COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy

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

April 6, 2017
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

Agenda

Time	#	Item	Contact
8:30	**I**	**CALL TO ORDER**	T. Fensky
8:35	**II**	**APPROVAL OF AGENDA** Introduction of Intern: Bryan Melo	
8:40	**III**	**APPROVAL OF BOARD MINUTES** • Draft of March 2, 2017 Regular Session Minutes	
8:50	**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	R. Harris K. Fishman
9:00	**V**	**FLEX** • Mobile Narcan Program Pilot • Investigation study protocol discussion • Review of 2016 Plan of Correction Data • David Johnson, new director of PMP	
9:30	**VI**	**POLICIES** • Amendments to Staffing Ratios Policy • Revision of Policy 2011-01 Storage of refrigerated/frozen meds	M. Chan D. Sencabaugh
10.00	**VII**	**ADVISORY** • Sale of Hypodermic Syringes & Needles	

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247 CMR 5.00: Orally and electronically transmitted prescriptions; prescription monitoring program reporting requirements.
247 CMR 6.00: Registration, Management and Operation of a Pharmacy.
247 CMR 9.00: Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies and Pharmacy Departments
247 CMR 12.00: Restricted Pharmacy
247 CMR 15.00: Continuous Quality Improvement Program
247 CMR 20.00: Reporting</td><td>V. Berg</td></tr>
<tr><td>11:00</td><td>IX</td><td>Reconsideration
Panagioitis Dendromiris: PHA-2014-0226, PH233039</td><td>S. Leadholm</td></tr>
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13	PHA-2016-0179- CVS #488- DS3157
14	PHA-2016-0193- Walgreens #2309- DS1876
15	PHA-2016-0195- Walgreens #10427- DS3611
16	PHA-2016-0226- Walgreens #3151- DS2470
17	PHA-2016-0212- Rite Aid #10051- DS3021
18	SA-INV-10162- Sacha Rudenauer- PT6381
19	SA-INV-10369- Lori Cavallaro- PT1467

12:30		**LUNCH BREAK**	
1: 30	**XI**	**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 discuss and evaluate the Good Moral Character as required for registration for pending applicant, notice of a probation violation and, petition of reinstatement.	CLOSED SESSION
3:00	**XII**	**ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)**	CLOSED SESSION
3:30	**XIII**	**M.G.L. c. 112, § 65C SESSION**	CLOSED SESSION
5:00	**XIV**	**ADJOURNMENT**	

COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

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

April 6, 2017

Board Members Present

Timothy Fensky, R.Ph. President
Susan Cornacchio, JD, RN, Secretary
Michael Godek, R.Ph., President-Elect (left 12:30)
Garret Cavanaugh, R.Ph.
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

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
Richard Harris, Program Analyst
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
Nathan Van Allen, PharmD, R.Ph.

TOPIC I. CALL TO ORDER 8:31 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 K. CONLEY, and voted unanimously to approve the agenda, deferring the Narcan Mobile presentation.
2.

Executive Director D. SENCABAUGH introduced APPE Intern B. Melo, and T. FENSKY asked other interns in the audience to stand up and introduce themselves.

3.
4.

TOPIC III.
APPROVAL OF BOARD MINUTES

5. Draft March 2, 2017, Regular Session Minutes

6. DISCUSSION: Motion by P. GANNON, seconded by C. BASILE, and voted unanimously to approve the agenda with minor changes.

TOPIC IV:
REPORTS (no applications this meeting) **TIME: 8:34 am**

7.

TOPIC V.

REPORTS
Applications Approved Pursuant to Licensure Policy 13-01, 8:50 am

DISCUSSION: M. BOTTO noted that during the past month there have been twenty-eight (28) change-of-managers, four (4) non-resident outsourcing facility registrations approved by staff.

So noted

Report of activities Probation Monitor
DISCUSSION: D. SENCABAUGH (for K.FISHMAN) provided the February 21, 2017 – March 28, 2017, Board of Pharmacy Statistics Report for the Probation monitor, which noted that there are forty-nine (49) licensees on probation, one (1) extension granted, and one (1) licensee did not cure within 30 days.

ACTION: So noted

Board Delegated Review Pursuant to BDCR Policy
D. SENCABAUGH reported that there were 11 Board Delegated Review (all Staff Assignments) cases heard on April 3, 2017. Nine (9) were self-reports of CE deficiency, which had all successfully remediated, and were closed. The other two (2) cases were consumer grievance complaints that were also closed with 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

Above Action Level Report Pursuant to Licensure Policy 16-04
V. THAKER reported that there were 6 above action level reports, 3 of which have been closed, and three still in progress.

ACTION: So noted

TOPIC V. **FLEX** **TIME: 10:01 AM**
Narcan Mobile Initiative

ACTION**:** DEFERRED

Investigational Study Protocol Discussion **TIME: 8:39 AM**

DISCUSSION: Presented by D.SENCABAUGH and H.ENGMAN.
The Board was presented an update regarding the compounding and dispensing of investigational, non-FDA approved drugs in community pharmacy settings.
Recent inspections have found that many community pharmacies have been involved in the storing, compounding, and dispensing of investigational drugs for the purposes of clinical studies and drug research. In conjunction with the Drug Control Program (DCP), the Board determined that investigational, non-FDA approved drugs are NOT permitted to be compounded or dispensed in a community setting at this time. Upon discussion with Board members, it was recommended that the Board staff draft guidance on this issue in collaboration with other public health agencies whom may also have oversight into this matter. Board member K.CONLEY recommended looking at other state Boards of Pharmacy procedures which provide guidance on such matters and suggested research into New Jersey laws that permit community pharmacies to engage in similar practices.

ACTION: None warranted. The Board staff will draft guidance on this issue to be reviewed at a subsequent meeting.

Review of 2016 Plan of Correction Data **TIME: 8:53 AM**

DISCUSSION: J.TRIFONE presented a summary of 2016 plans of correction data.

- Number of Field Investigations:
  - Upon addition of 4 new field investigators, there was a 34% increase in the number of investigations (1334 inspections in chain pharmacies and 350 inspections in non-chain pharmacies), with ¾ of inspections meeting satisfactory conditions.
- Plans of Correction (POC) submitted:
  - There was a 4% increase in the number of plans of correction statements (427 POC issued to chain pharmacies and 96 POC issued to non-chain pharmacies) this year. There were an average of 44 POC issued on a monthly basis, with 27% of them requiring subsequent re-inspections.
- Top Field Investigation Deficiencies:
  - The most common type of noted deficiencies per data of compiled field investigation were as follows: refrigeration deficiencies in unit maintenance and proper logging of temperatures and the incorrect or deficient perpetual logging of CII medications.

- Board member, P.GANNON, suggested the addition of previous years' statistics to be included in some areas of yearly investigational report as to track trends more efficiently.

ACTION**:** None warranted.

David Johnson, Director of PMP Introduction **TIME: 8:47 AM**
Presented by J. LAVERY, Bureau HPL Directo
Newly hired Prescription Monitoring Program (PMP) director, David Johnson was introduced to the Board.

TOPIC VI **POLICIES** **TIME: 9:30 AM**

Revision of Policy 2011-012: Proper Storage of Refrigerated and Frozen Medications in a Pharmacy

DISCUSSION: M.CHAN presented an updated version of the refrigerated and frozen medication policy. It has been expanded to give more definitive guidance on how to handle drug products after temperature excursions. It also requires verification and documentation for how those products were handled, whether they were returned to active inventory or not. P.GANNON suggested an implementation date for requiring units to be frost-free with an automatic defrost cycle. This will be incorporated when the new regulation is promulgated. For now, the policy will just recommend such units.
ACTION: Motion by P.GANNON, seconded by M. GODEK and voted unanimously to approve revision of policy 2011-012.

Amendments to Staffing Ratios Advisory **TIME: 9:10 AM**

DISCUSSION: Presented by D.SENCABAUGH
Guidance document was proposed to Board in order to clarify intern-preceptor ratios in academia vs dispensing roles. Certain scenarios exist where a single preceptor is in charge of 4 or more pharmacy interns, which may pose a public safety concern. The proposed guidance document's purpose is to provide clarification as to the maximum number of interns allotted per preceptor when the interns are engaging in dispensing roles.

ACTION: NO VOTE**.** Language in the guidance document requires further clarification and will include more specific examples of intern-preceptor roles (e.g. in an ambulatory care setting). It will be presented to the Board at a later date.

TOPIC VII **Advisory** **TIME: 10:07 am**

Sale of Hypodermic Syringes and Needles

DISCUSSION: Presented by M.CHAN

This advisory was presented to the Board in order to provide guidance as to the appropriate sale of hypodermic syringes and needles in the Commonwealth. The revision recommends the stocking of single unit of use syringe, for those who do not want multiples.

ACTION: Motion by K.CONLEY, seconded by C.BASILE and voted unanimously to approve advisory.

TOPIC VIII REGULATION REVIEW UPDATE TIME: 9:38 am

247 CMR section 5:00 Orally and Electronically transmitted prescriptions, prescription monitoring program reporting requirements

DISCUSSION: Presented by V. BERG

ACTION: Motion by M.GODEK, seconded by A.STEIN, and voted by the majority of those present, to approve the updates to the regulations and to schedule a public hearing.

247 CMR section 6.00 Registration, Management, and Operation of a Pharmacy

DISCUSSION: Presented by V. BERG

ACTION: Motion by M.GODEK, seconded by A.STEIN, and voted by the majority of those present, to approve the updates to the regulations, including 247 CMR 6.13 and to schedule a public hearing.

247 CMR section 9:00 Code of Professional Conduct, Professional Standards for Registered Pharmacists, Pharmacies, and Pharmacy Departments

DISCUSSION: Presented by V. BERG

ACTION: Motion by M.GODEK, seconded by A.STEIN, and voted by the majority of those present, to approve the updates to the regulations, and to schedule a public hearing.

247 CMR section 12:00 Restricted Pharmacy
Presented by: Vita Berg

DISCUSSION: Presented by V. BERG

ACTION: Motion by M.GODEK, seconded by A.STEIN, and voted by the majority of those present, to approve the updates to the regulations and to schedule a public hearing.

247 CMR section 15:00 Continuous Quality Improvement
Presented by: Vita Berg

DISCUSSION: Presented by V. BERG

ACTION: Motion by M.GODEK, seconded by A.STEIN, and voted by the majority of those present, to approve the updates to the regulations and to schedule a public hearing.

247 CMR section 20.00 Reporting
Presented by: Vita Berg

DISCUSSION: Presented by V. BERG

ACTION: Motion by M.GODEK, seconded by A.STEIN, and voted by the majority of those present, to approve the updates to the regulations and to schedule a public hearing.

TOPIC IX **RECONSIDERATION** **TIME: 09:13 AM**

PHA-2014-0226 Pangiottis Dendromiris, PH233039 **Time:** 10:26 AM

Recusal: Heather Engman, Board Counsel, recused and was not present for the discussion or vote pertaining to this matter.

Discussion: S. Leadholm presented and summarized the investigative report pertaining to this matter.

Action: Motion by R. TINSLEY, seconded by S. CORNNACHIO , and voted unanimously by those present, to deny a hearing on the motion. There was a further motion by E. TAGLIERI, seconded by P. BOUVIER, and voted unanimously by those present to deny reopening the matter.

TOPIC X **Open File Review**

Case #1

PHA-2016-0108 Western Mass Compounding Center, DS89965 Time: 10:10 AM

RECUSAL: NONE

DISCUSSION: Investigator P.SEED presented and summarized the investigative report that pertained to these matters.

• ISP-4954-Retail Compliance and ISP-4965-795 Compliance inspections were performed on 3/17/2016. Deficiencies were observed on both inspections and Plans of Correction (POC) submitted.

• The response from MOR Sprecher to compounding hydrocodone SR 50mg capsules is that, according to USP<1151>, their product labeled SR is not an extended-release product by definition and therefore they do not compound hydrocodone-only extended release products. The MOR indicates that 247 CMR 9.04 (8) is not applicable to their practice.

• Letters of Medical Necessity were not readily retrievable during the inspection.
PHA-2016-0108 Complaint was opened regarding the practice of compounding and dispensing hydrocodone and oxycodone oral dosage forms that are similar to commercially available products, including immediate release and extended release products.

• WMCC failed to comply with:
•247 CMR 9.04 (8) regarding the dispensing of hydrocodone-only extended release products;
•Federal Food Drug, and Cosmetic Act, Section 503A (b)(1)(D), regarding compounding regularly or in inordinate amounts any drug products that are essentially copies of a commercially available drug product; and
•USP<795> regarding quality control procedures (weight range of filled capsules was not performed and documented prior to the March 2016 inspection).
In review of materials submitted upon request, WMCC compounded:
•a prescription written for “Roxicet 325mg/5mg/5mL oral solution”
•morphine sulfate 20mg suppositories written by a Physician Assistant (PA) licensed in Connecticut. The PA is not licensed in Massachusetts.
•Prescriptions for hydrocodone SR 50mg capsules twice a day and compounded hydrocodone 20mg every 6 hours as needed for pain.

•Prescriptions for compounded oxycodone SR capsules in various strengths (e.g., 64mg, 65mg, 70mg, 72mg, 80mg) dosed at one capsule eight times a day. Ten of the most recent prescriptions submitted thru 9/2016 were written as "OxyCONTIN capsule 65mg".
•Prescriptions for compounded oxycodone concentrated oral solution in various strengths (e.g., 14mg/mL, 16mg/mL, 18mg/mL, 20mg/mL) dosed every 4 hours as needed for pain.

• There are multiple commercially available single entity oxycodone and hydrocodone products, as well as morphine sulfate products.

• March 20, 2017 – Retail and <795> inspections performed. POC issued for compounding and distributing non-patient specific placebo and blinded ramelteon for a clinical trial at Hartford Hospital. Upon recommendation of counsel, owner Sprecher would not provide written documentation or discuss any details of the blinded bulk product compounded for the clinical trial.

ACTION: Motion by M.GODEK, seconded by E.TAGLIERI, and voted unanimously by those present, to refer the matter (PHA-2016-0108) 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 monthly reporting to the Board (in the form of a spreadsheet) of all compounds, monthly for a period of 3 months and then quarterly for 3 quarters, to be subject to random audit. Additionally, to discontinue compounding similarly available commercial products.

Case #2
PHA-2016-0091 Amherst Pharmacy, LLC., DS89775 Time: 10:31AM

RECUSAL: NONE

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

• On August 21, 2015, OPP Inspectors conducted a USP <795> inspection & found compounded non-sterile preparations of hydrocodone capsules were dispensed on 36 occasions between August 21, 2014 to August 21, 2015. SA-INV opened to assess the practice of compounding and dispensing the capsules.

• Two patients were being dispensed the hydrocodone capsules. Patient 1 was described as referred from local pain management center after failing multiple therapies and having elevated LFT's. Patient 2 was described as failing multiple therapies. Letters of medical necessity were submitted referring to multiple failures of therapy for both patients. The physician was an internal medicine specialist employed at a local adult and pediatric outpatient clinic. No specialty in pain medicine according to BORIM.

• MOR provided, Master Formulation Records (MFRs) and compounding records for the transactions. The compounding records differed from MFRs in ingredients, preparatory instructions, and quality control (no parameters or documentation of QC in compounding records).

• Compounding records preparatory instructions had internal errors (capsule size, amount of ingredients, no QC). The Compounding records, prescriptions, dispensing records, and perpetual inventory were inconsistent. Perpetual inventory for hydrocodone 20mg capsules with notation for hydrocodone powder. Transactions recorded in GM of powder rather than capsules. GM of powder in perpetual inventory did not correspond to

compounding records, dispensing logs, or prescriptions. Failed to complete reconciliations for the powder/capsule log on 6 occasions in 2015.

• MOR also indicated that the hydrocodone capsules were compounded for patient 2 with directions for around the clock use to avoid having to purchase more expensive clinically similar extended release product. MOR ceased compounding the hydrocodone capsules in Jan-Feb 2016 after advanced notice to patients & providers to develop continuity plan.

• Remediated other deficiencies including QC parameters and documentation of results. Recent inspection had one minor deficiency to use more detailed descriptions of topical lotions, ointments, and liquids which was remediated.

ACTION: Motion by M.GODEK, seconded by A.STEIN, and voted unanimously by those present, to refer the matter (PHA-2016-0091) 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 monthly reporting to the Board (in the form of a spreadsheet) of all compounds, monthly for a period of 3 months and then quarterly for 3 quarters, to be subject to random audit. Additionally, discontinue compounding similarly available commercial products and refer the prescribing physician to BORIM.

Case #3
PHA-2016-0109 Trang Pharmacy, DS3581 Time: 10:36 AM

RECUSAL: NONE

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

• Complaint open due to inspectional deficiencies observed during 6/3/16 inspection.
Unlicensed technician
-Blister pack quantities did not match prescription labels
-One tablet/capsule was taped to prescription labels as identification
-MOR's CSOS credentials used by pharmacy staff for ordering of schedule II's
-Medications in prescription vials that were unlabeled or lacked complete information
• Pharmacy was re-inspected on 9/8/16 and was found to be substantially in compliance.

ACTION: Motion by A. STEIN, seconded by M. GODEK, and voted unanimously by those present, to refer the matter (PHA-2016-0109) 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 with special terms to include all staff read, and attest to having read, the following: 247 CMR sections 8, 9, and 15.

Case #4

PHA-2016-0238 Brown's Rexall Drug, DS1240 Time: 10:40 AM

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

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

• During routine retail compliance inspection (ISP-4838) conducted on August 15, 2016, Investigators cited multiple deficiencies including; absence of Right to Know and Patient Consultation Area signage, inconsistent reconciling C-II's every 10 days, CSOS authorization not available, multiple expired medications (100+) on the shelf, absence of a graduated cylinder, tap water used for reconstitution, Master Formulation Record for magic mouthwash was not observed and no compounding record filled out, no sign-off for annual CQI training for staff, and label for compounded medication did not have note, This is a Compounded Preparation.

• MOR indicated that he consulted with his pharmacist and received guidance and suggestions from the inspectors and a plan of corrective action was immediately developed and implemented to remediated the identified deficiencies

• MOR provided a signed attestation indicating the Plan of correction was completed and fully implemented in two phases 8/28/2016 and 10/21/2016 and is confident that action taken and policy and procedures written have addressed all identified deficiencies

• Follow up retail compliance inspection conducted on February 15, 2017, improvement from prior inspection but deficiencies noted, POC by 3/9/2017, owner stepped down as MOR

ACTION: Motion by M.GODEK, seconded by P.BOUVIER, and voted unanimously by those present, to refer the matter (PHA-2016-0238) 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 having the new MOR read, and attest to having read, the following: The ADVISORY ON NEW MANAGERS OF RECORD and completing a COMPLIANCE INSPECTION Self-Inspection tool (both located on the Board's website).

Case #5
PHA-2016-0197 IntegriScript, Inc., DS89726 Time: 10:48 AM

RECUSAL: NONE

DISCUSSION: Investigator M. BROSNAN presented and summarized the investigative report that pertained to these matters.

• On August 11, 2016, a routine compliance inspection (ISP-6134) was completed and multiple deficiencies were observed. They were:
• A Medical Records staff member could gain entry to the locked Pharmacy area via her badge access card.
• Refrigerator temperature loggers reported 49 occurrences of out of range temperatures as low as 33.6 degrees Fahrenheit for Refrigerator #3 with no remediating action taken. There was no audible alarm activated on the "LogTag" system. Temperatures were recorded and electronically logged every hour. Recorded temperature logs were only being printed out at the end of the month with no one checking for high, low or out of range temperatures.

• One of the drawers in the freezer containing a vial of vaccine was frozen/frosted shut, and was unable to be opened during inspection.
• An action policy for responding to out of range temperature readings to ensure the integrity of stored medications was not readily retrievable during the inspection.
• Incorrect Beyond Use Dates (BUDs) were assigned to dispensed Non-Sterile compounds. A staff pharmacist questioned at the time of inspection could not articulate proper BUDs per USP 795.

• The Manager of Record at the time submitted a response and documentation including policies which remediated all deficiencies.

• A complaint was then opened against the DS, and a new MOR responded that many of the deficiencies could be attributed to high MOR turnover, and attention to other areas incorrectly considered more important.

• The Current MOR stated that he is confident that with the new changes in leadership, a renewed focus on standardization, training, and accountability, IntegriScript, with the continued assistance of CPS will work to achieve and maintain full compliance. He reiterated that the staff at IntegriScript understands the importance of compliance and the leadership will continue to reinforce that.

• A satisfactory retail inspection(ISP-6389) was conducted March 21, 2017

ACTION: Motion by P. GANNON, seconded by C. BASILE, to send a notification of violation of probation in which further discipline has been imposed to EXTEND THE PROBATION FOR AN ADDITIONAL 6 MONTHS.

Case #6
PHA-2016-0233 Christopher Foresman, PT7300 Time: 10:52 AM

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote in this matter.
DISCUSSION: Investigator C. MOGNI presented and summarized the investigative report that pertained to these matters.

• Long-time employee of Family Pharmacy

• Became part of corporate team in 2014 working as a trainer and project manager

• No responsibility for security issues

ACTION: Motion by P. GANNON, seconded by C. BASILE, and voted unanimously by those present, to DISMISS PHA-2016-0233, no discipline warranted.

Case #7
PHA-2016-0231 Kevin Merck, PH27156 Time: 10:56 AM

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

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

• MOR at several Family Pharmacy locations

• MOR at Family Pharmacy Heywood Hospital (closed 9/22/2016) responsible for access to pharmacy by pharmacy tech and front store manager without a pharmacist being present

• Purchased corporate inventory for Family Pharmacy.

• Inadvertently stored less than 2 years of records on site.

• Shared CSOS certificate with others

.

• Did not ensure the CII safe was locked (code kept under keyboard)

• Completed 31 CE law Pharmacy Regulatory Specialist program.

ACTION: Motion by A. STEIN, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2016-0231) 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.

Case #8
PHA-2016-0232 Michael Webb, PH18093 Time: 11:10 AM
RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote on this matter.
DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

• Long-time employee of Family Pharmacy (MOR Heywood Hospital 2001-2009, MOR Winchendon 2009-2011, MOR Ashburnham 2011-2016, MOR Gardner 2016-present

• Stored records< 2yrs old for at least Heywood Hospital in Ashburnham

• CII transfer without using 222 form (on one occasion only)

• Never allowed support staff in pharmacy without pharmacist present, did not purchase or maintain corporate inventory

• In process of completing 31 law CE program for Pharmacy Regulatory Specialist.

ACTION: Motion by M. GODEK, seconded by C. BASILE, and voted unanimously by those present, to refer the matter (PHA-2016-0232) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for STAYED PROBATION with special terms to include completion of the 31-hour law CE program for Pharmacy Regulatory Specialist. Upon completion, authorizes the Board to the Dismiss the complaint with no further discipline.

Case #9
PHA-2016-0235 Karen Taylor- PT21491 Time: 11:07 AM
RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote on this matter.
DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

• Pharmacy technician who entered Family Pharmacy Heywood Hospital without a pharmacist being present (was not licensed at the time)

• Admits to entering the pharmacy without a pharmacist on duty

• Had alarm code and keys for pharmacies in Heywood Hospital, Ashburnham, Athol, and Winchendon as Front Store Manager

• Became licensed 11/11/16

• Never had code to CII safes

ACTION: Motion by K. CONLEY, seconded by G. CAVANAUGH, and voted unanimously by those present, to DISMISS PHA-2016-0235, no violation.

Case #10
PHA-2016-0234 Joann Sleeper, PT1539 TIME: 11:10 AM

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:

- Joann Sleeper, pharmacy technician, entered Family Pharmacy at Heywood Hospital without a pharmacist being present.
- Technician Sleeper possessed alarm code and keys to said pharmacy
- Sleeper alleges that she only accessed the pharmacy without pharmacist supervision on one occasion.
- Currently employed at Gardner Family Pharmacy with no alarm code or keys

ACTION: Motion by E.TAGLIERI, seconded by C.BASILE, and voted unanimously by those present, to dismiss PHA-2016-0234, no discipline warranted, remediation complete, and to issue an advisory letter to inform technician to not access restricted pharmacy areas without direct supervision of a licensed pharmacist.

Case#11
PHA-2016-0230 Hamid Mohaghegh, PH17643 TIME: 11:11 AM

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:

- Complaint, Hamid Mohaghegh, as the listed owner of Family Pharmacy, has had previous DEA and BORP violations related to complaints heard at the December, 2016 Board meeting for violations related to eight Family Pharmacy locations.
- These complaints include failure to maintain accurate records that are readily retrievable, failure to maintain complete and accurate transfer records, failure to maintain 2 years of records on site, not revoking Power Of Attorney (POA), granting keys and alarm codes to non-pharmacists, allowing techs access to Schedule II safe, sharing of CSOS credentials, and POAs not granted by proper authority
- Pharmacist Mohaghegh claims some of the allegations were identified and corrected prior to the inspections and site visits April 2016-August 2016, but provided partial or no direct response to some allegations.

- Pharmacist Mohaghegh stated it was the responsibility of MORs and officers to ensure compliance.
- Complainant has ceased store-to-store medication transfers except pursuant to a need for a CVI prescription. Discrepancies existed with MORs on record with Board, as compared to his response.
- As part of his improvement plan, a new Vice President was hired, consultant and NPSC were engaged, pharmacy locks and alarm codes were changed, and is in the process of requiring that all pharmacists obtain their own, unique CSOS credentials.

ACTION: Motion by E.TAGLIERI, seconded by G.CAVANAUGH, 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 probation for one year, complete 30 CE hours on pharmacy regulatory affairs, attest to reading 247 CMR in its entirety, DEA handbook in its entirety, and MGL 94C. Copies of completed self-inspection tools for all Family Pharmacy locations must also be submitted.

Case #12

PHA-2016-0229 CVS #114, DS2821 TIME: 11:23 AM

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:

- Report of an unknown loss of 544 lorazepam 1mg tablets. This loss was discovered during an inventory reconciliation in April, 2016.
- Daily counts, reviewed cycle counts, balance on hand reports as well as the order adjustment reports to include at least 3 months prior to loss were conducted and video footage was also reviewed.
- All loss prevention baselines were reviewed with pharmacy staff.

ACTION: Motion by P.GANNON, seconded by A.STEIN, and voted unanimously by those present, to refer to refer to the matter to the office of prosecution for the issuance of an order to show cause for stayed probation for six months conditioned upon the logging of a perpetual inventory for all benzodiazepines for a period of six months, reconciliation of all benzodiazepines every ten days, and take an exact count within 60 days.

Since biennial counts are due this calendar year, D. SENCABAUGH suggested sending a letter recommending 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.

Motion by P. GANNON, seconded by E.TAGLIERI, and voted unanimously by those present, to authorize the Executive Director to draft and send such a letter.

Case#13

PHA-2016-0179 CVS #488, DS3157 TIME: 11:45 AM

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

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

- Report of Loss of Controlled Substance (RLCS) of 100 Oxycodone HCL 10mg tablets at CVS Pharmacy #488 on or about August 15, 2015.
- Loss was discovered while completing a weekly perpetual inventory. Loss Prevention team was able to rule out active losses and investigated for diversion by current pharmacy team members, but did not uncover a reason for the loss.
- OPP Investigator reviewed CVS #488's reported loss of controlled substances history, and this is the only loss reported since 1/1/15.

- A Retail Compliance (ISP- 5761) inspection at CVS Pharmacy #488 was completed on August 11, 2016 with no deficiencies noted.

ACTION: Motion by A.STEIN, seconded by P.GANNON, and voted unanimously by those present, to refer 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.

Case #14
PHA-2016-0193 Walgreens #2309, DS1876 TIME: 11:52 AM
RECUSAL: M.GODEK and W.COX recused and were not present for the discussion or vote on this matter.

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

- RLCS- loss of 319 oxycodone 10mg tablets on or about September 12, 2016.
- MOR indicated that on September 12, 2016, she completed her weekly perpetual inventory and discovered that the inventory was off by 100 tablets of oxycodone 10mg tablets
- Loss Prevention Manager completed an audit and determined the loss was 319 tablets.
- MOR submitted to OPP copies of perpetual inventories, ordering invoices, 222 forms, and the 2016 Annual Controlled Substance Inventory. OPP investigator reviewed these reports, along with a report from the PMP, and found nothing to support the reported loss of 319 tablets.
- MOR submitted a new statement on 2/1/17, indicating that the 9/12/16 inventory was actually off by 129 oxycodone 10mg and that she was incorrect in the first report. Perpetual logs submitted to OPP confirmed that statement.
- MOR Farber indicated that as a result of this incident, she makes sure that all the Pharmacists complete their own Schedule II count and that the technicians are not allowed to handle these medications. She also indicated that she has been completing counts on this product daily since the occurrence without a discrepancy.
- Walgreens #2309 has had no other reported losses since January 1, 2015

ACTION: Motion by P.GANNON, seconded by P.BOUVIER, 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 and to authorize a consent agreement for a reprimand.

Case #15
P**HA-2016-0195 Walgreens #10427, DS3611 TIME: 11:55 AM**
RECUSAL: M.GODEK and W.COX recused and were 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- loss of 100 oxycodone 10mg tablets on or about August 30, 2016, Walgreens #10427 reported the loss occurred on or about August 23, 2016.
- A SA-INV was opened. MOR Francois Lortongsy indicated that Staff Pharmacist Nina Huynh discovered the loss during routine weekly reconciliation.
- An internal investigation involving LP and MOR Lortongsy was conducted and an error likely occurred during receipt of a shipment when scanning the product into inventory. An item may have been scanned twice when the shipment was actually short.

- Corrective action included requiring RPh to match the items manually against the invoice as well as scanning in the items during receipt. Also, cameras were repositioned to cover the CII safe and receiving area.
- OPP Walgreens #10427 had not reported a loss prior to this incident and the loss represented approximately 0.4% of annual inventory.
- A complaint was then opened based on the response from Walgreens #10427 to the SA-INV. MOR Lortongsy was notified and declined to provide any further information.

ACTION: Motion by P.GANNON, 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 and authorize a consent agreement for a reprimand.

Case #16

PHA-2016-0226 Walgreens #3151, DS2470 TIME: 11:56 AM

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

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

- RLCS- 100 methylphenidate 10mg tablets (1 bottle of 100 tablets) were discovered lost on July 4, 2016 by the overnight pharmacist while doing CII perpetual inventory
- MOR indicated that she reviewed the past 30 days of receiving, invoices, sales and inventory and was unable to determine the cause of the loss
- Asset Protection conducted an investigation and was unable to determine how the medication was lost but did not suspect diversion. No security cameras were covering the area of the CII cabinet at the time.
- Plan of correction included the installation of a camera above the CII cabinet on 7/14/2016 and triple count on Schedule II Controlled Substances: Intern or CPhT must count twice and the RPh does the final count (circle amount and initial). Schedule II stock bottles placed back in stock as soon as prescription is completed and Schedule II cabinets are always locked and keys are at a safe location or with the pharmacist

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ACTION: Motion by P.GANNON, seconded by K.CONLEY, 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 a reprimand.

Case #17

PHA-2016-0212 Rite Aid #10051, DS3021 TIME: 12:00 PM

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

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

- RLCS- loss of 60 Oxycodone 5mg tablets on or about June 25, 2014, due to a suspected prescription miscount.
- Oxycodone was inventoried by the pharmacy manager on June 22nd and only one prescription was dispensed after being inventoried. The counts for this drug matched with the computer system, the perpetual log, and the actual count after this fill on June 22, 2014.
- Attempts were made to contact patient to confirm the loss but the pharmacy was unable to validate that an excess quantity was dispensed

- Corrective action included reinforcement of the policies to circle the quantity on both the prescription label and the hardcopy to ensure they both match, and verification of the on-hand quantity in the computer system versus what is physically present after the prescription is filled and verified.
- MOR also delivered formal discipline action to the Staff Pharmacist on duty when the suspected prescription miscount occurred.

ACTION: Motion by P.GANNON, seconded by C.BASILE, 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 a reprimand.

Case #18
SA-INV-10162 **Sacha Rudenauer PT6381** **TIME: 12:05 PM**
RECUSAL: NONE

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

- Nationally Certified and MA Registered Pharmacy Technician Rudenauer began working as a "pharmaceutical technician" in February 2015 at the PCSO's Correctional Facility. She contacted the BORP in March of 2015 to request information on her scope of practice because there was no pharmacist at the site. The facility receives pharmacy services through SOPS.
- The BORP responded to her questions in a series of emails. Technician Rudenauer specifically asked whether she was permitted to input physician orders into the pharmacy system for the offsite pharmacists to review. BORP response was "pharmacy technician performing [sic] to assist the pharmacy in any professional capacity must have a pharmacist present on site to supervise."
- BORP then spoke with SOPS in July 2015 regarding Technician Rudenauer's position. SOPS indicated that she worked as a medical assistant rather than a pharmacy technician. BORP then requested a copy of Technician Rudenauer's job description in August of 2015 "to determine if you are acting within the scope of your pharmacy technician's license" and PCSO submitted a copy of the job description as requested.
- This investigator reviewed the job description and the job title was listed as pharmacy technician and included general duties including the handling of controlled substances. Of note, the job was open to any license technician, LPN, or RN. No further documentation of contact with Technician Rudenauer was recorded until August 2016 when BORP staff contacted her to verify if she still worked as a pharmacy technician at the PCSO.
- After that, this SA-INV was opened in September of 2016. Technician Rudenauer submitted a response that detailed her duties. First, she does not practice under the direct supervision of a pharmacist. She is an employee of PCSO. She is not an employee of SOPS or the third-party vendor contracted to provide pharmacy services.
- A review of her duties showed that she does not administer controlled substances; perform DURs; receive new or omitted prescription information; or conduct prescription transfers. She does request refills from prescribers; conduct clinical conflict resolution; contact prescribers concerning drug order clarification or therapy modification; provide patient counseling; and perform dispensing process validation without direct pharmacist supervision. She also assists the transporting and handling of Schedule II controlled substances without direct pharmacist supervision.
- Technician Rudenauer also expressed frustration and anger at the fact that no one contacted her regarding her technician duties after she submitted her job description. She indicated that her self-report and request for a review of her job led her to believe that she was fine to work as a pharmacy technician as along as she didn't perform data entry.

- She felt that the length of time for a response until August or September 2016 was also unfair as BORP staff were aware that she was working and should have acted more quickly. She described that her duties do not require a pharmacist and an unlicensed administrative assistant would be able to function in her position and she is being penalized for her additional certifications and education

ACTION: Motion by E.TAGLIERI, seconded by M.GODEK, and voted by the majority of those present by those present, to close the staff assignment due to no discipline warranted. The facilities will be referred to DCP, and an advisory will be issued to the Sheriff's Office of all counties stating that pharmacy technicians may not practice without pharmacist supervision. A letter will be sent to Technician Rudenauer stating that she may not work as a pharmacy technician without pharmacist supervision. R.TINSLEY voted against this action.

Case #19
SA-INV-10369 **Lori Cavallaro, PT1467** **TIME: 12:14 PM**
RECUSAL: NONE

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

- SOPS reported to BORP staff that other technicians worked without pharmacist oversight in other sheriff's offices including BCSO. A SA-INV was then opened that concerned Technician Cavallaro who was reported to have been working without pharmacist oversight at the BCSO Correctional Facility. Technician Cavallaro submitted a response to the SA-INV that detailed her duties. This investigator also gathered evidence of her duties from witnesses at the facility.
- First, she does not practice under the direct supervision of a pharmacist. She is an employee of a third-party vendor contracted by the BCSO to provide medical and nursing services. She is not an employee of SOPS or the SOPS third-party vendor contracted to provide pharmacy services.
- A review of her duties showed that she does not administer controlled substances; perform DURs; provide patient counseling; or conduct prescription transfers. She does request refills from prescribers; receive new or omitted prescription information; conduct clinical conflict resolution; contact prescribers concerning drug order clarification or therapy modification; and perform dispensing process validation without direct pharmacist supervision. She also assists the transporting and handling of Schedule II controlled substances without direct pharmacist supervision.
- The job description that was submitted by Technician Cavallaro listed the job title as pharmacy technician. The duties were those performed by pharmacy technicians including the handling of controlled substances. Furthermore, the job was only opened to registered pharmacy technicians.

ACTION: Motion by P.GANNON, seconded by M.GODEK, and voted by the majority of those present, to close the staff assignment due to no discipline warranted. The facilities will be referred to DCP, and an advisory will be issued to the Sheriff's Office of all counties stating that pharmacy technicians may not practice without pharmacist supervision. A letter will be sent to Technician Cavallaro stating that she may not work as a pharmacy technician without pharmacist supervision. R.TINSLEY voted against this action.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 4/6/2017 General Session
2. Draft Minutes of the 3/2/2017 Meeting
3. Draft Revision of Policy # 2011-01Storage of Refrigerated/Frozen meds.
4. 2016 Plan of Correction Data
5. Draft Revision to Advisory on Staff Ratios, Dedicated Training Personnel, and Pharmacy Intern Direct Supervision
6. Draft Revision to Sale of Hypodermic Syringes and Needles
7. Report on applications Approved Pursuant to Licensure Policy 13-01
8. Report of activities Probation Monitor 2/21/17 – 3/28/2017
9. Report of Board Delegated Review Session from 4/3/2017
10. Memo to the Board of Pharmacy from Vita Berg, Chief Board Counsel regarding status update of Pharmacy Reform Regulation and Regulatory Review, and request for approval of edit to 247 CMR 6.13
11. Memo from Board Counsel S. LEADHOLM in the matter of Panangiotis Dendromeris PHA-2014-0226,
12. Investigation report in the matter of PHA-2016-0108 Western Mass Compounding Center, DS89965
13. Investigation report in the matter of PHA-2016-0091 Amherst Pharmacy, DS89775
14. Investigation report in the matter of PHA-2016-0109, Trang Pharmacy, DS3581
15. Investigation report in the matter of PHA-2016-0237, CVS #299, DS3596,
16. Investigation report in the matter of PHA-2016-0238, DS1240, PHA-2016-0238
17. Investigation report in the matter of PHA-2016-0197, IntegriScript, DS89726
18. Investigation report in the matter of PHA-2016-0233, Christopher Foresmen, PT17300
19. Investigation report in the matter of PHA-2016-0231, Kevin Merck, PH27156
20. Investigation report in the matter of PHA-2016-0232, Michael Webb, PH18093
21. Investigation report in the matter of PHA-2016-0235, Karen Taylor, PT21491
22. Investigation report in the matter of PHA-2016-0234, Joann Sleeper, T1539
23. Investigation report in the matter of PHA-2016-0230, Hamid Mohaghegh, PH17643
24. Investigation report in the matter of PHA-2016-0229, CVS #114, DS2821
25. Investigation report in the matter of PHA-2016-0193, Walgreens #2309, DS1876
26. Investigation report in the matter of PHA-2016-0195, Walgreens #10427, DS3611
27. Investigation report in the matter of PHA-2016-0226, Walgreens #3151, DS2470
28. Investigation report in the matter of PHA-2016-0212, Rite Aid 10051, DS3021
29. Investigation report in the matter of SA-INV-10162, Sacha Rudenauer, PT6381
30. Investigation report in the matter of SA-INV-10369, Lori Cavallaro, PT1467

Respectfully submitted by:

S. CORNACCHIO, R.Ph.
Secretary