. S. CORNACCHIO asked if the licensees would be warned before the first investigation using the Tool. D. SENCABAUGH agreed to discuss if the resources allowed for notification. P. GANNON recommended a window for onsite inspection similar to JCO window to allow for daily activities to be completed. N. VAN ALLEN indicated most questions on the tool related to

reviewing documents made readily available by pharmacies, and would not require the licensee to present for most of the inspection. K. TANZER asked how will the Tool be communicated to licensees. B. FRISCH answered that a message would be sent through the distribution list, and D. SENCABAUGH also said the Tool would be announced at stakeholder meetings. A. STEIN expressed concern for misinterpretation of the questions and asked if the questions were validated. P. GANNON recommended elicited feedback from licensees regarding the Tool before using it. Board Members agreed to continue discussing tool at April 5th Board Meeting and commended N. VAN ALLEN for work creating the Tool.

Action: No action warranted

VII: Policies:

Policy: 2016-02: Controlled Substance Loss Policy Update

TIME: 9:25 AM

Presented by: M. CHAN, K. MORTON

Discussion: M. CHAN explained that the intent of the increased loss reporting timeframe from 1 day to 7 days was to allow additional time for licensees to investigate and reconcile suspected losses. M. CHAN explained that the flow of the updated policy was improved and will be easier to follow. Requirements for reporting were added in an appendix as a quick resource. The changes presented are intended to be short term as the full policy is being evaluated as a lean six sigma project.

D. SENCABAUGH elaborated that many licensees were reporting insignificant losses. W. FRISCH clarified that the regulation requires a “significant amount” to be reported, but the DEA does not define it. Pharmacies should review the DEA’s guidelines to determine what a “significant amount” would be for their specific pharmacy.

P. GANNON asked for clarification on what the definition of business days would be as pharmacies are usually open 7 days per week. P. GANNON asked that business days be clearly defined as a footnote, but that the proposed changes were a good step forward.

L. GIAMBARRESI asked what is required of licensees if another loss occurs during an on-going investigation. K. MORTON responded that licensees should record all losses and the Board would follow-up all for all relevant information during an investigation.

ACTION: Motion by S. HERNANDEZ, seconded by A. STEIN and voted unanimously by all those present to approve the updated policy with the noted change.

Policy: 2018-01: Update Regarding Permitted Prescription Changes **TIME: 9:32 AM**

Presented by: M. CHAN

Discussion: M. CHAN presented a revision of the joint policy regarding prescription changes. H. ENGMAN indicated the authority listed was outdated, and that more relevant citations were available. They should be removed.

W. FRISCH updated Board Members that a pending bill would allow changing refills from a 30 day supply to a 90 day supply (or vice versa) without contacting the prescriber.

P. GANNON suggested adding the initials of the pharmacy personnel who made the change to the documentation section.

ACTION: Motion by A. STEIN, seconded by P. GANNON and voted unanimously by all those present to approve the updated policy with noted changes.

Policy: Staff Action Policy 13-01: Overall License Approval to include tech trainees
TIME: 9:36 AM

Presented by: M. CHAN

Discussion: M. CHAN discussed including language to allow Board staff to process license requests for Technician Trainees.

ACTION: Motion by T. FENSKY, seconded by L. GIAMBARRESI and voted unanimously by all those present to approve changes to Staff Action Policy 13-01

Policy: Staff Action Policy 14-01: GMC Tech Trainee **TIME: 9:36 AM**

Presented by: M. CHAN

Discussion: M. CHAN discussed including language to allow Board staff to identify Technician Trainees who are Good Moral Character candidates.

ACTION: Motion by T. FENSKY, seconded by S. HERNANDEZ and voted unanimously by all those present to approve changes to Staff Action Policy 14-01.

Presented by: M. CHAN

Discussion: M. CHAN discussed several changes to the Board Delegated Review (BDR) staff action policy. The Environment Monitoring section was removed as there is a separate staff action policy to address it. The Continuing Education language was also revised to reflect current practice. The impetus for the policy changes was to allow the BDR group authority to approve waiver renewals.

M. GODEK asked if in the purpose section there was a redundant statement. W. FRISCH indicated the purpose intentionally calls out the waiver statement.

Board members discussed the use of the term “disposed”. H. ENGMAN suggested changing to “resolved”.

ACTION: Motion by T. FENSKY, seconded by K. TANZER, and voted unanimously by all those present to approve Staff Action Policy 14-02 with noted changes.

VIII: REGULATIONS

1. 247 CMR 9.00: Professional Practice Standards

TIME: 9:56 AM

Presented by: Heather Engman, JD

Discussion: D. SENCABAUGH opened floor to comments from Board Members. H. ENGMAN explained that after discussion, MABORP would implement all changes in the regulation and bring back to Board in April 2018.

P. GANNON raised concern CMR 9.01(5) language would prevent “brown vs white bagging”. H. ENGMAN recommended considering “permitted by Board Policy” to address nuisances. P. GANNON suggested copying NABP language once published.

P. GANNON recommended 9.01 (16) not be stricken completely, but become waivable. S. CORNACCHIO suggest Board Members use CMS language used in previous meeting. H. ENGMAN advised Board Members to keep regulation broad if considering keeping language. T. FENSKY motioned, K. TANZER seconded, and unanimous vote to strike 9.01(16).

P. GANNON discussed 9.01 (23) and possibility of regional manager who is not RPh. D. SENCABAUGH indicated it is licensee responsibility to adhere to Massachusetts regulations. P. GANNON motioned, J. LANZA seconded, and unanimous vote to strike 9.01 (23).

H. ENGMAN suggested reducing 9.03(2)(3)(4) to statement “A licensee may not engage in advertising that is false, deceptive, or misleading.”

T. FENSKY asked what the intent of 9.04(14) was. B. FRISCH indicated intent was for non-licensed pharmacies so there is accountability and that a Massachusetts pharmacist verified even

if work had been outsourced. M. GODEK inquired about regulations during a natural disaster. H. ENGMAN indicated provisions are in place if the governor declares a state of emergency.

A. STEIN inquired about the applicability of 9.07 to veterans who receive medication from VA, enter a care facility, and the facility would be unable to repackage the medications. T. FENSKY and S. HERNANDEZ said it was up to the facility to determine policies and procedures.

L. GIAMBARESSI questioned the proposed language change in 9.01(22) and asked if pharmacy manager was acceptable name tag language. H. ENGMAN indicated minimum requirement was to include pharmacist so patient knows who is counseling on medication and that pharmacies are not restricted to language as long as minimum present.

T. FENSKY recommended changed language from “specialty” to “compliance” packaging in 9.08(4). S. HERNANDEZ suggested no PRN medications but all controlled substances be permitted. T. FENSKY cautioned allowing Schedule II and III medications in multi-med, single-dose packaging as pharmacy would not be able to take packaging back for reconciliation because the chain of custody would have been lost. B. FRISCH suggested working with a smaller group of people to revise language.

P. GANNON recommended broadening provisions in 9.09 to all 105 CMR licensees regarding use of E-Kit. D. SENSABAUGH discussed Joint Policy with Drug Control Program to discuss other entities. T. FENSKY recommended striking language of automatic technology and providing guidance as technologic changes occur frequently. D. SENSABAUGH indicated that intent is that if the machine can function according to licensing body, licensee would be permitted to use. T. FENSKY asked about entities that fall under two licensing bodies. D. SENSABAUGH felt a Joint Policy should address that issue. B. FRISCH proposed striking whole section as MABORP wants oversight but does not want to limit licensees. P. GANNON asked if NABP had an opinion on automatic dispensing machines. T. FENSKY stated NABP was pro-technology in pharmacy practice. B. FRISCH suggested bringing policy to advisory committee for review. H. ENGMAN suggested adding language “A pharmacy may only supply E-Kits to types of facilities approved by Board”

B. FRISCH indicated MABORP would revisit 9.10 based on comments, and revisit 9.11 and 9.12 to be overruling.

P. GANNON agreed with suggestion to remove PPA from 9.13(1)(a).

M. GODEK in favor of striking 9.13(1)(b). P. GANNON motioned, seconded by T. FENSKY, and voted unanimously to strike 9.13(1)(b).

P. GANNON motioned, seconded by S. HERNANDEZ, and unanimously approved to use separate provision for 9.14(1)(a) stating “The process for transfers of CVI should be handled the same way as federally controlled substances. CVI may be transferred up to the maximum refills permitted by law and the prescriber’s authority” and strike 9.14(2)(3).

P. GANNON suggested mandating accessing PMP when dispensing Schedule II medication. T. FENSKY and S. CORNACCHIO indicated accessing PMP during dispensing was best practice and mandating would be logistically difficult for licensees.

P. GANNON motioned, L. GIAMBARESSI seconded, and unanimously voted to alter provision in 9.18 to state “A pharmacy shall dispense or recommend...”

P. GANNON requested the year be included in 9.19(2).

P. GANNON motioned to strike 9.19(3), seconded by L. GIAMBARESSI and voted unanimously to strike 9.19(3).

B. FRISCH recommended deleted 9.14(4) and create overarching Best Practices recommendation. S. CORNACCHIO recommended using language in 9.19(h) as a template.

P. GANNON asked MABORP to revisit 9.19(13) and Board Members will revisit.

P. GANNON requested a discussion on 9.23(2) and change (i) to place ownice on working pharmacist not the MOR and shorten (h) after medication.

NO ACTION WARRANTED

IX. Open File Review Time: 11:44 am

Case #1
PHA-2017-0178 CVS #166, DS34449 Time: 11:44 am

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

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

- RLCS- #1,054 tramadol 50mg tablets on or about July 10, 2017, and #464 lorazepam 1mg tablets on or about September 5, 2017.
- MOR indicated both losses were discovered via corporate controlled substance monitoring and an investigation did not uncover a reason for either loss.
- Corrective action submitted indicated the pharmacy team has been retrained on proper inventory and dispensing processes, including cycle counts, order receipt, and the double counting of controlled substances during production.
- CVS Pharmacy #166 has three prior reported losses including benzodiazepines and a zolpidem loss resulting in (PHA-2016-0157). The Board voted for a stayed probation effective 11/28/17 to include monthly counts of all zolpidem and benzodiazepines for 12 months.

ISP was conducted on January 30, 2018. POC was issued for schedule II safe not locking, expired schedule II's not reconciled from 11/5/17 thru 12/12/17, Loose tabs/caps/debris in rx vial

drawers (repeat deficiency), and no documentation available on day of inspection for the Consent Agreement item 4, f (documentation that the area pharmacy supervisor or loss prevention reviewed balance on hand modification cover pages for zolpidem tartrate products).

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present, to dismiss PHA-2017-0178, provided that they send evidence that a complete controlled substance inventory had been take and tramadol successfully reconciled.

Case #2

PHA-2017-0211

CVS #299, DS3596

Time: 11:47 am

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

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

- Unknown RLCS of 58 oxycodone 10mg tablets & 102 hydrocodone-acetaminophen 5-325mg tablets that occurred on October 26, 2017.
- MOR investigation consisted of reconciliation of all C-II, review of cycle counts, biennial inventory, staffing schedules, and inventory reports, and review of policy and procedures. No further discrepancies or deviations from P&P were identified.

At completion of investigation, MOR was unable to definitively determine reason for loss but reported that the oxycodone loss was likely due to dispensing error.

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

Case #3

PHA-2017-0189

Alexanders Pharmacy, DS6349

Time: 11:48 am

RECUSAL: None

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

- Inspectional deficiencies observed during ISP-7760 on 9-15-17 involving outdated signage, a pharmacy technician practicing with an expired license, and the pharmacy failed to observe the standards in USP <795>.
- The USP <795> violation included using Donnatal elixir that the patient brought from another pharmacy to compound DTO/Donnatal preparation, no prescription for the compounded preparation, labelling DTO/Donnatal elixir as “opium tinc (deodorized)” only. Significantly,

the pharmacy was disciplined for the same USP<795> violations and were put on probation that ended on 7-29-17. POC issued and remediation was completed in timely manner.

Last inspected on 1-8-17, pharmacy cited for not having a naloxone standing order. POC issued and remediation was completed in timely manner. No other violations observed.

ACTION: Motion by P. GANNON, seconded by L. GIAMBARRESSI, and voted unanimously by those present, to dismiss complaint, no discipline warranted, but increase the frequency of inspections at the Inspector's discretion.

Case #4

PHA-2017-0199

Walgreens #2471, DS3635

Time: 11:52 am

RECUSAL: M. GODEK recused and was present for the discussion or vote on this matter.

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

Inspectional deficiencies on 9/1/17 for out of range temperatures above 46°F from 4/26/17-5/19/17 with no documented action taken for the only refrigerator in the pharmacy and missing temperature logs from 2/2017 and 3/2017;

- Initial POC sent by PDM and final POC sent by Interim MOR Le alleged Walgreens P&P were followed properly and all deficiencies were remediated on 5/19/17 when the break room refrigerator was moved into the pharmacy with refrigerated products moved into that refrigerator on 5/19/17 and the thermometer was changed.

- MOR Bancroft Wisocky provided a response indicating she initially contacted some manufacturers (no documentation) and determined refrigerated drugs/vaccines had not lost potency; no follow up with prescribers or customers was done.

- Refrigerated items determined to have been in the refrigerator during the excursion period and still in the refrigerator returned to a reverse distributor on 10/25/17.

- No vaccines were administered from 4/26/17-5/19/17.

- Pharmacy staff was retrained on how to respond to out of range refrigerator temperatures.

- Inspected 02/05/2017 with no deficiencies for refrigeration or vaccines.

ACTION: Motion by L. GIAMBARRESSI, , seconded by T. FENSKY, and voted unanimously by those present, to Dismiss PHA-2017-0199, no discipline warranted, already remediated.

Case #5

SA-INV-12420

New England Home Therapies, DS3486

Time: 11:57 am

RECUSAL: None, but C. JEAN-FRANCOIS was out of the room for the first minute of discussion on this matter.

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

Failure to report the Sterile Compounding Report Form 1/1/2017-6/30/17 in the due date of 8/15/2017;

- MOR Matthews requested an extension on 8/14/17 which was granted to 8/21/17 and requested another extension on 8/21/17 which was granted to 9/1/17;
- MOR Matthews alleged the email granting the extension to 9/1/17 was overlooked due to dealing with a reported abnormal result;
- The finalized report was submitted on 11/2/17;
- MOR Matthews has implemented a calendar reminder and is working with corporate on ways to make it easier to transcribe the data onto a spreadsheet;
- Last inspected 12/1/17 (ISP-8667) with no deficiencies.

ACTION: Motion by P. GANNON, seconded by A. STEIN, and voted unanimously by those present, to CLOSE SA-INV-12420, no discipline warranted, and remediation complete.

Case #6

PHA-2017-0181

Hoai Tran, PH234900

Time: 11:59 am

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

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

Tran's case had been presented to the Board in a previous meeting, and it was determined that she should come in for an Investigational Conference, to discuss ratio problems at her store. She had suggested that she was forced to be out of compliance with regards to ratios by her supervisor. Since that meeting however, the supervisor has left CVS employ, and Tran was transferred to a CVS pharmacy in New Hampshire.

ACTION: Motion by A. STEIN, seconded by S. HERNANDEZ, and voted unanimously by those present, to dismiss the complaint, no discipline warranted. It was pointed out that the case can be re-opened if the pharmacist returned to practice in Massachusetts and was implicated in ratio non-compliance in the future.

Topic X:
Read by M.GODEK

EXECUTIVE SESSION

Time: 12:06 pm

DISCUSSION:

ACTION: At 12:06 PM President M. GODEK read the statement on reasons for Executive Session.

At 12:07 PM, M. GODEK called for a motion to enter Executive Session: Motion by S. HERNANDEZ, seconded by P. GANNON and voted unanimously by roll call to enter Executive Session.

M. Godek, yes; A. Stein, yes; S. Cornacchio, yes; L. Giambarresi, yes; K. Tanzer, yes; S. Hernandez, yes; P. Gannon, yes; T. Fensky, yes; C. Jean-Francois, yes; J. Lanza, yes; A. Raja, yes.

Topic XI:

M.G.L. 65 C

Time: 12:08 PM

DISCUSSION: None

ACTION: President M. Godek request a motion to enter M.G.L 65 c Session for the first time.

At 12:31 pm, Motion by T. FENSKY, seconded by L. GIAMBARRESSI and voted unanimously to enter M.G.L. chapter 65 c Session:

Topic XI:

M.G.L. 65 C

Time: 2:06 pm

DISCUSSION: None

ACTION: President M. Godek request a motion to enter M.G.L 65 c Session for the second time.

At 12:31 pm, Motion by T. FENSKY, seconded by P. GANNON and voted unanimously to enter M.G.L. chapter 65 c Session:

A. RAJA leaves the meeting at 3:00 pm

P. GANNON leaves the meeting at 4:26 pm

Topic XII:

ADJOURNMENT OF MEETING

Time: 5:05PM

ACTION: Motion by T. FENSKY seconded by A. STEIN, and voted unanimously by those present, to adjourn from General Session. (A. RAJA and P. GANNON did not vote, they had left the meeting)

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 3/1/18 General Session
2. Draft Minutes of the 2/01/18 Meeting
3. Report on Applications approved pursuant to Licensure Policy 13-01
4. Report on probation
5. Report on Board Delegated Complaint Review to licensure policy 14-02
6. Report on Above Action Levels approved by Staff Action 16-04
7. Report on Pharmacy Substance Use Disorder Program
8. Waiver Application: Genoa Healthcare, Acton, Greenfield, Holyoke, and Marlborough
9. Application: Crown Colony Pharmacy: to conduct non-sterile complex compounding
10. Application: Hannaford Supermarket #8017 (DS3578); Change of Manager
11. Policy: 2016-02 Controlled Substance Loss Policy
12. Policy: 2018- Update regarded permitted prescription changes
13. Staff Action Policy 13-01: License Policy to include Technicians-In- Policy:
14. Staff Action Policy 14-01 GMC's technician-in-training
15. Staff Action Policy 14-02 BDCR Policy adding waiver renewal staff action
16. Summary of Public Comments 247 CMR 9.00 Professional Practice Standards
17. Investigation report in the matter PHA-2017-0178- CVS #166, DS3449
18. Investigation report in the matter PHA-2017-0211- CVS #299, DS3596
19. Investigation report in the matter PHA-2017-0189- Alexanders, DS6349
20. Investigation report in the matter PHA-2017-0199- Walgreens #2471, DS3635
21. Investigation report in the matter SA-INV-12111- New England Home Therapies, DS3486
22. Investigation report in the matter PHA-2017-0181- Hoai Tran, PH234900

Respectfully Submitted,

Kim Tanzer, PharmD, RPh
Secretary