

COMMONWEALTH OF MASSACHUSETTS

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

September 30, 2014
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		
8:45	III	APPLICATIONS <ol style="list-style-type: none"> 1. Whole Health Pharmacy- New Community Pharmacy 2. Assured Pharmacy- New Community Pharmacy 3. Remedium Pharmacy- New Community Pharmacy 4. Berkshire Community Pharmacy- New Community Pharmacy 5. Neighborhood Pharmacy- Relocation 6. Health Care Technology- Wholesale Distributor 7. Quality Zone Pharmacy- New Community Pharmacy 		
10:00	IV	APPROVAL OF BOARD MINUTES <p align="center">Draft August 5 , 2014 Regular Session Minutes Draft September 9, 2014 Regular Session Minutes</p>		
10:05	V	REPORTS <ol style="list-style-type: none"> 1. Applications approved pursuant to Licensure Policy 13-01 	Reports	R. Harris D. Sencabaugh
10:10	VI	REGULATIONS: <ol style="list-style-type: none"> 1. Proposed amendment to 247 CMR 4.00 pursuant to Chapter 159 of the Acts of 2014. 		H. Engman

10:40	VII	POLICIES: 1. Plan of Correction Policy Revision		W. Frisch
10:50	VIII	FLEX SESSION 1. Board Update: a. Introduction of Intern: Joviane Contave 2. Valor Act DPH Policy 3. DEA schedule of Hydrocodone products and Tramadol		D.Sencabaugh V.Berg K. Ryle
11:10	IX	FILE REVIEW 1. SA-INV-4418, Pharmahealth Pharmacy, DS3056 2. SA-INV-4418, Pharmahealth Long Term Care, DS8972 3. PHA-2014-190, Aucella Drug, DS1213 4. PHA-2014-0222, Frank Fritz, PH16552 5. PHA-2014-0172, Westminster Pharmacy, DS3327 6. PHA-2014-0177, Joseph Serio, PH16941		W. Frisch
12:00		LUNCH BREAK		
1:00	X	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. 1. Specifically, the Board will discuss and evaluate the <u>Good Moral Character</u> as required for registration for pending applicants, petitions for termination of probation, and petitions reinstatement.		CLOSED SESSION
3:00	XI	M.G.L. c. 112, 65C SESSION		CLOSED SESSION
5:00	XII	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

Tuesday, September 30, 2014

Board Members Present

Karen Ryle, RPh, President
Patrick Gannon, RPh, MS, President-elect
Edmund Taglieri, RPh, MSM, NHA,
Secretary
James DeVita, RPh
Jane F. Franke, RN, MHA
Richard Tinsley, MBA, MEd
Joanne Trifone, RPh (Left meeting @
4:04PM)
Anita Young, RPh, EdD.
Timothy Fensky, R.Ph.
Anthony Perrone, MD, MBA, R.Ph

Board Members Not Present

Board Staff Present

David Sencabaugh, RPh, Executive Director
David Dunn, R.Ph, Associate Executive Director
Heather Engman JD, MPH, Board Counsel
Kelly Ann Barnes, JD, RPh, Director of Pharmacy
Quality Assurance
Vita Berg, DHPL Chief Board Counsel
Richard Harris, Program Analyst
Samuel Penta, RPh, Senior Investigator
Anthony Bartucca, RPh, Investigative Consultant
Christina Mogni, RPh, Investigator

Board Staff Not Present

TOPIC:

I. CALL TO ORDER

DISCUSSION: A quorum of the Board was present. President, K. RYLE chaired the meeting and asked if anyone in the audience was recording the meeting; no one indicated that they were recording the meeting. K. RYLE also announced that the Board was recording the meeting.

ACTION: At 8:39 a.m. K. RYLE, called the September 30, 2014, meeting of the Board of Registration in Pharmacy to order.

TOPIC:

II. APPROVAL OF AGENDA

DISCUSSION: None.

ACTION: Motion by, A. YOUNG, seconded by E.TAGLIERI and voted unanimously to approve the Agenda with the noted change. A.PERRONE was not present for the vote.

TOPIC:

III. APPLICATIONS

A. Application for New Community Pharmacy

1. Whole Health Pharmacy, 596 West Main St., Hyannis

DISCUSSION: Proposed MOR / Co-Owner Karryn Lewis and Co/ Owner Brian Lewis present this application to Manage and Operate a New Community Pharmacy. Proposed Manager of Record (MOR) Lewis has been a registered pharmacist since 2012. Proposed MOR Lewis indicates that Whole Health Pharmacy will be a traditional independent pharmacy providing traditional pharmacy services including immunization. Proposed MOR Lewis utilizes the prescription monitoring program one to two times weekly for new patients. Board members questioned Brian Lewis involvement in the pharmacy operations. Proposed MOR Lewis stated that Brian Lewis would provide back office support and not work in the pharmacy. Board members reviewed with the Brian Lewis that as a non-licensed individual Brian Lewis could not assist in the pharmacy department in anyway. The Board recommended that Brian Lewis seek to be licensed as a technician to prevent any unlicensed practice. Representatives from Whole Health Pharmacy provided satisfactory answers to the Board's questions regarding lack of an additional staff pharmacist and the abbreviated weekend hours.

ACTION: Motion by A.YOUNG, seconded by P. Gannon, and voted unanimously to approve the Whole Health Pharmacy Application to Manage and Operate a New Community Pharmacy pending a successful inspection.

TOPIC:

III. APPLICATIONS

B. Application for New Community Pharmacy

9:07AM

3. Assured Pharmacy, 255 Bear Hill Road, Waltham

DISCUSSION: Michael Schneider, Chief Operating Officer, for Assured Pharmacy presented this Application to Manage and Operate a New Community Pharmacy. Mr. Schneider provided the Board with background on Assured Pharmacy. The proposed Waltham location would be Assured Pharmacy's first pharmacy in Massachusetts for the Texas based company. Assured Pharmacy offering is for a "closed door pharmacy" focusing on the dispensing of federally controlled substances specifically pain management. Mr. Schneider informed the Board that Assured works with pain management physicians and patient on patient care agreement and that Assured Pharmacy staff would pick up prescriptions from the physician office and fill for the patient. The Board had many concerns regarding the business model and practices of Assured Pharmacy:

1. Fragmenting patient care by limiting practice to pain management Assured Pharmacy "picking up prescriptions" at the physician office in violation of 247 CMR 9.04
2. The Board was concerned that the patient agreement with physicians would interfere with a patient freedom of choice

3. The proposed Manager of Record listed on the Application to Manage and Operate a New Community Pharmacy was not a Massachusetts licensed pharmacist.

4. The Application to Manage and Operate a New Community Pharmacy did not contain any waivers of 247 CMR to support the application. -Waivers would be required for this business model.

5. The Board would like to see a detailed business model for the proposed Community Pharmacy.

ACTION: Motion by E.TAGLIERI, seconded by, A. YOUNG, and voted unanimously, to take no action on the Assured Pharmacy, Application to Manage and Operate a New Community Pharmacy until Assured Pharmacy submits a complete application with waivers.

TOPIC:

III. Applications

8:54AM

Application for a New Community Pharmacy

4. Remedium Pharmacy, 119 Drum Hill Road, Chelmsford

RECUSAL: A. YOUNG, recused herself, and was not present for the discussion or vote involving this matter.

DISCUSSION: Proposed Manager of Record (MOR) Warren DeForge and Attorney Paul Garbarini presented this Application to Manage and Operate a New Community Pharmacy. Proposed MOR DeForge has relocated from Texas where he was a nuclear pharmacist with prior experience as an MOR. MOR DeForge informed the Board that Remedium Pharmacy would provide traditional pharmacy services. MOR DeForge is not currently and immunizing pharmacist so vaccinations were not part of the initial offering. MOR DeForge and Attorney Garbarini were questioned by the Board regarding Remedium Pharmacy Attestation to compound non sterile preparations; after a discussion of the services contemplated Attorney Garbarini indicated that Remedium would amend its application to engage in complex compounding. MOR DeForge is not currently enrolled in the Massachusetts Prescription Monitoring Program, he had found it a useful tool while employed in Texas. Board members stressed to proposed MOR DeForge that the non –pharmacist owner could not have any say in the operation of the pharmacy that proposed MOR DeForge was responsible for the operation of the pharmacy department. MOR DeForge and Attorney Garbarini were able to satisfactorily address the Board concerns regarding security of controlled substances, after-hours patient care due the lack of Sunday hours of operation.

ACTIONS: Motion by J. DeVITA, seconded by, T. FENSKY, and voted unanimously to approve the Remedium Pharmacy Application to Manage and Operate a New Community Pharmacy pending receipt of amended application with waiver to not engage in non-sterile complex compounding and a successful inspection.

TOPIC

III. APPLICATIONS

5. New Community Pharmacy

Berkshire Community Health, 725 North St., Pittsfield

DISCUSSION: Proposed Manager of Record (MOR) Machaffin and Director of Pharmacy Keith Preston presented this application to Operate and Manage a New Community Pharmacy.

Proposed MOR Machaffin and Director Preston informed the Board that the new retail / 340B

pharmacy will replace the current employee pharmacy. Proposed MOR Machaffin indicated he had previous experience as an MOR at Big Y (5 years) and has been an employee of Berkshire Medicals center for 5 years. Proposed MOR Machaffin reported that the 340B inventory would be a virtual inventory managed by its pharmacy software. Director of Pharmacy Compliance W. FRISCH inquired if the transition from a clinic / employee had been communicated to the Drug Control Program. Director Preston indicated that the desire was to have a minimal impact on pharmacy services; therefore the desire was to obtain the retail license first and then coordinate with the Drug Control Program the surrender of the clinic license.

It was noted that the application must be amended with the address corrected from 725 North St. Pittsfield to 741 North St., Pittsfield. The application also lacked a compounding attestation, MOR Machaffin indicated that no NIOSH products would be compounded, however, Berkshire Community Pharmacy will purchase a containment hood. Director of Pharmacy Quality Assurance K. BARNES questioned how the containment hood would be vented with the changes that may presented by USP <800>.

The application contained the following one (1) waiver request:

- a. 247 CMR 6.02 (5) Pharmacy Signage. Pharmacy Director Preston stated "We have no plans to promote outside competition with the local retail pharmacies in our immediate area."

ACTION: Motion by J. DeVITA, seconded by P.GANNON, and voted unanimously to approve the Berkshire Community Pharmacy application to Manage and Operate a New Community Pharmacy and Waiver of 247 CMR 6.02 (5) pending the receipt of an amended application, attestation of compounding activity, and successful inspection.

Topic

III. Application for Relocation of a Community Pharmacy

9:47 AM

5. Neighborhood Pharmacy, 600 Technology Park Drive, Suite 100, Billerica

DISCUSSION: Manager of Record Greene and General Manager Todd Durnak presented the application for the relocation of a Community Pharmacy. MOR Green informed the Board that the relocation of Neighborhood Pharmacy would allow all of the businesses owned by Neighborhood Diabetes to be all in the same building. The Board question Neighborhood Pharmacy representatives regarding the abbreviated weekend hours. MOR Greene indicated that the majority of Neighborhood Pharmacy's business is delivery and that shorted Saturday hours 8:00AM to 10:00AM was to satisfy Florida pharmacy regulation. It was noted that the application would need to be amended to reflect the ability to provide CII and CIII medications. It was noted that Neighborhood Pharmacy would provide an amended application. The Board instructed Board Staff to work with Neighborhood Pharmacy on the filing of appropriate waivers of 247 CMR to support Neighborhood Pharmacy's desire to not compound. Neighborhood Pharmacy was instructed to file a Petition for a Waiver of the Provisions of 247 CMR Licensure of a Pharmacy and or Pharmacy Department of the following three (3) requirements:

1. 247 CMR 6.02 (4): The pharmacy or pharmacy department shall maintain on the premises at all times a sufficient variety and supply of medicinal chemicals and preparations which are necessary to compound and dispense commonly prescribed medications in accordance with the usual needs of the community.
2. 247 CMR 9.01(16): A pharmacist shall not refuse to compound customary pharmaceutical preparations except upon extenuating circumstances.

3. 247 CMR 6.01 (5)(a)4: A balance capable of accurately weighing quantities as small as 13 milligrams, which balance shall be tested and sealed by the state or local sealer of weights and measures annually.

ACTION: Motion by J. TRIFONE, seconded by T. FENSKY, and voted unanimously to approve the Neighborhood Pharmacy application for Relocation of a Community Pharmacy pending receipt of an amended application, waivers of compounding, and successful inspection. J. DEVITA was not present for the vote.

TOPIC:

III. Applications To Operate as a Wholesale Distributor
Health Care Technology, 200 Butterfield Drive, Ashland

DISCUSSION: Jane Sutton, Treasurer of Health Care Technology, presented this application to Operate as a Wholesale Distributor. Ms. Sutton informed the Board that Health Care Technology is a specialty distributor of products to hospitals. Health Care Technology is seeking licensure as a wholesale distributor due to the fact that it resells pre-made kits to hospitals that contain normal saline for injection. It was noted that during the application review that due to the fact that Health Care Technology would only be selling kits containing normal saline that it may want to amend its application to reflect only the sale of schedule VI products. Director of Compliance W.FRISCH question Treasure Sutton, regarding if Policy and Procedures were in place for Expired Products, Recalls, and Latex Free products.

ACTIONS: Motion by A. PERRONE seconded by, E.TAGLIERI, and voted unanimously to approve the Health Care Technology application to Operate as a Wholesale Distributor, pending receipt of an amended application limiting sales to schedule VI products and a successful inspection.

Topic

III. Application for a New Community Pharmacy

Quality Zone Pharmacy Corp, 355 Belmont Ave., Springfield

10:12AM

RECUSAL: A.YOUNG, recused herself, and was not present for the discussion or vote of this matter.

DISCUSSION: Proposed MOR Imbrahim, and Attorney Paul Garbarini, presented the application to Manage and Operate a New Community Pharmacy. The proposed pharmacy would be a department with in Food Zone Supermarket. The representatives from Quality Zone were able to satisfy the Board's concern for the security of the pharmacy when the pharmacy department is closed and the supermarket is open. Proposed MOR Imbrahim indicated that he has no prior experience as a Manager of Record. Board members stressed to proposed MOR Imbrahim that as MOR he was responsible for the operation of the pharmacy. Proposed MOR Imbrahim indicated that he is not currently a certified immunizer. Proposed MOR Imbrahim indicates that he does utilize the Massachusetts Prescription Monitoring Program (PMP). Quality Zone's initial application contained a request to waive all compounding, however after discussion Attorney Garbarini will amend Quality Zone's waiver petition for the following:

1. 247 CMR 6.02 (4): The pharmacy or pharmacy department shall maintain on the premises at all times a sufficient variety and supply of medicinal chemicals and preparations which are necessary to compound and dispense commonly prescribed medications in accordance with the usual needs of the community.

2. 247 CMR 6.01 (5)(a)4: A balance capable of accurately weighing quantities as small as 13 milligrams, which balance shall be tested and sealed by the state or local sealer of weights and measures annually.

ACTION: Motion by E.TAGLIERI, seconded by, P.GANNON, and voted unanimously to approve the Quality Zone Application to Operate and Manage a New Community Pharmacy pending the receipt of the appropriate waivers and a successful inspection. A.YOUNG was not present for the discussion and vote of this matter.

TOPIC

IV. Approval of Board Minutes

1. Draft September 9,2014, Regular Session Minutes

DISCUSSION: None.

ACTION: Motion by E. TAGLIERI seconded by J. DeVita , voted unanimously to approve the September 9, 2014, Regular Session Minutes. R.TINSLEY and J. TRIFONE abstained.

TOPIC

IV. REPORTS

1.Applications Approved Pursuant to Licensure Policy 13-01

DISCUSSION: R. HARRIS noted that during the past month there has been twenty-three (23) change of managers, seven (7) renovation / expansion, and three (3) store closing.

ACTION: So noted.

BREAK 10:22AM-10:45AM

TOPIC

VI. REGULATIONS

Draft Proposed Amendments to 247 CMR 4.00 pursuant to Chapter 159 of The Acts of 2014.

DISCUSSION: The Board was presented with Draft proposed amendments to 247 CMR Section 4.00, "Personal Registration Renewal; Continuing Education Requirements.

As required by the Act of 2014, there is to be an increase in the total amount of contact hours required for license renewal from fifteen (15) contact hours annually to twenty (20) contact hours of continuing education. Two new requirements are:

Pharmacists who are directly engaged in or oversee sterile compounding will be required to devote at least five (5) contact hours of continuing education to sterile compounding.

Pharmacist who are directly engaged in or oversee non-sterile compounding activities will be required to devote at least three (3) contact hours to non-sterile complex compounding.

Section 4.02 (8) was updated to be consistent with M.G.L. c. 112 § 1(c) and the updated Valor Act policy for continuing education for members of the armed forces.

A line by line review was conducted by Board Counsel H.ENGMAN and all changes were captured on the projection screen for members and the audience to observe.

ACTION: Motion by P.GANNON, seconded by E.TAGLIERI, and voted unanimously to approve the proposed amendments to 247 CMR 4.00, proceed with the EO485 review process, and if substantive changes are not required following EO485, to proceed with public comment and public hearing.

TOPIC

VII. Policies

1. Plan of Correction Policy #13-02 Revision

DISCUSSION

Director of Compliance W.FRISCH, outlined proposed changes to the Plan of Correction (POC) Policy that would allow Board Staff to review and close routine Plans of Correction resulting from compliance inspections via the use of a POC review team comprised of the Director of Quality Assurance/ or designee and the Director of Pharmacy Compliance/ or designee.

ACTION 1: Motion to approve by J.FRANKE, seconded by A.YOUNG, a voted unanimously to approve the revised Plan of Correction Policy 13-02.

ACTION 2: MOTION amend prior motion to approve by J.FRANKE, seconded by A. YOUNG, an voted unanimously to approve the revised Plan of Correction Policy 13-02 pending the inclusion of Triage Committee into the definitions section.

TOPIC:

VIII. FLEX SESSION

1. Board Updates

D. SENCABAUGH introduced Pharmacy Intern Joviane Contave, from Massachusetts College of Pharmacy.

2. Valor Act DPH Policy,

DISCUSSION: presented by Chief Board Counsel V.BERG. Board members were informed that DPH was instituting a uniform policy and requirements across all Boards ensure renewals for active members of the military.

ACTION: Motion by A.PERRONE and seconded by J. DeVITA, to approve Valor Act DPH POLICY for use by the Board of Registration in Pharmacy.

3. DEA Schedule of Hydrocodone products and Tramadol

Board President K.RYLE undated the Board of the impending DEA re-scheduling of Hydrocodone products to CII and Tramadol to CV. Board members were informed of the possible impacts this would have on pharmacists and their patients. Executive Director D SENCABAUGH indicated that he would notify the Board of Registration in Medicine (BORIM) of rescheduling of these products and the possible impacts to patient care. Director of Pharmacy Quality Assurance K.BARNES reported that the Board's website will be updated by October 1, 2014, to reference the requirements required by 247 CMR.

TOPIC

IX. FILE REVIEW

1. SA-INV-4418, **PharmaHealth Pharmacy,**

DS3056

DISCUSSION: A.BARTUCCA, presented the Staff Assignment.

The Staff Assignment was opened as a result of an anonymous complaint with four (4) allegations against PharmaHealth:

1. Batch Compounding

2. Pharmacist mis-representing self as a doctor
3. Offering pain cream to physician without a prescription
4. PharmaHealth involved in a Drug Study.

After careful consideration of all the facts and the responses provide by PharmaHealth representation relative to this matter the Board decided there was no evidence of a violation.

ACTION: Motion by E.TAGLIERI, seconded by T. FENSKY and voted unanimously to close the Staff Assignment due to insufficient evidence.

TOPIC

IX. FILE REVIEW

2. SA-INV-4418, **PharmaHealth Long-Term Care Inc.,** DS89728

DISCUSSION: A.BARTUCCA presented the Staff Assignment.

A Staff Assignment was opened as a result of an anonymous complaint with three (3) allegations against PharmaHealth Long-Term Care Inc.:

1. HIPPA violations
2. Provided compounded medications for clinical studies without valid prescriptions
3. Offered gift cards or other valuable consideration to prescribers.

After careful consideration of all the facts and the responses provide by PharmaHealth representation relative to this matter the Board decided there was no evidence of a violation.

ACTION: Motion by E.TAGLIERI, seconded by T. FENSKY, and voted unanimously to close the Staff Assignment due to insufficient evidence.

TOPIC:

IX. File Review

3. PHA-2014-190, **Aucella Drug** DS1213

DISCUSSION: Pharmacy Inspectors S.PENTA and C. MOGNI presented and summarized the investigation report.

As the result of a routine Pharmacy Compliance Inspection on July 11, 2014, a complaint was opened against Aucella Drug, multiple violations of Board of Pharmacy Regulations, unsanitary conditions, a facility and equipment in disrepair. The multiple violations resulted in the issuance of a Cease and Desist Order on July 11, 2014.

Inspector S. PENTA and C.MOGNI re-inspected Aucella Drug on September 29, 2014 and concluded that Aucella Drug was in substantial compliance with its Plan of Correction. It is the recommendation to lift the Cease and Desist at this time.

ACTION: Motion by E.TAGLIERI, seconded by J.FRANKE, and voted by majority to rescind the Cease and Desist Order, and refer the matter to the Office of Prosecution for an Order to Show Cause and authorize resolution of the matter with a Consent Agreement for Probation with terms to include, one (1) day suspension of Aucella Drug's Drug Store License DS1213, after which it will be placed on Probation for a term of 5 years. J.TRIFONE was opposed.

TOPIC:

IX. File Review

4. PHA-2014-0222, **Frank Fritz**, PH16552

DISCUSSION: Pharmacy Investigators S. PENTA and C.MOGNI presented and summarized the investigation report.

Pharmacist Fritz is the Owner and Manager of Record (MOR) of Aucella Drug. In his role of Owner and MOR, MOR FRITZ was responsible for operation and condition of Aucella Drug

that lead to the execution of the Cease and Desist Order, on July 11, 2014.

ACTION: Motion by K. RYLE, seconded by A. PERRONE, and voted by majority to refer the matter to the Office of Prosecution for issuance of an Order to Show Cause and Authorize resolution of this matter through a Consent Agreement for probation with terms to include:

1. One (1) day suspension of personal pharmacist registration.
2. Five (5) years of Probation.
3. Take and Pass the MPJE examination within 90 days.
4. Agree not to compound any preparations without the permission of the Board.
Perform self inspection.

J. TRIFONE opposed.

TOPIC

IX. File Review

5. PHA-2014-0172, **Westminster Pharmacy**, DS3327

DISCUSSION: Pharmacy Investigators S. PENTA and C.MOGNI presented and summarized the investigation report.

During a routine pharmacy compliance and United States Pharmacopeia (USP) <795> inspection, investigators observed multiple violations, which prompted Westminster Pharmacy to voluntarily suspend its compounding services and initiate a substantial Plan of Correction. Pharmacy Investigators S. PENTA reported that Westminster Pharmacy was compounding a sterile preparation (cyclosporine ophthalmic drops for veterinary use) in a non-sterile unsanitary environment. The pharmacy did not have the primary or secondary engineering controls required for sterile compounding. As a result of the Investigators findings Westminster Pharmacy conducted a recall of all cyclosporine product compounded within the 30 days of the USP <795> Compliance inspection.

Westminster Pharmacy was re-inspected for retail compliance on September 19, 2014. The Inspectors confirmed that all deficiencies identified during the June 16, 2014 had been addressed.

ACTION: Motion by P. GANNON, seconded by E.TAGLIERI, and voted unanimously to refer the matter to the Office of Prosecution for the issuance of an Order to Show Cause and to authorize resolution of the matter by Consent Agreement with terms to include: two (2) years of Probation and agreement not to conduct sterile or non-sterile compounding during the length of the probation agreement.

TOPIC

IX. File Review

6. PHA-2014-0177, Joseph Serio, PH16941

DISCUSSION: Pharmacy Investigators S. PENTA and C. MOGNI presented this complaint. Pharmacist Serio is the Owner/ Manager of Record of Westminster Pharmacy (DS3327). MOR Serio in his role as Owner / Manager of Record was responsible to the operations that resulted in the multiple retail compliance and USP <795> violations. As a result of his conduct Westminster Pharmacy voluntarily suspended all compounding activities.

ACTIONS: Motion by P. GANNON, seconded by E.TAGLIERI, and voted unanimously to refer the matter to the Office of Prosecution for the issuance of an Order to Show Cause and authorize resolution of this matter with a Consent Agreement with terms to include:

1. Two (2) years' probation
2. MOR Serio to submit and attestation of a review of 247 CMR
3. Take four (4) contact hours of continuing education specific to Pharmacy Law
4. Agree not compound any sterile or non-sterile compounded products during the length of the probation agreement

Lunch Break

TOPIC:

X. EXECUTIVE SESSION (M.G.L. c. 30A, §21(a))

DISCUSSION: K. RYLE noted that the Board would not return to open session following closed session.

ACTION: At 1:25 p.m., motion by P. GANNON, seconded by J. FRANKE, and voted by Roll Call vote: (1) unanimously by roll call to enter Executive Session. K. RYLE: yes; J. DEVITA: yes; J. TRIFONE: yes; J. FRANKE: yes; A. YOUNG: yes; P. GANNON: yes; R. TINSLEY: yes. E. TAGLIERI: yes.

TOPIC

XI. M.G.L. c. 112 §65C SESSION

DISCUSSION: None

ACTION: At 2:11 p.m., motion by J. DeVITA, seconded J. FRANKE, and voted unanimously to enter into M.G.L. c. 112 65C Session.

TOPIC:

XII. ADJOURNMENT

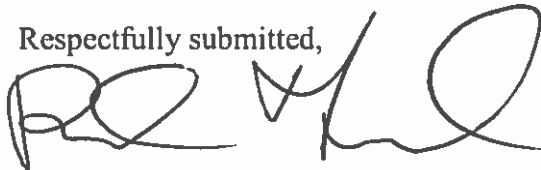
DISCUSSION: None.

ACTION: At 5:01PM, motion by J. FRANKE, seconded by P. GANNON, and voted unanimously to adjourn.

LIST OF EXHIBITS USED DURING THE MEETING

1. Preliminary Agenda for the September 30, 2014 Regularly Scheduled Meeting
2. Application to Manage and Operate a New Community Pharmacy, Whole Health Pharmacy.
3. Application to Manage and Operate a New Community Pharmacy, Assured Pharmacy
4. Applications to Manage and Operate a New Community Pharmacy, Remedium Pharmacy
5. Application to Manage and Operate a New Community Pharmacy, Berkshire Community Pharmacy
6. Application for to Operate a Wholesale Distributor, Health Care Technology
7. Application to Manage and Operate a New Community Pharmacy, Quality Zone Pharmacy
8. Draft August 5, 2014 Regular Session Minutes
9. Report of Applications approved pursuant to Licensure Policy 13-01
10. Plans of Correction Policy 13-02 (revision)
11. Proposed Amendment: 247 CMR 4:00
12. DPH Valor Act Policy

Respectfully submitted,

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the end.

Richard Tinsley, M.Ed. MBA, Secretary