COMMONWEALTH OF MASSACHUSETTS

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

June 2, 2015 239 Causeway Street ~ Room 417 A&B Boston, Massachusetts 02114

Agenda

Time	#	Item	Exhibits	Contact
9:00	1	CALL TO ORDER		
9:05	11	APPROVAL OF AGENDA		
9:10	111	APPROVAL OF BOARD MINUTES Draft of May 5, 2015 Regular Session Minutes		
9:15	IV	FLEX SESSION 1. DHPL Probation Policy 2. Pharmacy Intern Introduction- Vishal Thaker & Ellen Colman 3. Pharmacy Advisory Committee Update a. May 29 th Sub Committee Meeting b. Future Meeting c. New Topics for Committee 4. Expedited Partner Therapy Reminder		V. Berg D. Sencabaugh K. Barnes
9:30	V	APPLICATIONS 1. Cape Cod Healthcare, Inc. – New Community Pharmacy 2. MBS Pharma Care, Inc. – New Community Pharmacy 3. Western MA Compounding Center- Transfer of Ownership 4. Central Pharmacy- Transfer of Ownership		
10:10	VI	REPORTS Applications approved pursuant to Licensure Policy 13-01	Reports	R. Harris

10:15	VII	FILE REVIEW		
		PHA-2014-0096, Pharmacy Corporation of America, DS3599		
		2. PHA-2014-0144, Hopkinton Drug, DS8191		
		3. PHA-2014-0179, Critical Care Systems, DS3327		
		4. SA-INV-6182, Omnicare of Northern Massachusetts, DS3458		
		5. SA-INV-6710, Boston Home Infusion, DS2623		
		6. PHA-2015-0016, Rite Aid 10197, DS2571		
		7. PHA-2015-0022, Alfred Kallini, PH26622		
		8. SA-INV-6869, The Whittier Pharmacist, DS3587		
		9. SA-INV-6907, Sherif Mohamed Dessouky Ibrahim, PH235180		
		10. PHA-2015-0045, Preferred Pharmacy Solutions, DS3542		
11:00	VIII	M.G.L. c. 112, 65C SESSION		CLOSED SESSION
11:30	IX	REGULATIONS: Proposed amendments to 247 CMR 6.00: Registration, Management and Operation of a Pharmacy or Pharmacy Department. Proposed amendments will include institutional sterile compounding pharmacy licensure and application process and provisional licenses issued pursuant to Section 25 of Chapter 159 of the Acts of 2014.		H. Engman
12:30		LUNCH BREAK		
1:30	Х	M.G.L. c. 112, 65C SESSION	CLO	SED SESSION

2:15	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 applicants and petitions for termination of probation	
2:45	XII	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)	CLOSED SESSION
3:15	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 2, 2015

Board Members Present

Board Members Not Present
Karen Conley, RN, DNP

Patrick Gannon, R.Ph., MS, President Edmund Taglieri Jr., R.Ph., MSM, NHA President-elect Richard Tinsley, MBA, M.Ed., Secretary Timothy Fensky, R.Ph., FACA

Catherine Basile, Pharm D, R.Ph. (arrived @ 9:04AM)

Susan Cornacchio, JD, RN.

Garrett Cavanaugh, R.Ph.

William Cox CPht Michael Godek, R.Ph.

Andrew Stein, Pharm D, R.Ph.

Phillippe Bouvier, R.Ph. (arrived @ 9:11AM)

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

<u>DISCUSSION</u>: A quorum of the Board was present. President P.GANNON chaired the meeting and asked if anyone in the audience was recording the meeting; no one indicated that they were recording the meeting. P. GANNON also announced that the Board was recording the meeting.

<u>ACTION</u>: AT 9:00AM P.GANNON, called the June 2, 2015, meeting of the Board of Registration in Pharmacy to order. Quorum was established by roll call, P. GANNON; yes, E.TAGLIERI; yes, R.TINSLEY; yes, G. CAVANAUGH; yes, S.CORNACCHIO;

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yes, W. COX; yes; T.FENSKY; yes; M. GODEK; yes, A. STEIN: yes. C.BASILE and P. BOUVIER were not present at the time of roll call.

TOPIC II.

APPROVAL OF AGENDA

DISCUSSION: None

<u>ACTION</u>: Motion by E.TAGLIERI, seconded by T. FENSKY, and voted unanimously to approve the Agenda C. BASILE and P. BOUVIER were not present for the discussion and vote of this matter.

TOPIC III.

APPROVAL OF BOARD MINUTES

1. Draft May 5, 2015, Regular Session Minutes

DISCUSSION: None

ACTION: Motion by T.FENSKY, seconded by M. GODEK, and voted unanimously to approve the Draft May 5, 2015, Regular Session Minutes. P.BOUVIER was not present

TOPIC IV.

IV. FLEX SESSION

1. DHPL PROBATION POLICY:

<u>DISCUSSION</u>: Chief Board Counsel V.BERG presented the uniform DHPL Probation Policy for ratification by the board. The new policy seeks to define the specific staff actions authority for Board the Executive Director and the Probation Monitor. The policy is designed to allow for administrative action of routine occurrences conserving board time for complex matters.

<u>ACTION</u>: Motion M.GODEK, seconded by T. FENKY and voted unanimously to approve the DHPL Division Policy 15-01 Delegation of Authority for Staff Action Relative to Monitoring Licensure Conditions.

2 Pharmacy Intern Introductions:

<u>DISCUSSION</u>: D.SENCABAUGH formerly introduced Board of Registration in Pharmacy Advanced Professional Practice Experience Interns, Vishal Thaker and Ellen Colman, from Northeastern College of Pharmacy and Massachusetts College of Pharmacy and Health Sciences University respectively.

3 PHARMACY ADVISORY COMMITTEE UPDATE:

<u>DISCUSSION:</u> D. SENCABAUGH updated the board on Pharmacy Advisory Committee. D. SENCABAUGH informed the board that the next meeting of the Advisory committee would take place on Friday, June 26, 2015. D.SENCABAUGH

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pointed out that the Sub-Committee for Abnormal Results would meet from 10:00AM-12:00PM to continue work on the topic. D. SENCABAUGH informed board members that the full Pharmacy Advisory Committee would convene in the afternoon from 1:00-3:00 PM.

D. SENCABAUGH indicated to the board the meeting of the full Pharmacy Advisory Committee in order to meet the requirements of c.159 it would be prudent to ask the committee to provide input on "Emerging Models of Coordinated Pharmacy Services" in addition to the topics already being considered by the committee. M.GODEK volunteered to be the liaison from the board to the committee for this topic.

ACTION: Motion by R.TINSLEY, seconded by T. FENSKY to approve and forward to

ACTION: Motion by R.TINSLEY, seconded by T. FENSKY to approve and forward to the Pharmacy Advisory Committee Recommendation 15-03 "Emerging Models of Coordinated Pharmacy Services" and select board member Michael Godek as the liaison

K.BARNES and W. FRISCH provided the board with an update of the Pharmacy Advisory sub-committee on Abnormal Results process document. K. BARNES thanked board member T. FENSKY for his participation. K. Barnes indicated that a lot was accomplished at the May 29, 2015 meeting regarding the ISO 5 classified space regarding draft guidance and workflow for compounding pharmacies. W. FRISCH echoed the sentiment and reiterated the desire to provide the compounding community clear guidance on safe compounding and it is not the OPP intent to close a pharmacy make it as safe as possible for the public.

4. Expedited Partner Therapy Reminder

<u>DISCUSSION:</u> D Sencabaugh informed the Board of a request from the Bureau of Infectious Disease to remind pharmacist of the requirement to honor prescription for Expedited Partner Therapy. K. BARNES recognized Pharmacy Intern E. COLEMAN for her efforts on researching the 2010 policy. D SENCABAUGH made members aware that the Board staff would make the document available via the Board's website and via its distribution list. P. GANNON indicated a desire for more frequent updates and to continue to look forward ways to improve communication with licensees to improve patient access.

TOPIC V.
APPLICATIONS

9:42

1. Cape Cod Healthcare, Inc.

New Community Pharmacy 2 Jan Sebastian
Way, Hyannis, MA. 02563

<u>DISCUSSION</u>: Pharmacy Director Peter Scarafile represented Cape Cod Healthcare. The proposed MOR, Angela Medeiros PH26680 was unable to attend as she was on maternity leave. She would be a first-time MOR. This is for a regular retail adjacent to the outpatient clinic, open 9 hours weekdays, 5 hours on Saturday, and closed Sunday. The plan is to close the current DCP registered pharmacies in conjunction with openings, and AED David Dunn reminded them to contact DCP regarding their plans.

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Cape Cod Healthcare needs to correct number 14 in their attestation, since they have a scale and intend to perform simple and moderate compounding as necessary. Patients needing care on Sunday would be referred to urgent care within the facility.

MOR Medeiros is registered with PMP, and they plan to offer immunizations.

ACTION: Motion by E. TAGLIERI, seconded by, C. BASILE, and voted unanimously to approve the license for this community pharmacy, pending successful inspection, and correction of #14 on the attestation.

TOPIC V.: APPLICATIONS

2. MBS Pharma Care, Inc. New Community Pharmacy 1035B Providence Road, Whitinsville, MA 01588

<u>DISCUSSION</u>: Attorney Paul Garbarini, proposed MOR Ruth Collins, and owner Michael Botros represented MBS Pharma Care. The planned business model is to cater to homebound, "frail", duel eligible clients by offering free delivery services. Although the concept includes interactions with Elder Care Services and the VNA, patients will all have Freedom of Choice.

Proposed MOR Collins, who has served as MOR 2 times previously, will register for PMP. They will not be filling 340B prescriptions.

Concerns about the safe and security in general were answered to the board's satisfaction. Director of Compliance, W. FRISCH voiced concerns over the use of blister cards in general, and asked that they make sure they have adequate space dedicated to their use.

MBS Pharma Care, Inc. submitted waiver request for 247 CMR 6.02(5) regarding signage, and 247 CMR 9.01(15) regarding limiting services to specific segments of the population.

ACTION: Motion by M. GODEK, seconded by, T. FENSKY, and voted unanimously to approve the license for this community pharmacy, with waivers, pending successful inspection.

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TOPIC V:

3. Western MA Compounding Center Transfer of Ownership TIME: 10:16AM 138 Memorial Avenue, West Springfield,

<u>DISCUSSION:</u> Western, MA Compounding Center was represented by Attorney Paul Garbarini and Mr. Bradley Sprecher, who will be the sole owner and officer. He has been an employee pharmacist under the current ownership. He is not applying for any waivers. If successful, Mr. Sprecher would retain the current MOR for 2 months, to assist with the transition.

According to Mr. Sprecher, the business model of this pharmacy will be exclusively non-sterile compounding, of which 60% is for veterinary clients and 40% for humans. Although the vast majority of prescriptions are mailed or delivered, there is a small lobby for a prescription pick-up option. The main service area will be Western Massachusetts, but currently the pharmacy has clients in Vermont and Connecticut.

Board President P. GANNON suggested that the pharmacy consider "PLUMBS" as a resource for veterinary prescriptions. Board member A.STEIN suggested always getting an animal's weight.

ACTION: Motion by T. FENSKY, seconded by C. BASILE, and voted unanimously, to approve the application for the change for ownership.

TOPIC V.:

APPLICATIONS

4. Central Pharmacy Transfer of Ownership TIME: 10:26AM 1349 Commonwealth Ave, Allston, MA 02134

<u>DISCUSSION</u>: Attorney Paul Garbarini and R.Ph. Gene Pelikhov, proposed MOR, represented "Mona Pharmacy Corporation", dba Central Pharmacy. There are no waivers in place, and none being applied for. Since they have a scale, and plan to continue compounding, they need to correct #14 on their attestation.

Although they currently have no provision for "after hours" coverage, proposed MOR Pelikhov is discussing that with new owners. There is currently a part-time pharmacist, 6 technicians, and 2 interns on staff.

Member T. FENSKY suggested that Central Pharmacy not wait for USP 800 to come out before getting prepared to properly handle NIOSH drugs.

ACTION: Motion by T. FENSKY, seconded by G. CAVANNAUGH, and voted unanimously, to approve the transfer of ownership, pending correcting the attestation, in particular # 14, to read "yes".

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TOPIC VI. REPORTS

Applications Approved Pursuant to Licensure Policy 13-01

10:34AM

DISCUSSION: R HARRIS noted that during the past month there have been fifteen (15) Change of Managers, two (2) renovation/expansions and one (1) nuclear pharmacist, approved by staff action.

ACTION: So noted

TOPIC VII

1. PHA-2014-0096; Pharmacy Corporation of America, DS3599

DISCUSSION: C.MOGNI presented and summarized the investigative report the pertained to this matter. The report outlined an Abnormal Result that was not reported to the Board. Pharmacy Corporation of America voluntary; cease compounding for an approximately six months, performed a through root cause analysis, and instituted a substantive Plan of Correction that included replacement of the HVAC system. W. FRISCH reported that the licensee worked closely with the Board. W. FRISCH indicated following the POC the facility and the environmental monitoring was improved. The Board noted the work of the facility learning curve for licensees on reporting requirements which they recommended highlighting in the closing documents to make the reporting responsibilities clear to the licensee. ACTION: Motion by T. FENSKY, seconded by C. BASILE and voted unanimously

to dismiss the complaint discipline not warranted, with the inclusion of an advisory statement of the reporting requirements for Abnormal Results.

TOPIC

VII. FILE REVIEW

2. PHA-2014-0144, Hopkinton Drug, (DS8191)

RECUSAL: A. STIEN

DISCUSSION: C. COLLINS presented and summarized the investigative report that pertained to this matter. A complaint was opened by a PBM alleging that Hopkinton Drug dispensed medications to patients in states where it did not possess the necessary non-resident pharmacy licensure. MOR indicated that at the time (2013) he was unaware of the licensing requirement and once informed cease shipments to any states that Hopkinton was not licensed in. The MOR indicated in the response that Hopkinton has improved their process with their shipping department to ensure that they only ship into states where they licensed. T. FENSKY was concerned that the complaint came from a PBM and not the pharmacy board of the state were the nonlicensed activity took place. H.ENGMAN informed the Board that it lacked jurisdiction over this matter.

ACTION: Motion by T. FENSKY, seconded by C.BASILE, and voted unanimously to dismiss the complaint with discipline not warranted with the non-licensed violations being reported to the National Associated Boards of Pharmacy (NABP).A. STIEN was not present for the discussion or vote on this matter.

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TOPIC

VII. FILE REVIEW

3. PHA-20140179, Critical Care Systems, (DS3327)

RECUSAL: M. GODEK

DISCUSSION: C. MOGNI presented and summarized the investigative report pertaining to this matter. A complaint was opened due to a June 2014 <797> compliance inspection that resulted in multiple deficiencies. Critical Care Systems voluntarily cease compounding activities on June 23, 2014 and was closed until May 22, 2015 when a <797> compliance inspection indicated no deficiencies. W. FRISCH noted that the licensee had been cooperative and compliant and had made multiple improvements to its facility, employee training and environmental monitoring. W. FRISCH was concerned that Critical Care had yet to provide evidence of employee training. W FRISCH shared additional concerns that the facility had multiple deficiencies that resulted in the prolonged closure of the facility. The Board shared the same concern that the facility should have a period of monitored operation. ACTION: Motion by T.FENSKY, seconded by A. STIEN, and voted unanimously to refer the matter to the Office of the Prosecution, for the issuance of an order to show cause, and to authorize resolution of the matter with a consent agreement for one (1) year of probation with terms to include: (a) evidence of staff completion of Critical Point training both live and written components, (b) prove of training for anyone compounding at the facility. (c) two (2) successful USP <797> compliance inspections during the probationary period. (d) audit by board staff of aseptic technique competency. M. GODEK was not present for the discussion or vote of this matter.

TOPIC

VII.

FILE REVIEW OPEN SESSION suspended at 11:03AM

TOPIC

VIII. M.G.L c. 112 §65C SESSION

DISCUSSION: None

ACTION: At 11:05 AM P Gannon called the meeting to order. Motion by E. TAGLIERI, seconded by C. BASILE and voted unanimously to enter into M.G.L. c.112 §65C Session for the purpose of conducting an Investigative Conference. H. ENGMAN introduced legal intern Laura Deponio.

*Suspension 65C session and return to Open Session Time 11:57AM ACTION: Motion by A. STIEN seconded by E.TAGLIERI and voted unanimously to suspend M.G.L. c 112 §65 C Session and return to Open Session.

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Approved on June 30, 2015 RM

TOPIC

IX. REGULATIONS

TIME: 11:57AM – 12:30PM

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.

<u>DISCUSSION</u>: H. ENGMAN displayed on the screen for the board members and the audience board members suggestions and comments were captured and reflected in the document by track changes. Board members were informed of the need to revisit section 6.0 due to the requirement for the licensure of institutional sterile compounding facilities. Board members were also informed of the need to allow for provisional licenses for facilities that demonstrate substantial compliance with regulation. The new yet to be number sections added were entitled "6.0X Application for Institutional Sterile Compounding Pharmacy License" and 6.1X: "Provisional Licenses". Board members were asked to review previous approved sections of the draft proposed regulation to see if all areas would apply for the two additional license types.

LUNCH BREAK 12:30PM – 1:30PM

TOPIC

X. M.G.L c. 112 §65C SESSION- Investigative Conference

DISCUSSION: P. GANNON called the Session to order;

<u>ACTION:</u> At 1:28PM Motion by E.TAGLIERI, seconded by T. FENSKY and voted unanimously to enter into M.G.L. c.112 §65C Session for the purpose of conducting an Investigative Conference.

TOPIC XI.

EXEXCUTIVE SESSION

DISCUSSION: P. GANNON called the session to order

<u>ACTION:</u> At 2:20PM. Motion by R. TINSLEY, seconded by E. TAGLIERI and voted unanimously by roll call vote, P. GANNON; yes, E. TAGLIERI; yes, T. FENSKY; yes, S. CORNACCHIO; yes, R. TINSLEY; yes, C. BASILE; yes, A. STIEN; yes, G. CAVANAUGH; yes, M. GODEK; yes, P. BOUVIER; yes, W. COX; yes.to enter into executive session.

TOPIC

VII. FILE REVIEW

DISCUSSION: None

ACTION: At 3:02PM the Board resumed Open File review:

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TOPIC

VII. FILE REVIEW

4. SA-INV-6182 Omnicare of Northern Massachusetts, (DS3458)

RECUSAL: S. CIORNACCHIO

DISCUSSION: C. MOGNI presented and summarized the investigation report that pertained to this matter. Evidence indicates that Abnormal Results occurred at the facility on multiple occasions. The root cause was identified to be HEPA filter failures and upstream issues. Each instance of Abnormal result was remediated. The facility twice ceases compounding of sterile products on July 8 and September 22, 2014. The facility closed on October 18, 2014 relocating to Peabody, MA. ACTION: Motion by R.TINSLEY, seconded by C. BASILE, and voted unanimously to close the staff assignment as remediate was completed. S. CORENACCHIO was not present for the discussion or vote on this matter.

TOPIC

VII. FILE REVIEW

5. SA-INV- 6710; Boston Home Infusion, (DS2623)

<u>DISCUSSION:</u> W. FRISCH presented and summarized the investigation report that pertained to this matter. Evidence indicates that the licensee reported an Abnormal Result from environmental monitoring their buffer room. Licensee cease compounding of sterile products perform remediation and performed additional environmental monitoring which was satisfactory. Compounding resumed on December 4, 2014.

<u>ACTION:</u> Motion by G. CAVANAUGH, seconded by R. TINSLEY, and voted unanimously to close the staff assignment with discipline not warranted

TOPIC

VII FILE REVIEW

6. PHA-2015-0016; Rite Aid 10197, (DS2571)

RECUSAL: G.CAVANAUGH, W COX

DISCUSSION: M. VASQUEZ presented and summarized the investigation report that pertained to this matter. Evidence indicated that during a routine retail compliance inspection it was discovered that the location had two (2) technicians in training that had worked greater than 1,000 hours without taking the pharmacy technician examination, a violation of 247 CMR 8.03 (3). The MOR indicated that he would contact the district office monthly for an accounting of technician in training hours. Board was concerned that the chain should have a better method of support for store level MOR assisting with the record keeping function. The Board desires the inclusion of an advisory statement reminding the licensee of its responsibility under 247 CMR

<u>ACTION:</u> Motion by M. GODEK, seconded by P. BOUVIER, and voted by majority to dismiss the complaint with discipline not warranted and include in the closing documentation and advisory statement regarding the responsibility to comply with

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247 CMR. 8.00. R.TINSLEY was opposed. G. CAVANAUGH and W. COX were not present for the discussion and vote of this matter.

TOPIC

VII. FILE REVIEW

7. PHA-2015-0022; Alfred Kallini, PH26622

DISCUSSION: C. COLLINS presented and summarized the investigation report pertaining to this matter. Evidence indicates that Pharmacist Kallini was deficient in Pharmacist Continuing education contact hours for 2012 (7 contact hours / 5 live), 2013 (5 live contact hours) and 2014 (1 PMP contact hour) and submitted credits in excess of the maximum allowable credits hours for one day, eight (8). in violation of CMR 247 4.03 (4) (b) (8). In the licensee's response he submitted proof of the completion of 39.5 contact hours of pharmacist continuing education.

ACTION: Motion by E. TAGLIERI, seconded by A. STIEN, and voted unanimously to dismiss the complaint with discipline not warranted as the deficiency was successfully remediated.

TOPIC

VII. FILE REVIEW

8. SA-INV-6869, The Whittier Pharmacist, (DS3587)

RECUSAL: E. TAGLIERI

DISCUSSION: C.MOGNI presented and summarized the investigation report pertaining to this matter. Evidence indicates that the licensee reported multiple instances of Abnormal Results to the Board and voluntarily ceases compounding. The licensee performed a complete cleaning, and updated daily and weekly cleaning protocols. Additional environmental monitoring conducted by a third party vendor returned no actionable results. Compliance inspections for <797> and retail compliance were conducted on March 17, 2015, and April 3, 2015, respectively and both were noted to be sufficiently compliant. The Board noted that there were multiple instances of Abnormal Results and that the licensee though compliant with the reporting requirement submitted at the last possible instance.

ACTION: Motion by T. FENSKY, seconded by C. BASILE and voted unanimously to close the staff assignment with discipline not warranted with the inclusion of an advisory statement in to the licensee regarding the reporting requirements for Abnormal Results contained within 247 CMR 06.15. E.TAGLIERI was not present for the discussion or vote of this matter.

TOPIC

VII. FILE REVIEW

9. SA-INV-6907; Sherif Mohamed Dessouky Ibrahim, PH235180

<u>DISCUSSION</u>: C. COLLINS presented and summarized the investigation report pertaining to this matter. Evidence indicates that the licensee failed to complete the required 15 contact hours of pharmacist continuing education for 2014 in violation of 247 CMR 4.03 (4) (b). The self—reported deficiency arose from the licensee

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misunderstanding of the continuing education requirement for new graduate licensees. Pharmacist Ibrahim is a 2012 graduate of a foreign school of pharmacy receiving is Massachusetts registration in 2014 following the successful completion of the FPGE and MPJE requirements. The licensee provided evidence of the completion of 15 contact hours of pharmacist continuing education in January of 2015.

<u>ACTION:</u> Motion by A. STIEN, seconded by T.FENSKY and voted unanimously to close the staff assignment due to appropriate remediation.

TOPIC

VII FILE REVIEW

10. PHA-2015-0045; Preferred Pharmacy Solutions, (DS3542)

DISCUSSION: C. MOGNI presented and summarized the investigation report pertaining to the matter. The evidence indicated that the during a <797> compliance audit it was discovered that the licensee failed to report Abnormal results to the Board for two instances in violation of 247 CMR 6.15 (7). The MOR indicated that he misinterpreted the environmental analysis report from his vendor. It was noted that the licensee to immediate action to remediate the situation to include end product testing and adverse patient monitoring which yielded no product contamination or adverse patient events. Board members were concerned regarding the lack of notification to the Board. K BARNES indicated that there has been a learning curve for licensees and testing companies regarding the environmental monitoring reports. K BARNES indicated that as she and W. FRISCH continue to work with the licensee the knowledge exchange is allowing the licensee to evaluate and assess their vendors instead of being led by them. W. FRISCH noted that the POC instituted by the licensee was robust including weekly self-monitoring of the environment. ACTION: Motion by T.FENSKY, seconded by C. BASILE and voted by majority to dismiss the complaint with discipline not warranted with the inclusion of an advisory statement reminding the licensee of the reporting requirements for Abnormal Results contained with 247 CMR 6.15. M.GODEK and R.TINSLEY opposed.

TOPIC

XII. ADJUDICATORY SESSION

DISCUSSION: P. GANNON called the session to order.

<u>ACTION</u>: At 3:39PM motion by R. TINSLEY, seconded by M. GODEK, and voted unanimously to enter into Adjudicatory Session.

TOPIC

XIII. Resume M.G.L. c 112 §65 C Session

DISCUSSION: P. GANNON called the session to order

<u>ACTION</u>: At 3:59PM motion by E.TAGLIERI, seconded by T. FENSKY, and voted unanimously to resume M.G.L. c 112 §65 C Session.

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Suspension 65C session and return to Open Session Time 11:57AM <u>ACTION</u>: Motion by A. STIEN seconded by E.TAGLIERI and voted unanimously to suspend M.G.L. c 112 §65 C Session and return to Open Session.

TOPIC XI

EXEXCUTIVE SESSION

DISCUSSION: P. GANNON called the session to order

ACTION: At 2:20PM. Motion by R. TINSLEY, seconded by E. TAGLIERI and voted unanimously by roll call vote, P. GANNON; yes, E. TAGLIERI; yes, T. FENSKY; yes, S. CORNACCHIO; yes, R. TINSLEY; yes, C. BASILE; yes, A. STIEN; yes, G. CAVANAUGH; yes, M. GODEK; yes, P. BOUVIER; yes, W. COX; yes.to enter into executive session.

TOPIC

XII. ADJUDICATORY SESSION

DISCUSSION: P. GANNON called the session to order.

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

TOPIC

XIII. Resume M.G.L. c 112 §65 C Session

DISCUSSION: P. GANNON called the session to order

<u>ACTION</u>: At 3:59PM motion by E.TAGLIERI, seconded by T. FENSKY, and voted unanimously to resume M.G.L. c 112 §65 C Session.

TOPIC

XIV. ADJOURNMENT

DISCUSSION: None

ACTION: At 4:59PM Motion by M. GODEK, seconded by G. CAVANAUGH, and voted unanimously to adjourn the meeting.

LIST OF EXHIBITS USED DURING THE MEETING

- 1. Draft Agenda for the June 2, 2015 Regularly Scheduled Meeting.
- 2. Draft General Session Minutes from the May 5, 2015 meeting.
- 3. DHPL- Division Policy 15-01, "Delegation of Authority for Staff Actions Relative to Monitoring Licensure Conditions".
- 4. Draft Advisory Committee Recommendation Document 15-03, "Emerging Models of Coordinated Pharmacy Services."
- 5. Draft Memo to Board of Pharmacy's licensee regarding "Expedited Partner Therapy."
- 6. Application to Manage and Operate a New Community Pharmacy, Cape Cod Healthcare, Inc.

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- 7. Application to Manage and Operate a New Community Pharmacy, MBS PharmaCare, Inc.,
- 8. Application for Transfer of Ownership of Community Pharmacy, Trastulit, LLC.
- 9. Application for Transfer of Ownership of Community Pharmacy, Mona Pharmacy Corp.
- 10. Report Application Approved Pursuant to Licensure Policy 13-01.
- 11. Draft Proposed Amendments to 247 CMR 6.00; Registration, Management and Operations of a Pharmacy or Pharmacy Department. Proposed.
- 12. Draft Proposed Amendments to 247 CMR 6.00, Registration, Management and Operations of a Pharmacy or Pharmacy Department with track changes.
- 13. Investigation report in the Matter of Pharmacy Corporation of America, DS3599, PHA-2014-0096.
- 14. Investigation report in the Matter of Hopkinton Drug, DS8191, PHA-2014-0144.
- 15. Investigation report in the Matter of Critical Care System, DS3327, PHA-2014-0179.
- 16. Investigation report in the Matter of Omnicare of Northern Massachusetts, DS3458, SA-INV-6182.
- 17. Investigation report in the Matter of Boston Home Infusion, DS2623, SA-INV-6710.
- 18. Investigation report in the matter of Rite Aid 10197, DS2571, PHA-2015-0016
- 19. Investigation report in the matter of Alfred Kallini, PHA-26622
- 20. Investigation report in the matter of, The Whitter Pharmacist, DS3587, SA-INV-6097.
- 21. Investigation report in the matter of, Sherif Mohamed Dessouky Ibrahim, PH235180, SA-INV-6907
- 22. Investigation report in the matter of, Preferred Pharmacy Solutions, DS3542, PHA-2015-0045.

Respectfully submitted by:

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