

COMMONWEALTH OF MASSACHUSETTS

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

October 6, 2015
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

Agenda

Time	#	Item	Exhibits	Contact
8:30	I	CALL TO ORDER		P. Gannon
8:35	II	APPROVAL OF AGENDA <ul style="list-style-type: none">• Pharmacy Intern Introductions		
8:40	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">• Draft of August 4, 2015 Regular Session Minutes• Draft of September 1, 2015 Regular Session Minutes		
8:45	IV	APPLICATIONS <ul style="list-style-type: none">• Compare Quality Pharmacy (DS89874) –Petition to Waiver• Onco360 (DS89924)– Petition to Waiver• Smart-Pak Equine (DS3320)– Petition to Waiver• Apothecare South Shore (DS89820) Renovation/Expansion• Dedham Pharmacy & Medical Supply – New Community Pharmacy• Cape Cod Healthcare Pharmacy at Fontaine Outpatient Center- New Community Pharmacy		
9:15	V	REPORTS Applications approved pursuant to Licensure Policy 13-01	Reports	R. Harris

9:20	VI	<p>FLEX SESSION</p> <p>NABP Presentation NABP Member Relations and Government Affairs Dept. VPP Multi-state Inspection Blueprint Inspection Training and Services PMP InterConnect</p> <p>NAPB Pharmacist Prescriptive Authority Task Force Update NABP/AACP District 1 Meeting- Update Naloxone Standing Orders Advisories</p> <ol style="list-style-type: none"> 1. Staff Ratios 2. Pre-Filled Insulin Syringes 		<p>Josh Bolin T. Fensky D. Sencabaugh</p> <p>K. Barnes</p>
10:20	VII	<p>POLICIES</p> <p>Immunization policy- update</p>		<p>K. Barnes D. Sencabaugh</p>
10:50	VIII	<p>REGULATIONS:</p> <p><u>Proposed amendments to 247 CMR 9.00:</u> Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies and Pharmacy Departments. Proposed amendments will include provisions pertaining to naloxone, as required by M.G.L. c. 94C, § 19C.</p> <p><u>Proposed new regulation, 247 CMR 17.00:</u> Sterile Compounding.</p>		<p>H. Engman; D. Sencabaugh; K. Barnes; W. Frisch</p>
12:30		LUNCH BREAK		
1:30	IX	<p>Violation of Probation</p> <ol style="list-style-type: none"> 1. CVS Pharmacy 498 – DS3349, PHA-2013-0153 		<p>K. Fishman</p>
	X	<p>Monthly Report from Probation</p>		<p>K. Fishman</p>

1:45	XI	<p>FILE REVIEW</p> <ol style="list-style-type: none"> 1. PHA-2015-0084, Walgreens #2977, DS2250 2. PHA-2015-0085, Marc P. Johnson, PH23277 3. SA-INV-6911, Braintree Laboratories, WD472 4. SA-INV-7410, Braintree Laboratories, WD406 5. SA-INV-6743, Coram CVS/Specialty, DS89944 6. SA-INV-7732, Preferred Pharmacy Solutions, DS3542 7. SA-INV-7251, Home Infusion Solutions, DS3592 8. SA-INV-7397, Family Health Mart Pharmacy, DS3480 9. SA-INV-7086, Lynch Pharmacy, DS1994 10. SA-INV-7678, Rite Aid #10081, DS2971 11. PHA-2015-0074, Greater Boston Long Term Care, DS3306 12. SA-INV-7114, CVS #1006, DS2715 13. SA-INV-7677, CVS #477, DS3251 14. SA-INV-7084, CVS #477, DS3251 15. SA-INV-7184, BMC at Shapiro, DS89861 	
2:30	XII	<p>EXECUTIVE SESSION</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.</p> <p>Specifically, the Board will discuss and evaluate the <u>Good Moral Character</u> as required for registration for pending applicants, and petition for license reinstatement.</p>	CLOSED SESSION
3:30	XIII	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)	CLOSED SESSION
4:00	XIV	M.G.L. c. 112, 65C SESSION	CLOSED SESSION
5:00	XV	ADJOURNMENT	

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

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

October 6, 2015

Board Members Present

Patrick Gannon, R.Ph., MS, President
Richard Tinsley, MBA, M.Ed., Secretary
arrives @ 8:36AM
Timothy Fensky, R.Ph, FACA
Garrett Cavanaugh, R.Ph.
Susan Cornacchio, JD, RN.
William Cox CPht
Michael Godek, R.Ph.
Andrew Stein, Pharm D, R.Ph.
Phillippe Bouvier, R.Ph.

Board Members Not Present

Ed Taglieri, R.Ph. President
Elect
Karen Conley, DNP, RN
Catherine Basile, PharmD, R.Ph.

Board Staff Present

James Lavery, JD, Director, Division Health Professionals Licensure
David Sencabaugh, R.Ph, Executive Director
David Dunn, R.Ph, Associate Executive Director
Heather Engman, JD, MPH Board Counsel
Kelly Ann Barnes, JD, R.Ph, Director of Pharmacy
Quality Assurance
William Frisch, R.Ph, Director of Pharmacy Compliance
Richard Harris, Program Analyst
Monica Vasquez, Compliance Officer
Colleen Collins, PharmD, R.Ph. Contract Investigator
Christina Mogni, R.Ph. Investigator

TOPIC: I

CALL TO ORDER

DISCUSSION: P. GANNON called the meeting to order.

ACTION: At 8:34 AM the October 6, 2015, regularly scheduled meeting of the Board of Pharmacy was called to order. P. GANNON asked if anybody was recording the meeting. No one indicated that they were recording the meeting. P.GANNON indicated that the Board was recording the meeting. Quorum was established by a roll call: P. GANNON; yes, T. FENSKY; yes, S. CORNACCHIO; yes, C. BASILE; yes, W. COX; yes, A. STEIN; yes, M. GODEK; yes, G. CAVANAUGH; yes, P. BOUVIER; yes.

R.TINSLEY was not present for roll call.

D. SENCABAUGH introduced APPE rotation interns Shivam Patel and Abdullah Rifai from Northeastern University and Massachusetts College of Pharmacy and Health Sciences respectively.

TOPIC II.

APPROVAL OF AGENDA

Time: 8:34AM

DISCUSSION: D.DUNN noted that the September 1, 2015 minutes would be deferred to a future meeting. W. FRISCH noted that the deferral of staff assignment involving Family Health Mart Pharmacy to a future meeting.

ACTION: Motion by P. BOUVIER, seconded by W. COX and voted unanimously to approve the Agenda.

TOPIC III.

APPROVAL OF BOARD MINUTES

Time: 8:38AM

Draft August 4, 2015, Regular Session Minutes

DISCUSSION: None

ACTION: Motion by T. FENSKY, seconded by P. BOUVIER, and voted unanimously to approve the draft August 4th Minutes.

TOPIC IV.

APPLICATIONS:

1. Compare Quality Pharmacy Petition to Waive Compounding Time:8:38AM

DISCUSSION: Compare Quality Pharmacy was represented by Manager of Record Olga Olzaban, and Attorney Paul Garbarini. MOR Olzaban noted that Compare Quality was a small community pharmacy located within supermarket. MOR Olzaban noted that the pharmacy lacked space and had few calls for compounded preparations which were they transfer to local pharmacy that do compound. The Board was concerned not to set a precedent that allowing the waiver could limit patient access to compounded medications. The Board concluded that they could find no compelling evidence for granting the waiver. P GANNON stated “that in the best interest of the public that the service remains available.”

ACTION: Motion by M. GODEK, seconded by T. FENSKY, and voted unanimously to deny Compare Quality Pharmacy’s petition to waiver of regulation.

TOPIC IV.

APPLICATIONS

2. OncoMed360 Petition to Waive Regulation Time: 8:38AM

DISCUSSION: Oncome 360 is a specialty pharmacy servicing oncology patients. Pharmacy provides specialty oncology medications and support with no compounding of preparations.

ACTION: Motion by R.TINSLEY, seconded by T. FENSKY to approve the request to waive compounding regulations.

TOPIC IV.

APPLICATIONS

3. Smart Pak Equine. Petition to Waive Regulations TIME: 9:05AM

DISCUSSION: Smart Pak Equine was represented by consultant Dennis Lyons. Smart Pak is a vendor of equine supplies to include a dispensing pharmacy of CVI medications (antibiotics and anti-inflammatory). Smart Pak has made a business decision to exit the pharmacy market and is attempting to sell its prescription files. Smart Pak is requesting multiple waivers to regulations to be able to limit the pharmacist hours of availability to process the transfer request as the operations wind down. The pharmacy is secured within vast warehouse operations with a call center that is not open to the public. Mr. Lyons anticipated that the situation could last up to August of 2016 as that would mark the 1 year mark from when prescriptions cease to be dispensed and customers were notified.

ACTION: Motion by R. TINSLEY, seconded by A. STEIN and voted unanimously to approve the waivers of Board Regulations.

TOPIC IV.

APPLICATIONS

4. Apothecare South Shore Application for Renovation / Expansion

DISCUSSION: The board reviewed the application for the renovation of Apothecare at South Shore. W. FRISCH noted that the proposed renovation did not impact the compounding facility. W. FRISCH noted that

the applicant has been working with a consultant and the changes to provide additional area for dispensing activity that was much needed.

ACTION: Motion by T. FENSKY, seconded by W. COX and voted unanimously to approve Apothecare of South Shore's application for renovation / expansion.

TOPIC IV.
APPLICATIONS

5. Dedham Pharmacy and Medical Supply, Application to Manage and Operate a New Community Pharmacy
RECUSAL: P. BOUVIER, recused himself and was not present for the vote or discussion of this matter. S. CORNACCHIO recused when CVS was mentioned.

DISCUSSION: Proposed MOR L. Jassett, pharmacist / owner M. Sullivan , and attorney P. Garbarini appeared in support of Dedham Pharmacy and Medical Supply's application to Manage and Operate a New Community Pharmacy. Both pharmacist have previous experience as a manager of record and plan to use the Prescription Monitoring Program. The representatives were able to satisfactorily answer the boards questions regarding staffing, hours of operation, compounding, and security.

ACTION: Motion by M. GODEK , seconded by A. STEIN, and voted unanimously to approve Dedham Pharmacy and Medical Supplies application to Operate and Manage a New Community Pharmacy pending a successful compliance inspection.

TOPIC IV.
APPLICATIONS

6. Cape Cod Healthcare Pharmacy at Fountaine, Application to Operate and Manage a New Community Pharmacy

DISCUSSION: Peter Scarafile appeared in support of the application. Cape Cod Healthcare is seeking to establish a retail pharmacy in its Fountaine Medical building located in Harwich, MA. Cape Cod Healthcare has been in contact with Health Care Quality (HCQ) regarding the new retail pharmacy. Mr. Scarafile reports that HCQ had no issues with the retail pharmacy as the area was non licensed space. Mr. Scarafile indicated that this facility would be similar to the similarly board approved facility in Sandwich, MA. T.FENSKY noted the absence of a compounding designation and after a brief discussion it was decided that the application would be amended to include moderate compounding as assumed by the retail pharmacy license. The Board was satisfied with responses concerning staffing, systems, security and hours of operation. Mr Scarafile indicated that the pharmacy would engage in immunization and MTM services.

ACTION: Motion by R. TINSLEY; seconded by W. COX and voted unanimously to approve Cape Cod Healthcare Pharmacy at Fountaine's application to Operate and Manage and Operate a New Community Pharmacy pending receipt of an amended application regarding compounding service and a successful compliance inspection.

TOPIC V.
REPORTS

Applications Approved Pursuant to Licensure Policy 13-01 Time: 9:26AM

DISCUSSION: R HARRIS noted that during the past month there have been Thirty-Four (34) Change of Managers.

ACTION: So noted.

TOPIC VI
Flex Session:

1. NABP presentation: Mr. Josh Bolin, NABP Director of Member Relations and Government Affairs, provided a presentation to educate members on the services that NABP offers its member Board. The presentation

highlighted the Verified Pharmacy Program, The Multi-State Inspectional Blue Print, and Inspection Training Services.

Break 9:54AM- 10:06AM

2. NABP Pharmacist Prescriptive Authority Taskforce:

Board member T. FENSKY provided an update on his participation on a NABP taskforce for Pharmacist Prescriptive Authority. T. FENSKY indicated that the taskforce was working on authority for pharmacist working under a collaborative drug therapy management agreement to do more such as: assess patients, write prescriptions for common illness. D. SENCABAUGH thanked Mr. FENSKY for his participation on the taskforce, and all members that are involved with NABP. D SENCABAUGH noted that NABP is a valuable resource for the Board and that it is awesome for members to be at the forefront of new ideas.

3. NABP District 1 & 2 Meeting Update:

DISCUSSION: T. FENSKY provided a recap of the recently completed meeting. T Fensky noted that resolutions proposed by the Massachusetts Board regarding Brown Bagging / White Bagging and Naloxone were approved at the District 1 / 2 meeting and will move forward to be considered by all Boards of Pharmacy at the NABP annual meeting slated for May 2016. T. FENSKY informed the Board members that he has been nominated to represent District 1 on the NABP executive committee.

4. Naloxone Standing Order

DISCUSSION: K. BARNES updated the Board on the updates to the Naloxone Standing orders. K Barnes noted the work of APPE Intern S. PATEL on this project. K BARNES noted 4 updates to the naloxone standing order to improve on the process from a year ago; a) inclusion of store and license number to facilitate the chain store enrollment; b) inclusion of auto injectors to accommodate new delivery devices as they enter the market; c) updates to the training requirement; d) and changes to the pamphlet to include the auto injector. D. SENCABAUGH noted that pharmacies have crossed the 50% threshold of all pharmacies securing a Naloxone Standing Order. A. STEIN informed Board members of the cost / burden for independents to participate in the program. A. STEIN noted cost and packaging configuration available from wholesalers for naloxone and the atomizer could potentially burden the smaller community pharmacy approximately \$350.00. D. SENCABAUGH informed members that the Drug Control Pamphlet that is to be dispensed with all Schedule II and Schedule III products was now available. The pamphlet would be distributed by the distribution list to all key stakeholders. The Department is looking for a 10/23 start date for pharmacies to distribute to patients.

5. ADVISORIES

DISCUSSION: K. BARNES presented to Board members advisory letters to remind all pharmacists that are involved in complaints of regulatory violations that commonly occur. K. BARNES noted that if approved the advisories would be posted to the Board's website and be provided to the distribution list so that registrants are aware of the need to comply. The advisory letters would also be included in case closing notifications to registrants in cases involving the violations of 247 CMR where appropriate.

a. Staffing Ratios:

DISCUSSION: K. BARNES noted the number of cases of pharmacies that are discovered to be out of compliance with pharmacist to support help ratios that it's thought necessary to remind pharmacist of the proper ratio and the need to comply.

ACTION: Motion by G. CAVANAUGH, seconded by P. BOUVIER to approve the use of the draft advisory, post to the website and provide to the registrants by use of the board's distribution list.

b. Pre-Filled Insulin Syringes:

DISCUSSION: K. BARNES noted that the Board would be considering multiple cases of community pharmacies pre-filling insulin syringes for patients without the proper facilities. K. BARNES noted that this process is an aseptic transfer and needs to be performed in a facility designed to minimize contamination to safe guard the patient. K. BARNES noted that pharmacists are attempting to do the right thing to assist patients. K BARNES again noted that it is the desire to notify registrants in advance so that they had enough time notify patients and arrange for the appropriate transition of care. R. TINSLEY, noted that pharmacists were attempting to do the right thing and wanted to see the advisory worded affirmatively.

ACTION: Motion by R. TINSLEY, seconded M. GODEK and voted unanimously to approve the draft advisory on Pre-Filled Insulin Syringes with the noted language change to be used by board staff and to posted on the boards website and be provided to the registrant community via use of the boards distribution list.

TOPIC VII. IMMUNIZATION POLICY UPDATE

DISCUSSION: D. SENCABAUGH and K. BARNES provided the Board with a clarification of the Board Policy 2015-01 “Joint Policy on Pharmacist Administration of Vaccines” D SENCABAUGH noted that the Board had been contacted by registrants on multiple occasions with inquiries as to a pharmacist ability to provide Zostavax Immunizations with a standing order. The issue is that FDA has approved for the administration of Zostavax to adults 50 years and older. The Pharmacist Immunization policy allows for the administration of all CDC approved vaccines included as part of the ACIP adult immunization schedule. In June 2011, ACIP declined to recommend the Zostavax for adults aged 50 through 59 and affirmed its current recommendation that herpes zoster vaccine be routinely recommended for adults aged 60 years and older. Therefore, it was concluded that the practice of the administration of Zostavax to patients less than 60 years of age would be a violation of the pharmacist immunization policy. D SENCABAUGH noted that is believe there maybe confusion among the registrants regarding this. K.BARNES provided the board with an advisory on Zostavax immunization that would clarify the immunization policy explaining the CDC and ACIP guidelines. The advisory also notifies pharmacists that they must cease immediately the administration of Zostavax to patients under the age of 60.

TOPIC VIII. REGULATIONS

1. Draft amendments to 247 CMR 9:00: Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies and Pharmacy Departments: Proposed amendments will include provisions pertaining to naloxone, as required by M.G.L. c 94C §§ 19B & 19C.

DISCUSSION: The Board revisited the topic of the amendments requiring pharmacies in areas identified as high overdose incident to carry naloxone rescue kits. H ENGMAN noted that Board members had been provided with the updated statute for their review. H. ENGMAN noted that the incident areas would change and be updated from time to time and that it is the recommendation that high incident area list be published by the Board in consultation with the Bureau of Substance Abuse Services P. GANNON noted that flexibility was the key with list and that the Board of Pharmacy would have the discretion regarding the new list and the ramp up time for pharmacies. P. GANNON also noted that due to the statutory language there was not a lot of flexibility or discretion for the Board regarding this inclusion H.ENGMAN also noted that prior to publishing the list would need to come before the Board for approval.

H.ENGMAN also informed the board that as a result on the EO562 process and conversations with R. RODMAN deputy general counsel that multiple regulation contained with 105 CMR 700 were more suited as a pharmacist responsibility . Therefore, it is the recommendation that these regulations be rescinded from 105 CMR 700 and be incorporated in 247 CMR 9.00 this transfer would take place with no substantive changes allowing for the regulations to concise, and remove duplication. The relocated sections involve: a. Prescription Monitoring Program reporting; b. medical emergency interchange; c. oral prescriptions; d. generic substitution; e. prescription labeling.

ACTION: Motion by R.TINSLEY, seconded by T. FENSKY and voted unanimously to approve the draft proposed amendments to 247 CMR 9.00 and to proceed forward with the EO562 process and if no substantive changes forward the draft regulation for public comment.

2. Draft proposed new section 247 CMR 17.0 Sterile Compounding

DISCUSSION: Work continued on the draft of the proposed new section 247 CMR 17.00 was presented to the Board for review. The document was displayed on the screen for the Board members and audience to see. H.ENGSMAN captured the Board requests via track changes. K. BARNES and W. FRISCH led the discussion with the Board members on the new sections that Board staff had worked on since the September 6th meeting. The discussion focused on dedicated compounding rooms. K.BARNES reported that this section was the result of collaboration with the hospital stakeholders and from knowledge gained from tours of hospital facilities at their invitation. K. BARNES noted that the goal is to raise the bar not put a facility 'out of business W. FRISCH concurred on the need to raise the bar and noted the need for the room to be a classified space. K.BARNES and W. FRISCH conceded that the dedicated compounding room could be an issue for smaller hospitals. P. GANNON noted the trick is to strike a balance with a workable regulation. P. GANNON noted the need to raise the bar on safety if it is a stop sign provided it is not a four way stop sign.

TOPIC IX

VIOLATION of PROBATION

CVS #498 DS3349, PHA-2013-0153

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

Karen Fishman presented the file showing that CVS #498 had violated probation, having technicians exceeding hours who were not registered.

ACTION: Motion by T. FENSKY seconded by A. STEIN, and voted unanimously to extend the probation by 6 months (to 3/10/18) and require the DS to provide Policy and Procedures assuring that all pharmacy personnel are properly licensed according to 247 CMR 8.03 (3), and P&P regarding tracking hours of technicians in training

TOPIC X

MONTHLY PROBATION REPORT

Presented by Karen Fishman

So noted

TOPIC XI

FILE REVIEW:

1. PHA-2015-0084; Walgreen #2977, DS2250

RECUSAL: M. GODEK recused himself and was not present for the discussion or vote of this matter.

DISCUSSION: M. VASQUEZ presented and summarized the investigation report that pertained to this matter. The evidence indicates that the compliant was opened a result of multiple repeat inspectional deficiencies; expired CII medication not part of perpetual, improper assignment of BUD dates, water stained ceiling tiles. The MOR submitted a satisfactory POC its was noted that a follow up compliance inspection in June 2015 the store displayed substantial compliance.

ACTION: Motion by T. FENSKY, seconded by R. TINSLEY, and voted unanimously to dismiss complaint PHA-2015-0084 with remediation complete.

TOPIC XI
FILE REVIEW

2. PHA-2015-0085; Marc Johnson; PH23288

RECUSAL: M. GODEK recused himself and was not present for the discussion or vote of this matter.

DISCUSSION: M. VASQUEZ presented and summarized the investigation report that pertained to this matter.

The companion complaint against the MOR t was opened as a result of multiple repeat inspectional deficiencies; expired CII medication not part of perpetual, improper assignment of BUD dates, water stained ceiling tiles. That the MOR was responsible for. The MOR submitted a satisfactory POC its was noted that a follow up compliance inspection in June 2015 the store displayed substantial compliance.

ACTION: Motion by T. FENSKY, seconded by R. TINSLEY, and voted unanimously to dismiss complaint PHA-2015-0085 with remediation complete.

TOPIC XI
FILE REVIEW

3. SA-INV-6911; Braintree Laboratories WD472

DISCUSSION: M. VASQUEZ presented and summarized the investigation report that pertained to this matter. The evidence indicates that the facility had received a FDA form 483 and recall of product that was not reported to the board. The investigation revealed that the reporting requirements of 247 CMR are retained based and therefore the facility had no duty to report.

ACTION: Motion by M. GODEK, seconded by G. CAVANAUGH, and voted unanimously to close investigation SA-INV-6911 with no violation of board regulations.

TOPIC XI
FILE REVIEW

4. SA-INV-7410; Braintree Laboratories WD406

DISCUSSION: M. VASQUEZ presented and summarized the investigation report that pertained to this matter. The evidence indicates that the facility had received a FDA form 483 and recall of product that was not reported to the board. The investigation revealed that the reporting requirements of 247 CMR are retained based and therefore the facility had no duty to report.

ACTION: Motion by M. GODEK, seconded by P. BOUVIER, and voted unanimously to close investigation SA-INV-7410 with no violation of board regulations.

TOPIC XI
FILE REVIEW

5. SA-INV-6743; Coram CVS / Specialty DS89944

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

DISCUSSION: C. COLLINS presented and summarized the investigative report that pertained to this matter. The evidence indicates that the licensee properly reported to the board abnormal result as a result of environmental monitoring. It was noted that licensee appropriately remediated.

ACTION: Motion by T. FENSKY, seconded by M. GODEK, and voted unanimously to close investigation SA-INV-6743 with no violation.

TOPIC XI
FILE REVIEW

6. SA-INV-7732, Preferred Pharmacy Solutions, DS3542, in Haverhill, TIME: 11:42AM

DISCUSSION: W. FRISCH presented and summarized the investigation report that pertained to this matter. The evidence indicates that the registrant properly self-reported a failed certification due to a HEPA filter test conducted on June 18, 2015. Compounding was voluntarily stopped on June 19, 2015 and a contingency plan implemented. The HEPA filter was replaced on June 22, 2015. Follow up environmental monitoring was conducted; testing results from June 23 and 25, 2015 were acceptable and within USP <797> action levels. The registrant resumed compounding on June 29, 2015.

1.) ACTION: Motion by G. CVANAUGH, seconded by A. STEIN and voted unanimously to close staff assignment SA-INV-7732, with no violation.

TOPIC XI
FILE REVIEW

7. SA-INV-7251, Home Infusion Solutions, DS3592, in Falmouth, MA TIME: 11:43AM

DISCUSSION: W.FRISCH presented and summarized the investigative report that pertained to this case.

Evidence indicates that the registrant properly self-reported abnormal results from environmental monitoring conducted on March 16, 2015. The registrant ceased compounding on March 25, 2015 and implemented a contingency plan. Follow up environmental monitoring from April 2, 2015 was within USP <797> action levels. It was noted that an acceptable USP <797> inspection was conducted on April 15, 2015.

ACTION: Motion by A. STEIN, seconded W. COX and voted unanimously to close staff assignment SA-INV-7251 with no violation.

TOPIC XI
FILE REVIEW

8. SA-INV-7086, Daniel Lynch Pharmacy, DS1994 Newburyport, TIME: 11:45PM

DISCUSSION: C. MOGNI presented and summarized the investigation report that pertained to this matter. The evidence indicates that there were inspectional deficiencies noted at a retail compliance inspection and USP <795> inspections on 7/31/2014. The deficiencies included controlled substance recordkeeping, general cleaning, expired medications, refrigeration (primarily temperature logs), and the storage, handling and disposal of hazardous drugs. An inadequate POC was submitted and there were changes to the pharmacy without Board notification. The MOR submitted a comprehensive POC including a statement that all hazardous compounding ceased. A Renovation/Expansion Request was submitted for improvements an additional compounding area (not in use). A follow-up retail compliance inspection on 3/5/2015 showed no deficiencies with the pharmacy not compounding with hazardous drugs. A USP <795> inspection on 6/16/2015 found the pharmacy in compliance with no hazardous compounding.

ACTION: Motion by T. FENSKY, seconded by M.GODEK and voted unanimously to close staff assignment SA-INV-7086 with no discipline warranted

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TOPIC XI
FILE REVIEW

9. SA-INV-7678, Rite Aid #10081, DS2971, in Pepperell, TIME: 11:51AM

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

DISCUSSION: M Vasquez presented and summarized the investigation report that pertained to this matter. The evidence indicates that a pharmacy technician trainee indicated that she completed 2400 hours of pharmacy technician training on her pharmacy technician application. The MOR stated that the previous pharmacy manager did not follow up on her registration at the appropriate time. The MOR stated that she has checked all the other licenses and monitors new hires. W. FRISCH indicated that Rite Aid corporate is reviewing policy and procedures to address the technician trainee hours worked issue.

ACTION: Motion P. BOUVIER, seconded by A. STEIN, and voted unanimously to Close staff assignment SA-INV-7678 with discipline not warranted.

TOPIC XI

FILE REVIEW

#

10 PHA-2015-0074, Greater Boston Long Term Care, DS3306, West Roxbury, MA

DISCUSSION: M. VASQUEZ presented and summarized the investigation report that pertained to this matter. The evidence indicates that during a routine compliance inspection that the registrant compounded and dispensed pre-filled insulin syringes intended for injection without a Board inspected clean room. The MOR stated he was by an administrator at a nursing home to pre-fill syringes because they were worried about medication errors. The POC included transitioning patients to pens or have nursing home staff draw up doses and training pharmacy and nursing home staff.

ACTION: Motion by G. CAVANAUGH, seconded by A. STEIN and voted unanimously to dismiss complaint PHA-2015-0074 with discipline not warranted, send a board advisory regarding pre-filled insulin syringes to the registrant.

TOPIC XI

FILE REVIEW

11. SA-INV-7114, CVS #1006, DS3251

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

DISCUSSION: M.VASQUEZ presented and summarized the investigation report that pertained to this matter. The evidence indicates that registrant properly reported a loss of controlled substances. The store conducted an investigation and concluded loss was the result of a double dispensing.

ACTION: Motion by T. FENSKY, seconded by G. CAVANAUGH, and voted unanimously to close staff assignment SA-INV-7114 with no violation.

TOPIC XI

FILE REVIEW

12. SA-INV-7677; CVS 477, DS3251

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

DISCUSSION: M.VASQUEZ presented and summarized the investigation report that pertained to this matter. The evidence indicates that the store reported a loss of controlled substances via a DEA 106. The store conducted a full investigation including a review of CCTV footage and was unable to determine a cause for the loss. The board was concerned due to the amount of controlled substances involved in the loss. W. FRISCH noted that OPP does track controlled substances losses on a spreadsheet to help identify patterns.

ACTION: Motion by R. TINSLEY, seconded by W. Cox, to close staff assignment SA-INV-7677 with discipline not warranted. The motion failed to pass as the majority of members voted against the motion. Roll Call: P. GANNON; no, T. FENSKY; no, M. GODEK; no, G. CAVANAUGH; no, P. BOUVIER; yes; A.STEIN; no

ACTION: Motion by M. GODEK, seconded by A. STEIN, and voted unanimously to elevate staff assignment SA-INV-7677 to a complaint to be heard at a future meeting.

TOPIC XI

FILE REVIEW

13. SA-INV-7084; CVS #477, DS3251

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

DISCUSSION: M.VASQUEZ presented and summarized the investigation report that pertained to this matter. The evidence indicates that the store reported a loss of controlled substances via a DEA 106. The store conducted a full investigation concluding that the loss of controlled substances that the prescription was

dispensed twice confirmed by the store's POS system. The board was concerned with the operation of this location specifically the handling and accountability for controlled substances.

ACTION: Motion by M. GODEK, seconded by G. CAVANAUGH, and voted unanimously to elevate staff assignment SA-INV-7084 to a complaint for further investigation and to be heard at a future meeting.

TOPIC XI
FILE REVIEW

14. SA-INV-7184; BMC at Shapiro, DS89861

DISCUSSION: M. VASQUEZ presented and summarized the investigation report that pertained to this matter. The evidence indicates that the registrant properly reported the loss of a controlled substance. The store conducted a full investigation and concluded that the over dispensing the controlled substance was as the result of a miscount from a manufacturer bottle that contains 90 units instead of 100. The registrant will now double all controlled substance prescriptions.

ACTION: Motion by M. GODEK, seconded by A. STEIN, and voted unanimously to close staff assignment SA-INV-7184 with no violation.

LUNCH 12:22PM- 1:30PM

TOPIC XII
EXECUTIVE SESSION

DISCUSSION: P. GANNON called the session to order. At 2:00PM, P. GANNON informed the public that the Board would be in closed session for the remainder of the day. He read the reason why the Board would be in Executive Session.

ACTION: At 2:00PM motion by R. TINSLEY, seconded by W. COX and voted unanimously by roll call vote. P. GANNON; yes, T. FENSKY; yes, S. CORNACCHIO; yes, W. COX; yes, A. STEIN; yes, R. TINSLEY; yes, M. GODEK; yes, G. CAVANAUGH; yes, P. BOUVIER; yes.

TOPIC XIII.
ADJUDICATORY SESSION (M.G.L. c. 30A, §18)

DISCUSSION: P. GANNON called the session to order.

ACTION: At 2:08 PM motion by T. FENSKY, seconded by W. COX, and voted unanimously to enter into adjudicatory session.

TOPIC XIV
M.G.L. c 112 §65 C Session

DISCUSSION: P. GANNON called the session to order.

ACTION: At 2:14 PM motion by R. TINSLEY, seconded by M. GODEK voted unanimously to enter into M.G.L. c 112 §65 C Session. DISCUSSION: P GANNON called the session to order.

TOPIC XV.
ADJOURNMENT

DISCUSSION: None

ACTION: At 3:45PM motion by T. FENSKY, seconded by P. BOUVIER, and voted unanimously to adjourn the meeting.

LIST OF EXHIBITS USED DURING THE MEETING

1. Draft Agenda for the October 6, 2015 Regularly Scheduled meeting of the Board of Pharmacy.
 2. Draft General Session Minutes of the Regularly Scheduled Board of Pharmacy meeting held August 4, 2015.
 3. Petition for a Waiver of the Provisions of 247 CMR Licensure of a Pharmacy and or Pharmacy Department, Compare Quality Pharmacy, DS89874
 4. Petition for a Waiver of the Provisions of 247 CMR Licensure of a Pharmacy and or Pharmacy Department, Onco360, DS89924
 5. Petition for a Waiver of the Provisions of 247 CMR Licensure of a Pharmacy and or Pharmacy Department, Smart-Pak Equine, DS3320
 6. Application to Manage and Operate a New Community Pharmacy, Dedham Pharmacy and Medical Supply.
 7. Application to Manage and Operate a New Community Pharmacy, Cape Cod Healthcare Pharmacy at Fontaine Out Patient Center.
 8. Renovation/Expansion Request for Board Approval, Apothecare of South Shore.
 9. National Association of Boards of Pharmacy Overview, Verified Pharmacy Program.
 10. Report of applications approved pursuant to licensure policy 13-01
 11. Draft Example, Naloxone Standing Order For Retail Pharmacy.
 12. Draft Naloxone Pamphlet.
 13. Draft proposed Advisory on Zostavax Immunizations.
 14. Draft proposed Advisory on Pre-Filled Insulin Syringes.
 15. Draft proposed Advisory on Staff Ratios.
 16. Memo RE: Implementation of M.G.L. 94C §§ 19B & 19C Regulatory Review.
 17. Draft proposed amendments to 247 CMR. 9.00 Professional Practice Standards.
 18. Draft proposed amendments to 247 CMR 9.00; Professional Practice Standards with track changes.
 19. Draft new regulations 247 CMR 17.00; Sterile Compounding.
 20. Draft new regulations 247 CMR 17.00; Sterile Compounding with track changes.
 21. Memorandum, in the matter of CVS #498, PHA-2013-0153, violation of probation.
 22. Report, Monthly Report from Probation Monitor
 23. Investigative report in the matter of, Walgreens #2977, DS2250, PHA-2015-0084.
 24. Investigative report in the matter of , Marc P. Johnson, PH23277, PHA-2015-0085.
 25. Investigative report in the matter of, Braintree Laboratories, WD472, SA-INV-6911.
 26. Investigative report in the matter of, Braintree Laboratories, WD406, SA-INV-7410.
 27. Investigative report in the matter of Coram CVS/ Specialty, DS89944, SA-INV743.
 28. Investigative report in the matter of, Preferred Pharmacy Solutions, DS3592, SA-INV-7732.
 29. Investigative report in the matter of, Home Solutions, DS3592, SA-INV-7251.
 30. Investigative report in the matter of, Lynch Pharmacy, DS1994, SA-INV-7086.
 31. Investigative report in the matter of, Rite Aid Pharmacy 10081, DS2971, SA-INV-7678.
 32. Investigative report in the matter of, Greater Boston Long Term Care, DS3306, PHA-2015-0074.
 33. Investigative report in the matter of, CVS #1006, DS2715, SA-INV-7114.
 34. Investigative report in the matter of, CVS #477, DS3251, SA-INV-7677.
 35. Investigative report in the matter of, CVS #477, DS3251, SA-INV-7084.
 36. Investigative report in the matter of, BMC at Shapiro, DS89861, SA-INV-7184.
- Respectfully submitted by:

Richard Tinsley, MBA, M.Ed., Secretary