

COMMONWEALTH OF MASSACHUSETTS

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

June 30, 2015
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

Agenda

Time	#	Item	Exhibits	Contact
8:30	I	CALL TO ORDER		
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 June 2, 2015 Regular Session Minutes		
8:45	IV	APPLICATIONS <ol style="list-style-type: none">Joseph M. Smith Community Health Center- New Community PharmacyMaxim Pharmacy – New Community PharmacyBravo Pharmacy – New Community PharmacyNatick Family Pharmacy – New Community PharmacyFreedom Fertility Pharmacy- Renovation/ExpansionFreedom FP Fertility Pharmacy – Renovation/ExpansionBoulevard Compounding Center- Request to conduct high risk sterile compoundingLohxa- New Wholesale Distributor		
10:45	V	REPORTS Applications approved pursuant to Licensure Policy 13-01	Reports	R. Harris

10:50	VI	FLEX SESSION NABP/AACP District I & II Meeting Stakeholder Outreach/Update Special Meeting – July 16, 2015 Pharmacy Advisory Committee Update		D. Sencabaugh K. Barnes D. Dunn
11:00	VII	BOARD POLICY Board Policy 15-03 – Expedited Partner Therapy (EPT) Board Policy 15-01 – Joint Policy on Pharmacist Administration of Vaccines		
11:15	VIII	REGULATIONS: Proposed amendments to 247 CMR 6.00: Registration, Management and Operation of a Pharmacy or Pharmacy Department. Proposed amendments to 247 CMR 8.00: Pharmacy Interns and Technicians Proposed new regulation, 247 CMR 17.00: Sterile Compounding.		H. Engman; D. Sencabaugh; K. Barnes; W. Frisch
12:15		LUNCH BREAK		

1:15	IX	<p>FILE REVIEW</p> <ol style="list-style-type: none"> 1. PHA-2014-0160, CVS Pharmacy 9, DS16477 2. PHA-2015-0025, Neighborhood Pharmacy, DS89938 3. PHA-2015-0031, Plainville Prescription Center, DS1584 4. PHA-2015-0060, Jacquelyn Stanley, PH15712 5. PHA-2015-0035, Prescription Shoppe, DS89816 6. PHA-2015-0062, Joanne Sadrati, PH20276 7. PHA-2015-0056, Boston Community Pharmacy, DS89806 8. PHA-2015-0029, Milford Family Pharmacy, DS89907 9. PHA-2015-0030, Ashburnham Family Pharmacy, DS3314 10. SA-INV-5913, Johnson Compounding & Wellness Center, DS3579 11. SA-INV-5987 Johnson Compounding & Wellness Center, DS3579 12. SA-INV-6359, New England Life Care, DS3513 13. SA-INV-6474, New England Life Care, DS3513 14. SA-INV-6458, Boulevard Compounding Center, DS2943 15. SA-INV-7120, ACC Apothecary, DS3530 	
2:15	X	<p>Request for Termination of Probation</p> <ol style="list-style-type: none"> 1. Beth Thibault, PH21809, PHA-2014-0063 2. West River Pharmacy, DS3572, PHA-2011-0084 	K. Fishman

2:30	XI	<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.</p>	CLOSED SESSION
3:15	XII	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)	CLOSED SESSION
3:45	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 REGULARLY SCHEDULED MEETING
239 Causeway Street, Fourth Floor Room 417A
Boston Massachusetts, 02114**

June 30, 2015

Board Members Present

Patrick Gannon, R.Ph., MS, President
(Arrives 8:34AM)
Richard Tinsley, MBA, M.Ed., Secretary
Timothy Fensky, R.Ph, FACA (arrives 8:53AM)
Garrett Cavanaugh, R.Ph.
Catherine Basile, Pharm D, R.Ph.
Susan Cornacchio, JD, RN.
William Cox CPht
Michael Godek, R.Ph.
Andrew Stein, Pharm D, R.Ph.
Phillippe Bouvier, R.Ph.
Karen Conley

Board Members Not Present

Edmund Taglieri, Jr. R.Ph.

Board Staff Present

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: A quorum of the Board was present. Secretary R. TINSLEY opened the meeting and asked if anyone in the audience was recording the meeting; no one indicated that they were recording the meeting. R. TINSLEY also announced that the Board was recording the meeting. D. SENCABAUGH introduced C. ALWAYSARD the Board's APPE rotation intern.

ACTION: AT 8:30AM R. TINSLEY, called the June 30, 2015, meeting of the Board of Registration in Pharmacy to order. Quorum was established by roll call, R.TINSLEY;

Page **5** of **19**

Minutes of the Regularly Scheduled Meeting held on June 30, 2015

Approved on August 4, 2015 _____

yes, G. CAVANAUGH; yes, S.CORNACCHIO; yes, W. COX; yes; M. GODEK; yes, A. STEIN; yes. C. BASILE; yes, P. BOUVIER; yes, K. CONLEY; yes, P. GANNON and T. FENSKY were not present at roll call.

TOPIC II.

APPROVAL OF AGENDA

Time: 8:34AM

DISCUSSION: D.DUNN informed the Board the following applications would be removed from the Agenda Natick Family Pharmacy, Bravo Pharmacy, and Lohxa.

ACTION: Motion by C. BASILE, seconded by W. COX, and voted unanimously to approve the Agenda with the noted changes. P. GANNON and T. FENSKY were not present for the discussion and vote of this matter.

TOPIC III.

APPROVAL OF BOARD MINUTES

TIME: 8:35AM

Draft June 2, 2015, Regular Session Minutes

DISCUSSION: None

ACTION: Motion by C. BASILE, seconded by R. TINSLEY, and voted unanimously to approve the Draft June 2, 2015, Regular Session Minutes. T. FENSKY was not present For the discussion or vote on this matter. K. CONLEY abstained.

TOPIC IV.

APPLICATIONS:

TIME: 8:39

1. Joseph M Smith Community Health Ctr. New Community Pharmacy , Brighton

DISCUSSION: Manager of Record (MOR) Hinael Patel and Medical Director Elizabeth Molina attended the meeting in support of the application. The Joseph M. Smith Community Health Center provides primary and preventative care services. The pharmacy has operated as a 340B pharmacy under a DCP license since its inception in 2010. The Health Center will be relocating to a new larger facility and is seeking a retail drug store license to be able to service the community. The Health Center representatives indicated that they have notified DCP that they will discontinue their clinic license once they move into their new facility. The Community Health center sought waivers from compounding citing that they have had no need to compound and would refer patients requiring compounded preparation to Johnson's Health and Wellness Center. MOR Patel indicated that the pharmacy would not be providing immunization. MOR Patel is not enrolled in the PMP program, the Board recommended that she enroll and utilize the program. The Board was concerned with the lack of weekend hours; MOR Patel indicated that they are looking to add staff to expand the hours.

ACTION: Motion by R. TINSLEY, seconded by C.BASILE, and voted unanimously to approve the Joseph M. Smith Community Health Center's application to Manager and Operate a New Community Drug Store, and waivers of 247 CMR 6.01,5(a), 6.02 4, and 9.01 16 and pending a successful compliance inspection. T. FENSKY was not present for the discussion or vote of this matter.

TOPIC IV.

APPLICATIONS:

TIME: 8:49

2. Maxim Pharmacy New Community Pharmacy South Boston

DISCUSSION: Hein Vinh proposed MOR was present in support of Maxim Pharmacy's application to Operate and Manage a Community Pharmacy. MOR VINH he has been an MOR for 14 years and this would be his second pharmacy location. Maxim Pharmacy will be typical community pharmacy offer prescriptions, immunization and durable medical equipment supplies. MOR VINH indicated that he would be the MOR for the new location and that he will be promoting the staff pharmacist at his current location to MOR. MOR VINH attested to providing simple and moderate compounding and that he and his staff are enrolled and utilizing the PMP program.

ACTION: Motion by K. CONLEY, seconded by A. STIEN, and voted unanimously to approve the Maxim Pharmacy' application to Manage and Operate a Community Drugstore pending a successful compliance inspection.

TOPIC IV.

APPLICATIONS:

TIME: 8:55

1. Freedom Fertility Pharmacy Renovation / Expansion Byfield
2. Freedom FP Fertility Pharmacy

DISCUSSION: MOR Hillary Thibault, MOR Phil D'Amato, John Sisto, and Thomas Choate appeared in support of the applications for Renovation / Expansion of Lynnfield Drug DBA Freedom Fertility Pharmacy and Lynnfield Compounding Center DBA Freedom FP Fertility Pharmacy. The representatives indicated that they will be adding 4,500 square feet of currently unlicensed space to the existing pharmacy and updating their clean-room to be in compliance with USP <800>. The Freedom representatives and their contractor outlined the 6 phase construction plan and timeline for the pharmacy and clean room construction. Contractor Choate indicated that he has 40 years of experience in the design and construction of clean rooms noting that this was a medium scope project for his firm. Contractor Choate outlined the containment strategy and construction plan to the satisfaction of the Board. Directors K. BARNES and W.FRISCH noted that they had been in contact with Freedom Fertility representatives and they were comfortable so far and the planning was thoughtful. A. STIEN queried representatives regarding a contingency plan for the clean room in the event that there was an issue with construction. MOR Thibault indicated that this would not be necessary as the old cleanroom would not be decommissioned until the new cleanroom was certified.

ACTION: Motion by M. GODEK, seconded by T.FENSKY and voted unanimously to approve Lynnfield Drug DBA Freedom Fertility Pharmacy's application for Renovation / Expansion pending successful inspection.

ACTION: Motion by M.GODEK, seconded by C.BASILE and voted unanimously to approve Lynnfield Drug DBA Freedom FP Fertility Pharmacy's application for Renovation / Expansion pending successful inspection.

TOPIC IV
APPLICATIONS:

TIME: 9:08

3. Boulevard Compounding Center Request to conduct High Risk Sterile Compounding, Worcester
RECUSAL: A. STIEN was not present for the discussion or vote on this matter.
DISCUSSION: MOR Joseph Rosetti appeared before the Board in support of the request to expand Boulevard Compounding Pharmacy to High Risk Compounding. At the March 3, 2015, meeting the Board approved the Boulevard Compounding for Low and Medium Risk compounding deferring approval of High Risk compounding until additional training and formulation worksheet requirements were met. Director of Compliance W. FRISCH noted that he has been working with Boulevard and they had been cooperative. W. FRISCH noted that MOR Rosetti and Technician Brown had completed the required training. W. FRISCH noted that there still were questions regarding the BUD for CSP's that would be placed in the implantable pumps. MOR Rosetti indicated that he was unable to find a laboratory that was capable of performing the sterility testing at body temperature; therefore, Boulevard was incubating the products in their own incubator for 90 days at 98.6 degrees and would then send out for validation. W. FRISCH noted that he also had concerns regarding a "trimix" preparation due to the amount of alcohol the CSP never reaches a frozen state. MOR Rosetti indicated that he was in the process of validating the BUD. W. FRISCH indicated that Boulevard would be able to proceed with High Risk compounding with exception of CSP products that required an extended BUD beyond USP limits.
ACTION: Motion by P. GANNON, seconded by P. BOUVIER, and voted unanimously to approve Boulevard Compounding Center's request to commence High Risk sterile compounding and to formally advise the pharmacy that it may not compound drugs for implantable infusion pumps unless and until it has validation that the drugs maintain stability and sterility for the duration of time drugs are in the implantable infusion pump.

TOPIC V.
REPORTS

Applications Approved Pursuant to Licensure Policy 13-01 **9:23AM**

DISCUSSION: R HARRIS noted that during the past month there have been thirty (30) Change of Managers, one (1) renovation/expansions and one (1) nuclear pharmacist, approved by staff action.

ACTION: So noted

TOPIC VI.
FLEX SESSION

TIME: 9:24

1. NABP / AACP District 1 / 2 Meeting:

DISCUSSION: D SENCABAUGH informed the Board of the upcoming meeting scheduled for September 23-25 in Portsmouth, NH. D. SENCABAUGH highly recommended that members try to attend to gain perspective on how the other boards of pharmacy are tackling many of the same issues that confront this board. A. YOUNG former board member and treasurer for NABP District 1 addressed the Board echoing the benefits of attendance, the Continuing education opportunities especially in Opioids and Just Culture.

2. Stakeholder Outreach:

DISCUSSION: K. BARNES and W.FRISCH updated the Board on their outreach efforts as it related to the new compounding regulations. K. BARNES detailed their outreach efforts in working with; (a) HVAC company, (b) experts on the autologous eye drops and handling and compounding of blood products, (c) working with experts in radiopharmaceuticals, (d) and working with the hospitals more and more through MSHP through meeting and participation on conference calls. K. BARNES and W FRISCH continue to seek input on the development of the new regulations in hopes of having a set of regulations that are workable for all.

3. Special Meeting- July 16, 2015.

DISCUSSION: D DUNN informed the meeting that based on member feedback that a special meeting to continue the work on regulation would be scheduled for Thursday, July 16, 2015 for 9:00AM to 1:00PM.

4. Pharmacy Advisory Committee Update:

DISCUSSION: K. BARNES, M. GODEK provided updates from the June 26, 2015 meeting. The full day meeting consisted of two parts (1) morning session continued the work by the sub-committee on Abnormal Results and (2) the afternoon session was a meeting of the full committee to tackle the additional question of Central Fill and Remote Processing. P. GANNON thanked K. BARNES and M. GODEK for their work with the committee in order to get the board the answer to these important topics.

TOPIC VII

BOARD POLICY

TIME: 9:40

1. Board Policy 15-03 Expedited Partner Therapy

DISCUSSION: D. SENCABAUGH requested that the Board consider the adoption of POLICY 15-03 Expedited Partner Therapy. The Board was reminded that at the June 2, 2015 meeting they approved that a reminder be sent to all members of the Board's distribution list of the 2010 regulation allowing for Expedited Partner Therapy. H. ENGMAN reviewed the document with the Board and D. SENCABAUGH highlighted the "referral requirement" as the crux of the policy. The Board was concerned with the lack of patient information and the pharmacist limited access to a profile and patient allergies. Board members were in agreement that pharmacists must refer and that patients must get treated as the benefits out-weighed the risks.

ACTION: Motion by K. CONLEY, seconded by T. FENSKY, and voted by majority to approve Board Policy 15-03 Expedited Partner Therapy. R. TINSLEY opposed.

2. **BOARD POLICY 15:01** Joint Policy on Pharmacist Administration of Vaccines
DISCUSSION: D DUNN informed the need to update Board Policy 15-01 that was approved on January 6, 2015. The passing of Senate Bill as of April Pharmacy Interns are now allowed to provide immunization under the supervision of a pharmacist. This change necessitates a change to the policy to include Pharmacy Intern after Pharmacist and the update of question 7 on page 5. Board members reviewed the policy indicating a change to the Title to include Pharmacy Intern and to “strongly recommend as a best practice that pharmacist and pharmacy interns that provide immunizations be trained in basic life support. H. ENGMAN indicated that she would research the statute and would look to add to a future agenda.

ACTION: Motion by M. GODEK, second by C. BASILE and voted unanimously to approve Board Policy 15-01 with the noted changes to title and inclusion of basic life support training as a best practice.

BREAK 10:00AM – 10:08AM

TOPIC VIII

REGULATIONS

TIME: 10:09AM

1. Proposed amendments to 247 CMR 6.00: Registration, Management and Operation of a Pharmacy or Pharmacy Department. Proposed amendment will include institutional sterile compounding licensure and the application process for provisional licenses issued pursuant to Section 25 of Chapter 159 of the Acts of 2014.

DISCUSSION: H. ENGMAN displayed on the screen for the board members and the audience board members suggestions and comments were captured and reflected in track changes. H ENGMAN highlighted for the Board the changes to draft proposed 247 CMR 6.0 incorporating institutional and provisional licenses and the incorporation of the Board’s recommendation from the June 2, 2015 meeting.

ACTION: Motion by C.BASILE, seconded by P. BOUVIER, and voted unanimously to approve the proposed draft of 247 CMR 6.00: Registration, Management and Operation of a Pharmacy or Pharmacy Department and recommend that it is forwarded to the administrative review process.

TOPIC VIII

REGULATIONS:

TIME: 10:25AM

1. Proposed amendments to 247 CMR 8.00: Pharmacy Interns and Technicians.

DISCUSSION: H. ENGMAN displayed on the screen for the board members and the audience board members suggestions and comments were captured and reflected in track changes. D. SENCABAUGH noted the proposed changes for the Board, (a) the

Page 10 of 19

Minutes of the Regularly Scheduled Meeting held on June 30, 2015

Approved on August 4, 2015 _____

establishment of a Technician Trainee category for licensure. D. SENCABAUGH highlighted the need for such a category in the event of a diversion that there would be documentation of the event to prevent the individual from securing a position at another pharmacy with a chance to divert. D. SENCABAUGH highlighted changes to the Pharmacy Intern language requiring that a Pharmacy Intern be enrolled in a Doctor of Pharmacy Program; additionally nonresident graduates from an accredited college of pharmacy that have been accepted into a Massachusetts based residency program and not yet a registered pharmacist would be allowed to apply to be a pharmacy intern during the interim period.

TOPIC VIII.

REGULATION:

TIME: 11:25AM

2. Proposed draft regulation 247 CMR 17:00 Sterile Compounding.

DISCUSSION: H. ENGMAN displayed on the screen for the board members and the audience board members suggestions and comments were captured and reflected in track changes. K. BARNES and W. FRISCH informed the Board members of the new section to 247 CMR 17.00 and the general requirements that compounding pharmacies will need to adhere to. W. FRISCH and K. BARNES highlighted for the Board which requirements, mirrored USP <797>, sought to clarify the chapter, and requirements that would exceed the chapter. Continued discussion on the proposed Sterile Compounding regulation to be held at the July 16th meeting.

LUNCH BREAK

12:00PM – 1:05PM

TOPIC IX.

FILE REVIEW:

1. PHA-2014-0160; CVS PHARMACY, DS16477 **TIME:1:05PM**
RECUSAL: S. CORNACCHIO recused herself and was not present for the discussion or vote on this matter.

DISCUSSION: M. VASQUEZ presented and summarized the investigative report pertaining to this matter. Evidence indicates that there were multiple inspectional deficiencies, including but not limited to failure to maintain perpetual inventory, record keeping for the return/ disposal of expired drugs, maintenance of refrigerator / freezer temperature logs prompting a phone conversation from W. FRISCH to the CVS pharmacy supervisor. A Plan of Correction was submitted by the MOR and accepted by OPP. On subsequent compliance inspections July 2014, and May 2015 yield repeat deficiencies. Board was concerned that despite a new MOR problem persisted and that this location should have a monitoring period of satisfactory compliance.

ACTION: Motion by T. FENSKY, seconded by C. BASILE, and voted unanimously to refer the matter to the office of the prosecution for the issuance of an order to show

Page **11** of **19**

Minutes of the Regularly Scheduled Meeting held on June 30, 2015

Approved on August 4, 2015 _____

cause and to authorize resolution of this matter with a consent agreement for 1 year of probation with terms to require an attestation from all pharmacists, the current MOR, the area supervisor, and the former MRO (if he/she still works for CVS) to the reading and understanding of 247 CMR.

TOPIC IX.

FILE REVIEW:

2. PHA-2015-0025; Neighborhood Pharmacy , DS89938 TIME: 1:14PM

DISCUSSION: C. COLLINS presented and summarized the investigation report that pertained to this matter. Evidence indicates that OPP was notified by the Attorney General's Office that Neighborhood Pharmacy improperly billed Medicare via the utilization of an automatic refill program, and this action was not report to the Board. Neighborhood Pharmacy agreed to a settlement with Mass Health and did not feel the settlement agreement constituted discipline.

ACTION: Motion by M. GODEK, seconded by A. STIEN, and voted unanimously to dismiss the complaint with discipline not warranted.

TOPIC IX

FILE REVIEW

3. PHA-2015-0031 Plainville Prescription Center DS1584 TIME: 1:16PM

4. PHA-2015-0060 Jacquelyn Stanley PH15712

DISCUSSION: C. Collins and S. PENTA presented a summarized the investigation report that pertained to these matters. A routine retail compliance inspection conducted of March 2, 2015, revealed multiple deficiencies including but not limited to, multiple sanitation violations, out dated medications and pharmaceuticals, Tier 1 Hazardous material, numerous violations of Board regulations and town ordinances. . W FRISCH indicated that the MOR and sole pharmacist has worked hard to improve the facility and that some of the issues with the building were beyond her control as a tenant of the building. W. FRISCH note the POC and the inclusion of waivers for compounding. The Board was concerned that the MOR had allowed for the conditions of the store to degrade over time and that the MOR was the sole pharmacist employed at the location.

ACTION: Motion by P. GANNON, seconded by R. TINSLEY, and voted unanimously to approve the waivers; (a)

ACTION: Motion by T. FENSKY, seconded by K. Conley, and voted unanimously to refer the complaint against Plainville Prescription Center to the office of the prosecution for the issuance of an order to show cause, and to authorize resolution of this matter with a consent agreement for 2 years probation.

ACTION: Motion by T. FENSKY, seconded by K. Conley, and voted unanimously to refer the complaint against Pharmacist Jacquelyn Stanley to the office of the prosecution for the issuance of an order to show cause, and to authorize resolution of this matter with a consent agreement for a reprimand preconditioned on Board's receipt of documentation demonstrating: (a) completion of 4 contact hours of pharmacist continuing education related to pharmacy law; (b) attest to the reading of

247 CMR 2.00 et seq.; (c) completion of 2 years of pharmacist continuing education for calendar years 2013, and 2014.

TOPIC IX

FILE REVIEW

5.PHA-2015-0035; Prescription Shoppe DS8916 TIME: 1:28PM

DISCUSSION: C. MOGNI presented and summarized the investigation report that pertained to this matter. OPP received an anonymous complaint that MOR Sadrati had been absent from the Prescription Shoppe for approximately 7 months. A routine retail compliance inspection yielded multiple deficiencies including but not limited to: an unalarmed front door, CII in an unlocked cabinet, Power of Attorney not in place for pharmacists signing CII orders, MOR absent since May 2014. The owner of the Prescription Shoppe was identified as Vashkar Karim, R.Ph. It was noted that the deficiencies were not addressed and that the pharmacy closed on April 10, 2015. The Board was pleased with the lack of compliance on the part of the pharmacist owner and MOR to allow the drugstore to operate without an MOR for a prolong period of time.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously to refer the complaint against the Prescription Shoppe to the office of the prosecution for the issuance of an order to show cause, and to authorize resolution of this matter with a consent agreement with a reprimand.

ACTION: Motion by T. FENSKY, seconded by C. BASILE, and voted unanimously to refer the complaint against Pharmacist Joanne Sadrati to the office of the prosecution for the issuance of an order to show cause, and to authorize resolution of this matter with a consent agreement for a non-disciplinary stayed probation with terms to include: (a) completion of 2 contact hours of pharmacist continuing education related to pharmacy law, (b) attest to the reading of 247 CMR 2.00 et. Seq., (c) provide proof of completion of 2 years of pharmacist continuing education for calendar years 2013, and 2014, if found deficient open a complaint against Joanne Sadrati's pharmacist registration, (c) attest to reading Board Policy 98-010 "Policy on Extended Leave."

TOPIC IX

FILE REVIEW

6.PHA-2015-0056 Boston Community Pharmacy DS89806 TIME:1:37PM

DISCUSSION: M VASQUEZ presented and summarized the investigation report that pertained to this matter. Evidence indicates that the Board approved the drugstore license which was issued April 5, 2012. Evidence indicates that the drugstore never opened and that no narcotics or legend drugs were ever ordered or received by the pharmacy. OPP investigators attempted to conduct a routine retail compliance inspection on April 6, 2015 but were not able to gain access to the pharmacy. Pharmacist / Owner Karim indicates he plans to relocate Boston Community Pharmacy.

ACTION: Motion by P. GANNON, seconded by G. CAVANAUGH, and voted unanimously to have Board Staff notify the licensee outlining the pharmacy closure process in 247 CMR 6.09 requiring a formal closure within 14 days, and if the licensee is unwilling to voluntarily close the pharmacy, to refer the matter to prosecution.

TOPIC IX

FILE REVIEW

7.PHA-2015-0029; Milford Family Pharmacy, DS89907 TIME: 1:42PM

8.PHA-2015-0030; Ashburnham Family Pharmacy DS3314

DISCUSSION: C. COLLINS presented and summarized the investigation report that pertained to this matter. Evidence indicates Milford Family Pharmacy transferred expired CII medications to the Ashburnham Family Pharmacy without a DEA 222 for consolidation and return to a reverse distributor. The MOR indicated that multiple Family Pharmacies also engaged in this practice. The MOR indicates that the policy has now been changed and that the reverse distributor will pick up drugs for reverse distribution at the individual Family Pharmacy locations. Board members were concerned as to how multiple MORs would engage in this practice and lack a basic knowledge of regulation regarding the transfer of CII products.

ACTION: Motion by C. BASILE, seconded by M. GODEK, and voted by majority to dismiss the complaints against Milford Family pharmacy with no further discipline warranted because remediation was complete. T.FENSKY and A. STIEN opposed.

ACTION: Motion by C. Basile, seconded by K. Conley, to dismiss the complaint against Ashburnham family pharmacy. No vote taken.

DISCUSSION: T. FENSKY was concerned that multiple MOR would agree to such a practice that was a clear violation the DEA regulation that all should have known that the practice was wrong.

ACTION: Motion by P. GANNON, seconded by R.TINSLEY, and voted unanimously to; (a) rescind the prior vote to dismiss the complaints against Milford Family Pharmacies, (b) defer the matters at a future board meeting, (c) open a complaint against Vice President of Operations pharmacist M. MOEN and Pharmacist / Owner H. MOHAGHEGH regarding Family Pharmacy's corporate Controlled Substances handling practices.

TOPIC IX

FILE REVIEW

9.SA-INV-5913; Johnson Compounding & Wellness Center DS3579 TIME:1:58

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

DISCUSSION: C. COLLINS presented and summarized the investigation report that pertained to this matter. OPP received an anonymous complaint alleging Johnson's Compounding & Wellness Center was compounding and filling prescriptions for New Hampshire based naturopathic physicians. H. ENGMAN indicated that per M.G.L 94C as long as the physician prescriber is authorized to

prescribe in the state where they are licensed, the prescriptions are valid and there would be no violation.

ACTION: Motion by C. BASILE, seconded by W. COX, and voted unanimously to close the staff assignment with no violation.

**TOPIC IX
FILE REVIEW**

10. SA-INV-5987; Johnson Compounding & Wellness Center DS3579 TIME:2:00
RECUSAL: A. STIEN recused himself and was not present for the discussion or vote on this matter.

DISCUSSION: C. COLLINS presented and summarized the investigation report that pertained to this matter. Evidence indicates that OPP received self-reports of abnormal results from environmental monitoring from Johnson's Compounding & Wellness Center in April, September, and October of 2014. Compounding was voluntarily suspended for a period of time during the remediation period. Johnson's initiated an extensive POC making upgrades to the HVAC system and increased environmental sampling, subsequent <795> and <797> inspections conducted in February of 2015 were significantly compliant.

At a May 2014 compliance inspection it was revealed that Johnson's was compounding preservative-free sterile cyclosporine ophthalmic preparations with BUD of 14 days consistent with low risk compounds instead of 3 days as required by <797> for high-risk CSPs. Johnson's revised their designation for ophthalmic CSP as high risk preparations dispensed in single use droppers with a BUD of 3 days under refrigeration.

ACTION: Motion by W. COX, seconded by M. GODEK, and voted unanimously to close the staff assignment with no discipline warranted because remediation complete.

**TOPIC IX
FILE REVIEW**

11. SA-INV-6359 New England Life Care DS3513 TIME:2:04PM
RECUSAL: GODEK recused himself 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. OPP received a self-report of abnormal results from environmental sampling discovered during the biannual certification. The licensee voluntarily cease compounding for 1 day following a root cause analysis and a POC with guidance from board staff.

ACTION: Motion by G. CAVANAUGH, seconded by A. STIEN, and voted unanimously to close the staff assignment with remediation complete, no violation.

TOPIC IX

FILE REVIEW

12 SA-INV-6474 New England Life Care DS3513 TIME:2:0gPM
RECUSAL: GODEK recused himself 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. OPP received a self-report of abnormal results from environmental sampling of fungus that was found to be below USP Action limits. A deep cleaning was performed and retesting revealed presence of bacteria but no fungus. New England Life Care resumed compounding.

ACTION: Motion by P. BOUVIER, seconded by C. BASILE, and voted unanimously to close the staff assignment with remediation complete, no violation.

TOPIC IX

FILE REVIEW

14. SA-INV-6458 Boulevard Compounding Center DS2943 TIME 2:07PM
RECUSAL: STIEN recused himself 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. OPP received a self-report of an abnormal result from environmental sampling. The root cause was identified as a failed HEPA filter. The POC included the replacement of the positive laminar flow hood based on the failed HEPA filter leak test. Boulevard performed all necessary testing and certifications to ensure compliance with USP <797>.

ACTION: Motion by M. GODEK, seconded by K. CONLEY, and voted unanimously to close the staff assignment with remediation complete, no violation.

TOPIC IX

FILE REVIEW

15. SA-INV-7120: ACC Apothecary DS3350 TIME:
DISCUSSION: C. Mogni presented and summarized the investigation report that pertained to this matter. OPP received a claim from a PBM that ACC Apothecary may have dispensed the wrong medication. Based on the response provided by the MOR it was indicated that the compounded preparation was for a supplement mixture requiring 30 ingredients. The MOR indicated that based on ACC “compounding expertise” separated the mixture into 2 orders to ensure compatibility.

ACTION: Motion by R. Tinsley, seconded by A. STIEN and voted unanimously to close the staff assignment with no violation. B. COX was not present for the vote of this matter.

TOPIC X.

REQUEST FOR TERMINATION OF PROBATION:
2:15PM

TIME:

^^ 1. Beth Thibault; PH21809, PH21809, PHA-2014-0063

DISCUSSION: K. FISHMAN presented and summarized the licensee's request for the early termination of probation. The licensee entered into a Consent Agreement for 3 years' probation, effective May 15, 2014, as a result of her role in dispensing activities and record keeping while employed at H.L. Wardle Drug. Licensee petitioned the Board for early termination of probation due the fact that the licensee has completed the terms and conditions of the agreement. The licensee asserts that the probationary status of her license is a barrier to employment. The Board the discussed merits of the agreement or the licensee actions were the barrier to employment. The Board was sympathetic to the licensee's situation but concluded that the agreement was entered into voluntarily, too short a period of time had lapsed, and that it would be a dangerous precedent to set by shorting a probationary period.

ACTION: Motion by R. TINSLEY, seconded by P. GANNON and voted unanimously to reject Beth Thibault's request for termination of probation.

TOPIC X

REQUEST FOR TERMINATION OF PROBATION: TIME:2:27PM

2. West River Pharmacy; DS3527 PHA-2011-0084, PHA-2012-0251, PHA-2013-0099

DISCUSSION: K. FISHMAN presented and summarized the licensee's request for early termination of probation. The licensee entered into multiple consent agreement related to inspectional violations and laws and regulations governing the practice of pharmacy. The board reviewed the request and debated the incidents that lead to the agreements set to expire December 20, 2015. The Board concluded that it saw no reason to reduce the length of the probations as the agreement entered into was voluntary.

ACTION: Motion by R.TINSLEY, seconded by M. GODEK and voted unanimously to deny West River Pharmacy's request for termination of probation.

TOPIC XI.

EXEXECUTIVE SESSION

DISCUSSION: P. GANNON called the session to order

ACTION: At 2:32PM. Motion by P. GANNON, seconded by T.FENSKY and voted unanimously by roll call vote, P. GANNON; yes,; yes, T. FENSKY; yes, S.

CORNACCHIO; yes, R. TINSLEY; yes, C. BASILE; yes, K. CONLEY; yes, A.

STIEN; yes, G. CAVANAUGH; yes, M. GODEK; yes, P. BOUVIER; yes, W. COX; yes.to enter into executive session. P. GANNON announced that the board would or would return to open session

TOPIC

XII. ADJUDICATORY SESSION

DISCUSSION: P. GANNON called the session to order.

ACTION: At 3:39PM motion by M. GODEK, seconded by G. CAVANAUGH, and voted unanimously to enter into Adjudicatory Session.

TOPIC

XIII. M.G.L. c 112 §65 C Session

DISCUSSION: P. GANNON called the session to order

ACTION: At 3:55PM motion by T. FENSKY, seconded by C. BASILE, and voted unanimously to enter into M.G.L. c 112 §65 C Session.

TOPIC

XIV. ADJOURNMENT

DISCUSSION: None

ACTION: At 5:27PM Motion by T. FENSKY, seconded by K. CONLEY, and voted unanimously to adjourn the meeting.

LIST OF EXHIBITS USED DURING THE MEETING

1. Draft proposed Agenda for the June 30, 2015, Regularly Scheduled Meeting.
2. Draft General Session Minutes from the June 2, 2015, Regular Session.
3. Application to Manage and Operate a New Community Pharmacy , Joseph M. Smith Community Health Center.
4. Application to Manage and Operate a New Community Pharmacy , Maxim Pharmacy.
5. Application for Renovation/Expansion Request for Approval, Freedom Fertility Pharmacy.
6. Application for Renovation/Expansion Request for Approval, Freedom Fertility FP Pharmacy.
7. Boulevard Compounding Center-Request to conduct high risk sterile compounding.
8. Report of Applications Approved Pursuant to Licensure Policy 13-01.
9. Draft Board Policy 15-03 Expedited Partner Therapy.
10. Draft Board Policy 15-01 Joint Policy on Pharmacist Administration of Vaccines.
11. Draft proposed amendments to 247 CMR 6.00: Registration, Management and Operation of a Pharmacy or Pharmacy Department.
12. Draft proposed amendments to 247 CMR 6.00: Registration, Management and Operations of a Pharmacy or Pharmacy Department with track changes.
13. Draft proposed amendments to 247 CMR 8.00: Pharmacy interns and Technicians with track changes.
14. Draft proposed new regulations, 247 CMR 17.00: Sterile Compounding.
15. Investigation Report in the matter of CVS Pharmacy #9, DS16477, PHA-2014-0160.
16. Investigation Report in the matter of Neighborhood Pharmacy, DS89938, PHA-2015-0025.
17. Investigation Report in the matter of Plainville Prescription Center, DS1584, PHA-2015-0031.

18. Investigation Report in the matter of Jacquelyn Stanley, PH15712, PHA-2015-0060.
19. Investigation Report in the matter of Prescription Shoppe, DS89816, PHA-2015-0035.
20. Investigation Report in the matter of Joanne Sadrati, PH20276, PHA-2015-0062.
21. Investigation Report in the matter of Boston Community Pharmacy , DS89806. PHA-2015-0056.
22. Investigation Report in the matter of Milford Family Pharmacy, DS89907, PHA-2015-0029.
23. Investigation Report in the matter of Ashburnham Family Pharmacy, DS3314, PHA-2015-0030.
24. Investigation Report in the matter of Johnson Compounding & Wellness Center, DS3579, SA-INV-5913.
25. Investigation Report in the matter of Johnson Compounding & Wellness Center, DS3579, SA-INV-5987.
26. Investigation Report in the matter of New England Life Care, DS3513, SA-INV-6359.
27. Investigation Report in the matter of New England Life Care, DS3513, SA-INV-6474.
28. Investigation Report in the matter of Boulevard Compounding Center, DAS2943, SA-INV-6458.
29. Investigation Report in the matter of ACC Apothecary, DS3530, SA-INV-7120.
30. Memo, Request for termination of Probation, West River Pharmacy, DS3572.
31. Memo, Request for termination of Probation, Beth Thibault, PH21809.

Respectfully submitted by:

Richard Tinsley, MBA, M.Ed., Secretary