COMMONWEALTH OF MASSACHUSETTS

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

September 10, 2013 239 Causeway Street ~ Room 417 A&B Boston, Massachusetts 02114

PRELIMINARY AGENDA

Time	#	Item	Exhibits	Staff Contact	
8:30	I.	CALL TO ORDER Introduction of new Board Members			
8:30	II.	APPROVAL OF AGENDA			
8:35	111.	M.G.L. c. 112, § 65C SESSION	CLOSED SESSION		
10:00	IV.	1. 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 the following applicants: a. Steven Jerrea Rush applicant for registration as pharmacy intern; b. Justin Thomas Weyant applicant for registration as pharmacy technician; c. Brittany Jackacky applicant for registration as pharmacy technician; d. Justin T. Corchado applicant for registration as pharmacy technician; and e. Taylor Whitley Butler applicant for registration as pharmacist by reciprocity. f. Adam Thomas Gabriel	CLOSED SESSION		
		applicant for registration as pharmacy intern; Specifically, the Board will discuss and evaluate the reputation, character, physical condition or mental health, rather than professional competence, of the following individual: a. Nkemdillim Iffih, applicant for registration as pharmacist by reciprocity (reconsideration, matter previously deferred) 3. Approval of prior executive session minutes in accordance with M.G.L. ch.30A, § 22(f) for sessions held during the March 5, 2013 and July 2, 2013 meetings.			

10:30	V.	APPROVAL OF BOARD MINUTES		
		 June 4, 2013 Regularly Scheduled Meeting July 2, 2013 Regularly Scheduled Meeting 	Minutes	V. Berg
10:40	VI.	REPORTS		
		 Applications approved pursuant to Licensure Policy 13-01 Plans of Correction reviewed pursuant to Enforcement Policy 13-02 	Reports	M. Cittadino H.Engman
10:45	VII.	LICENSE STATUS CHANGE REQUESTS		
		John O'Sullivan, PH18979, Request for Pharmacist Reinstatement	Petition	H. Engman
11:00 — 11:45,	VIII.	FILE REVIEW 1. Michael Dubay, PH16047, PHA-2012-0129 2. CVS #1871, DS3286, PHA-2012-0041 3. G. Bhandari, PT12190, PHA-2012-0166 4. CVS #1861, DS2078, PHA-2012-0220 5. CVS #8437, DS3549, PHA-2012-0244 6. Ashley Lanzisera, PT7549, PHA-2013-001456 8. CVS #1026, DS2824, SA-INV-2919 9. CVS #1026, DS2824, SA-INV-2958 10. CVS #751, DS89718, SA-INV-3303 11. Janet Mary Robert, PH22670, PHA-2013-0026 12. Walgreens #3469, DS2593, PHA-2012-0175 14. Matthew Shea, PH27752, PHA-2012-0175 15. Courtney Torres, PT6162, PHA-2012-0177 16. Jessica Elliott, PT8627, SA-INV-3275 17. Elizabeth Murphy, PT6241, SA-INV-3275 18. Yenesh Groom, PT5355, PHA-2013-0055 20. Jessica Pauline, PH26390, PHA-2013-0073 21. Freedom Fertility Pharmacy, DS89717, SA-INV-4069 22. Freedom Fertility Pharmacy, DS89717, SA-INV-3257 23. Brian Marquis, PH23304, SA-INV-4124 24. Dung Nguyen, PH21900, PHA-2013-0057 25. Angela Burnham, PH25973, PHA-2013-0056 26. David Young, PH22919, PHA-2013-0056 27. Care Point Partners, DS89801, PHA-2013-0056 28. Richard Wagner, Jr, PH22708, PHA-2013-0044 30. Timothy Fensky, PH22009, PHA-2013-0044 31. The Whittier Pharmacist, DS2587, PHA-2012-0238 32. Ralph Luciano, PH18388, PHA-2013-0044 33. Oncomed, DS89702, PHA-2013-0043 35. Kimberly Gould, PH27266, PHA-2013-0043 36. North Shore Pharmacy Services, DS3458, PHA-2012-0250 37. Freedrick L. Rowe, JR, PH16931, PHA-2013-0069 38. Boston Home Infusion, DS2623, SA-INV-4190 39. Village Fertility, DS89658, SA-INV-3632	Investigation Reports for all complaints listed	S. Penta W. Frisch L. McKenna C. Lathum V. Berg

11:45 – 12:30	IX.	LUNCH		
12:30 – 3:00	VIII.	FILE REVIEW (continued) 40. Melinna Cepeda, PT11631, SA-INV-3176 41. Eaton Apothecary #2080, DS3511, SA-INV-3172 42. Henry Pelletier, PH15436, PHA-2012-0151 43. Michael Graham, PH232447, PHA-2013-0003 44. Pallimed, DS 3498, SA-INV-4302	Investigation Reports for all complaints listed	S. Penta W. Frisch L. McKenna C. Lathum V. Berg
3:00	C.	 Acton Compounding Pharmacy, DS2731 (current status) "Compounding" is in the name on the letter we received, however, our records indicate DS2731 as Acton Pharmacy 563 Massachusetts Avenue, Acton Application for approval of expansion to construct of a new sterile (USP 797) Compounding Room Boulevard Pharmaceutical Compounding Company, DS2943 (current status) 149 Shrewsbury Street, Worcester Application for approval of expansion to construct of a new non-sterile (USP 795) Compounding Room I.V.G. Veterinary Compounding Pharmacy 25 Armory Street, Boston Request for Waiver of 247 CMR 6.01(3) SJ Med-Sav Solutions 121 Brick Kiln Road, Suite 235, Chelmsford Reconsideration of Application for New Wholesale Druggist License Pentec Health Inc. Community (Compounding) Pharmacy Application, 120 Forbes Boulevard, Mansfield New Community Pharmacy Application True Care Pharmacy, Retail Pharmacy, Retail Pharmacy, 816 Varnum Avenue, Lowell 	Applications and supporting documents	M. Cittadino
4:30	XI.	New Community Pharmacy Application FLEX SESSION		
		 Additional Meeting in September/October 2014 Board Calendar Introduction to Secure Email Items for the next meeting 		
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 10, 2013

Board Members Present

James T. DeVita, RPh, President Anita Young, RPh, EdD, Secretary Jane F. Franke, RN, MHA Patrick M. Gannon, RPh, MS, FABC Anthony Perrone, RPh, MD, MBA Edmund Taglieri, RPh, MSM, NHA Richard Tinsley, MBA, MEd Joanne Trifone, RPh

Board Members Not Present

Karen Ryle, RPh

Board Staff Present

James Lavery, Division Director, DHPL
Margaret Cittadino, MEd, Associate Director
Heather Engman JD, MPH, Board Counsel
Vita P. Berg, JD, Board Counsel
Leo McKenna, RPh, PharmD,
Quality Assuarance Coordinator
Samuel Penta, RPh, Investigator Supervisor
William E. Frisch, Jr., RPh, Investigator
Cheryl Lathum, RPh, PharmD, Investigator
Joseph Sceppa, RPh, Consultant
Carrie Strasser, Board Staff

Board Staff Not Present

TOPIC:

I. CALL TO ORDER

<u>DISCUSSION</u>: A quorum of the Board was present. J. DEVITA announced that the meeting was being recorded and that a new amplification system is in use. J. LAVERY welcomed new board members, A. PERRONE and R. TINSLEY.

<u>ACTION</u>: At 8:37 a.m. J. DEVITA, President, called the September 10, 2013, meeting of the Board of Registration in Pharmacy to order.

TOPIC:

II. APPROVAL OF AGENDA

<u>DISCUSSION</u>: Board members reviewed the tentative agenda. V. BERG announced that certain items will be moved to the M.G.L. c. 112, § 65C Session from File Review, including

items 7 (Gonzales), 8 and 9 (CVS 1026), 16 (Elliot), and 39 (Village Fertility). Also, certain items will be deferred to the October Meeting, including Section V approval of July minutes; Section VII License Status Change (O'Sullivan); File Review 26 (Young), 35 (Gould), 36 (NSPS), and 37 (Rowe). There are no items added to the Flex Session.

<u>ACTION:</u> Motion by, P. GANNON, seconded by A. YOUNG, and voted unanimously to approve the agenda with the above changes.

TOPIC:

III. M.G.L. c. 112, § 65C SESSION

DISCUSSION: None

<u>ACTION</u>: Motion by A. YOUNG seconded by J. FRANKE and passed by unanimous roll call vote to enter into M.G.L. c. 112, § 65C Session at 8:45 a.m. J. DEVITA: yes; J.

TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; J. FRANKE: yes; P. GANNON: yes;

A. PERRONE: yes; R. TINSLEY: yes.

M.G.L. c. 112, § 65C SESSION (8:45 – 12:44p.m.)

TOPIC:

IV. EXECUTIVE SESSION

DISCUSSION: None

<u>ACTION</u>: Motion by A. YOUNG seconded by E. TAGLIERI and passed by unanimous roll call vote to enter into the Executive Session at 12.45 p.m. J. DEVITA: yes; J.

TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; J. FRANKE: yes; P. GANNON: yes;

A. PERRONE: yes; R. TINSLEY: yes.

EXECUTIVE SESSION (12:45 – 2: 00 p.m.) LUNCH BREAK (2:00 – 2:35 p.m.) CONTINUED EXECUTIVE SESSION (2:35 – 2:58 p.m.) RE-ENTER OPEN SESSION 3:00 p.m.

TOPIC:

V. APPROVAL OF BOARD MINUTES

- A. June 2013. DEFERRED TO OCTOBER MEETING.
- B. July 2013. DEFERRED TO OCTOBER MEETING.

TOPIC:

VI. REPORTS

1. Applications approved pursuant to Licensure Policy 13-01 DEFERRED TO OCTOBER MEETING.

VI. REPORTS

2. Plans of Correction reviewed pursuant to Enforcement Policy 13-02 DEFERRED TO OCTOBER MEETING.

VII. LICENSE STATUS CHANGE REQUESTS

1. John O'Sullivan, PH18979, Request for Pharmacist Reinstatement DEFERRED TO OCTOBER MEETING.

TOPIC:

VIII. FILE REVIEW

All DEFERRED to OCTOBER meeting, except item 20 (Pauline).

- 1. Michael Dubay, PH16047, PHA-2012-0129
- 2. CVS #1871, DS3286, PHA-2012-0041
- 3. G. Bhandari, PT12190, PHA-2012-0166
- 4. CVS #1861, DS2078, PHA-2012-0220
- 5. CVS #8437, DS3549, PHA-2012-0244
- 6. Ashley Lanzisera, PT7549, PHA-2012-0260
- 7. Deliluz Gonzalez, PT7710, PHA-2013-001456
- 8. CVS #1026, DS2824, SA-INV-2919
- 9. CVS #1026, DS2824, SA-INV-2958
- 10. CVS #751, DS89718, SA-INV-3303
- 11. Janet Mary Robert, PH22670, PHA-2013-0026
- 12. Walgreens #3469, DS2593, PHA-2012-0083
- 13. Adam Deletetsky, PH27726, PHA-2012-0175
- 14. Matthew Shea, PH27752, PHA-2012-0176
- 15. Courtney Torres, PT6162, PHA-2012-0177
- 16. Jessica Elliott, PT8627, SA-INV-2951
- 17. Elizabeth Murphy, PT6241, SA-INV-3275
- 18. Yenesh Groom, PT5355, PHA-2012-0224
- 19. Donald Montigny, PH22029, PHA-2013-0055
- 20. Jessica Pauline, PH26390, PHA-2013-0073
- 21. Freedom Fertility Pharmacy, DS89717, SA-INV-4069
- 22. Freedom Fertility Pharmacy, DS89717, SA-INV-3257
- 23. Brian Marquis, PH23304, SA-INV-4124
- 24. Dung Nguyen, PH21900, PHA-2013-0057
- 25. Angela Burnham, PH25973, PHA-2013-0056
- 26. David Young, PH22919, PHA-2013-0079
- 27. Care Point Partners, DS89801, PHA-2012-0256
- 28. Richard Wagner, Jr, PH22708, PHA-2013-0065
- 29. Sullivan's Healthcare, DS3335, PHA-2012-0240
- 30. Timothy Fensky, PH22090, PHA-2013-0041
- 31. The Whittier Pharmacist, DS2587, PHA-2012-0238
- 32. Ralph Luciano, PH18388, PHA-2013-0044
- 33. Oncomed, DS89702, PHA-2012-0236
- 34. Pamela Mortland, PH18776, PHA-2013-0043
- 35. Kimberly Gould, PH27266, PHA-2013-0067
- 36. North Shore Pharmacy Services, DS3458, PHA-2012-0250
- 37. Frederick L. Rowe, JR, PH16931, PHA-2013-0069
- 38. Boston Home Infusion, DS2623, SA-INV-4190
- 39. Village Fertility, DS89658, SA-INV-3632
- 40. Melinna Cepeda, PT11631, SA-INV-3176

- 41. Eaton Apothecary #2080, DS3511, SA-INV-3172
- 42. Henry Pelletier, PH15436, PHA-2012-0151
- 43. Michael Graham, PH232447, PHA-2013-0003
- 44. Pallimed, DS 3498, SA-INV-4302

TOPIC:

VIII. FILE REVIEW

20. Jessica Pauline (PH26390), PHA-2013-0073

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. Board investigators inspected West River Pharmacy (DS3572) in September 2012 and observed violations relating to the balance not being sealed, USP 795 violations, and documentation problems. During a subsequent inspection in December 2012, Board investigators found several deficiencies relating to West River's sterile compounding activities, including numerous USP 797 violations and lack of an ante room. As a result of these deficiencies, an immediate cease and desist notice was issued. At the time of these inspection, West River was already on probation for other infractions that occurred in 2011.

Jessica Pauline was MOR at West River from May 28, 2012 through November 12, 2012. Since she was present at the meeting to appear in connection with the new store application for Pentec, J. DEVITA invited her to speak to Board members and answer questions about the investigation into her license. Ms. Pauline has had no formal training in USP 797, but rather is self-taught. She nevertheless prepared a list of changes that she proposed for West River to address areas where she identified that it was not in compliance with USP 797. The areas she identified were not entirely the same as those identified by Board investigators. In October 2012, she signed an attestation that West River was in full compliance with USP 797. She advised board members that she conferred with counsel for West River and believed that it was appropriate to sign the attestation since there were planned corrections to the deficiencies she identified. As of Ms. Pauline's departure in November, however, West River had not implemented such changes. Ms. Pauline has since been employed at Pentec and has taught herself more about the requirements of USP 797.

Board Members were sympathetic with Ms. Pauline's testimony that she felt pressured by West River to sign the attestation. However, the Board was also concerned that she did not contact the Board after leaving West River to inform them of the deficiencies. Ms. Pauline signed a "non-disparaging" agreement which she asserts prevented her from speaking fully about proposed changes and deficiencies. Ms. Pauline was not present during the December 2012 inspection. She also asserts that she nevertheless sent an anonymous letter to the Board identifying the deficiencies with West River in November 2012. Board Members J. DEVITA and A. PERRONE were particularly concerned with Ms. Pauline's ability to act independently as an MOR at a subsequent pharmacy and her ability to successfully undertake future leadership responsibilities.

<u>ACTION</u>: Motion by E. TAGLIERI, seconded by A.YOUNG to refer this matter to the Office of Prosecution for the issuance of an Order to Show Cause. The motion further authorized, in the alternative, the resolution of this matter by consent agreement for one-year probation without restriction on Ms. Pauline's eligibility to serve as a pharmacy Manager of Record, and with further requirements that she

complete a certification program in USP 797 compounding, separate from her current company training. Motion PASSED by a majority vote in favor, over votes OPPOSED by J.DEVITA and A.PERRONE.

TOPIC:

X. APPLICATIONS

- A. Applications for Expansion
- 1. **Acton Compounding Pharmacy**, 563 Mass Ave, Acton, MA 01720 DEFERRED TO OCTOBER MEETING.

TOPIC:

X. APPLICATIONS

- A. Applications for Expansion
- Boulevard Pharmaceutical Compounding Center, 149 Shrewsbury Street, Worcester, MA
 DEFERRED TO OCTOBER MEETING.

TOPIC:

X. APPLICATIONS

- B. Applications for a Waiver of 247 CMR 6.01(3)
- 3. IVG Veterinary Compounding Pharmacy, 20 Cabot Road, Woburn, MA

 <u>DISCUSSION</u>: Justin McDowell, Manager of Record, and Patrick Welch, Medical Director at the co-owned clinic in Woburn appeared in connection with the pharmacy's application for a waiver of 247 CMR 6.01(3). 247 CMR 6.01(3) disallows ownership of a pharmacy or pharmacy department by a practitioner with prescribing privileges. H. ENGMAN explained that IVG has non-voting shareholders that have prescribing privileges and are minority owners with less than 1% of the shares of the IVG stock. The majority owner of IVG, and only voting shareholder, is retired as an active practitioner and no longer possesses a DEA or MA controlled substances registration. H. ENGMAN advised that similar provisions in regulations for long term care facilities and proposed regulations for adult day health care agencies restrict ownership of more than 5% by interested practitioners.

<u>ACTION</u>: Motion by J. DEVITA, seconded by A. YOUNG and voted unanimously to approve the waiver of 247 CMR 6.01(3).

TOPIC:

X. APPLICATIONS

- C. Reconsideration of an Application for a New Wholesale Distributor License
- 4. SJ Medsav Solutions LLC, 121 Brick Kiln Road, Suite 235, Chelmsford, MA <u>DISCUSSION</u>: Scot Finn, VP of Operations, and Melvin Sparkman, in business development, presented the pharmacy's reconsideration of its application for a new wholesale distributor license and answered the questions of the Board. Medsav would be acting as a "virtual" wholesaler. In June 2013, Medsav presented an application focused on the wholesale of medical supplies, which lies outside of the Board's jurisdiction. Medsav has since updated its application to include the wholesale of schedule VI substances. Medsav's only supplier for these schedule VI substances will be McKesson. The Board had concerns about chain of custody for the substances as they were shipped from McKesson to the consumer without

Medsav ever taking possession. Medsav takes title of the substances when they leave McKesson's factory, however, Medsav intends to rely entirely on McKesson to transport the medications with appropriate security mechanisms and appropriate environmental conditions to ensure that the integrity and effectiveness of the medications are not degraded. Medsav is certified as a disabled veteran-owned company; this status qualifies Medsav to obtain these substances at a lower rate from McKesson and in turn sell the substances at a lower rate to the customer. There may be limits on which customers may likewise qualify for the lower price although it was not made clear by Medsav's owners. The Board was concerned about issuing a wholesale distributor license to Medsav because there were no regulations in place concerning "virtual" wholesalers and there was no real way to monitor such a practice. Medsav would never store, maintain, or ship the substances from a facility. The Board requested more information from Medsav including a specific chain of custody plan, demonstrated success on the supply side, and specific evidence that this model works.

<u>ACTION</u>: Motion by J. DEVITA, seconded by E. TAGLIERI, and voted unanimously to take this matter under advisement and revisit the issue upon receipt of more information.

TOPIC:

X. APPLICATIONS

C. Applications for a New Store

5. Pentec Health Inc., 120 Forbes Boulevard, Suite 400, Mansfield, MA DISCUSSION: Barbara Knightly, VP of Pentec and Pharmacist in Charge for the Pentec facility in Pennsylvania, Jessica Pauline, proposed MOR for Pentec, and Greg Levine, attorney for Pentec, presented the pharmacy's application for a new community pharmacy and answered the questions of the Board. The Board expressed concerns about Ms. Pauline as MOR and discussed this matter in tandem with the File Review Matter for Jessica Pauline, PHA-2013-0073. Ms. Pauline has been with Pentec for 6 months. Pentec engages in low and medium, and high risk sterile compounding, and plans to do high-risk in the future. The Pentec facility in PA recently underwent an inspection by the PA Board of Pharmacy and the FDA. The PA Board of Pharmacy found Pentec in compliance. The FDA issued Pentec a 483. Pentec responded in a timely matter to the 483 and made changes to the hoods as required by the FDA. Pentec's MA pharmacy will primarily work with patients with spasticity disorders. hospice patients, and chronic pain patients. At this time, proposed MOR Pauline would be the only onsite pharmacist full time. A per diem pharmacist will fill in. S. PENTA noted that Ms. Pauline was the MOR at West River prior to starting with Pentec and had also been the MOR at Boston Home Infusion for three years. Boston Home Infusion is another compounding pharmacy where investigators noted deficiencies (lack of an anteroom) during the unannounced inspections last year. ACTION: Motion by J. TRIFONE, seconded by A. YOUNG, to approve this application, with Ms. Pauline as MOR, pending a successful inspection. J. DEVITA and A. PERRONE, opposed. Motion passed with a majority vote.

TOPIC:

X. APPLICATIONS

C. Applications for a New Store

6. True Care Pharmacy, 1275 Pawtucket Boulevard, #3, Lowell, MA DISCUSSION: Minesh Brahmbhatt, MOR, presented the harmacy's application for a new community pharmacy and answered the questions of the Board. Mr. Brahmbhatt obtained his pharmacy education in India and has been working for over 10 years in retail and mail order pharmacy settings. This pharmacy will be a general community pharmacy. While Mr. Brahmbhatt is certified to immunize, he does not plan to do so at this pharmacy. Mr. Brahmbhatt stated that he will not do sterile compounding at this facility, but will engage in nonsterile compounding. He is considering engaging in delivery services. Mr. Brahmbhatt will be the only key holder and is currently the only pharmacist on staff. During hours that the pharmacy is closed, Mr. Brahmbhatt will arrange for call forwarding for emergencies. He also has an arrangement for someone to cover for him during times he may not be able to work, until he hires another pharmacist. Mr. Brahmbhatt's only supplier will be Cardinal Health. For security, Mr. Brahmbhatt has a wired system in place, along with a wireless alarm system, motion detectors, a locked cabinet for CII medications and security cameras. Mr. Brahmbhatt stated that his CEs were current and stated he was aware of PMP reporting requirements. The Board expressed concern that Mr. Brahmbhatt was not currently registered with the PMP system to obtain and monitor patient prescription profiles. ACTION: Motion by J. FRANKE, seconded by P. GANNON, and voted unanimously to approve this application pending a successful inspection. J. TRIFONE and A. YOUNG strongly recommended that Mr. Brahmbhatt register for PMP reviewing access.

TOPIC:

XVI. ADJOURNMENT

DISCUSSION: None

ACTION: Motion by J. TRIFONE, seconded by A. YOUNG, and voted unanimously to adjourn at 5:59 p.m.

LIST OF EXHIBITS USED DURING THE MEETING

- 1. Preliminary Agenda for the September 10, 2013 Regularly Scheduled Meeting.
- 2. Investigative Report re: West River Pharmacy (DS3572) PHA-2012-0251, Donald Montigny (PH22029) PHA-2013-0055 and Jessica Pauline (PH26390), PHA-2013-0073.
- 3. Petition for a Waiver of the Provisions of 247 CMR, Licensure of a Pharmacy and or Pharmacy Department re: IVG Veterinary Compounding Pharmacy
- 4. Application for Licensure as a Wholesale Distributor re: SJ Medsav Solutions LLC
- 5. Application to Manage and Operate a New Community Pharmacy re: Pentec Health Inc.
- 6. Attestation of Intent to Conduct Sterile Compounding re: Pentec Health Inc.
- 7. Application to Manage and Operate a New Community Pharmacy re: True Care Pharmacy

Respectfully submitted,

Vita Palazzolo Berg, Board Counsel