

COMMONWEALTH OF MASSACHUSETTS

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

July 2, 2013
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

PRELIMINARY AGENDA

Time	#	Item	Exhibits	Staff Contact
8:30	I.	CALL TO ORDER		
8:30	II.	APPROVAL OF AGENDA		
8:30	III.	M.G.L. c. 112, § 65C SESSION	CLOSED SESSION	
10:00	IV.	EXECUTIVE SESSION 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, <u>character</u> , 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 <u>Good Moral Character</u> as required for registration for the following applicants: a. Nicholas Rothwell applicant for registration as pharmacy intern; b. Justin Odlin White applicant for registration as pharmacy technician; c. George Anthony Thomas applicant for registration as pharmacist by reciprocity; d. Daniel Boland applicant for registration as pharmacy technician; e. Kevin Wayne Sands applicant for registration as pharmacist by reciprocity; and f. Curtis Croteau applicant for registration as pharmacy technician.	CLOSED SESSION	
11:00	V.	APPROVAL OF BOARD MINUTES June 4, 2013 Regularly Scheduled Meeting	Minutes	V. Berg
11:05	VI.	REPORTS Applications approved pursuant to Licensure Policy 13-01	Reports	M. Cittadino
11:10.	VII.	LICENSE STATUS CHANGE REQUESTS 1. Mona-Lissa Frain Matthews, PH25272, PHA-2011-0193 2. Michelle McCrea, PH20675, PH-08-023 3. John J. Carey III, PH17893, PHA-2011-0062	Request	H. Engman K. Fishman

11:45	IX.	LUNCH		
12:30	X.	FILE REVIEW <ol style="list-style-type: none"> 1. Medi-Son Solutions, DS89749, PHA-2013-0032 2. Christopher Le, PH233115, PHA-2013-0034 3. CarePro Pharmacy, DS89838, PHA-2013-0052 4. Son Dinh, PH26530, PHA-2013-0053 5. CarePro, 1167 North Main Street, Randolph, MA New Store Application 6. West River Pharmacy, DS3572, PHA-2012-0251 7. West River Pharmacy DS3572, SA-INV2356 8. Donald. Montigny, PH22029, PHA-2013-0055 9. Boston Home Infusion, DS2623, PHA-2012-0248 10. Boston Home Infusion, DS2623, SA-INV-4190 11. Rachel E. Gallagher, PH25323, PHA-2013-0050 12. Critical Care Systems (Braintree), DS3327, SA-INV-3252 13. Kelvin P. Ma, PH23996, SA-INV-4130 14. Critical Care Systems (Burlington), DS3328, PHA-2012-0249 15. Charles O. Airhart, PH21738, PHA-2013-0066 16. Critical Care Systems (Shrewsbury), DS3330, SA-INV-3280 17. Matthew J. McLoughlin, PH23310, SA-INV-4131 18. Home Infusion Solutions, DS3592, PHA-2012-0255 19. James E. Hermansen, PH17587, PHA-2013-0064 20. Home Solutions, DS89639, SA-INV-3251 21. John D. Norcross, PH27663, SA-INV-4128 22. Lenox Village Pharmacy, DS3344, PHA-2012-0241 23. Richard P. Mole, PH15360, PHA-2013-0048 24. Long Term Pharmacy Solutions, Inc., DS3184, SA-INV-3279 25. Steven D. Geoffroy, PH18181, SA-INV-4125 26. New England Life Care, DS3513, SA-INV-3260 27. William J. Silva, PH21354, SA-INV-4129 28. Partners of Massachusetts LLC, DS3419, SA-INV-3281 29. David H. Huang, PH20989, SA-INV-3982 30. Preferred Pharmacy Solutions, DS3542, SA-INV-3266 31. Anthony Rozzi, PH17821, SA-INV-4132 32. Walgreens Infusions Services, DS3584, PHA-2012-0253 33. Scott N. Shepard, PH26048, PHA-2013-0062 34. Apothecare South Shore, DS89820, PHA-2012-0252 35. Geoffrey D. Peterson, PH27443, PHA-2013-0063 36. Johnson Compounding and Wellness Center, DS3579, SA-INV-3262 37. John Walczyk, PH26796, SA-INV-4119 38. Freedom Fertility Pharmacy, DS89717, SA-INV-4069 39. North Shore Pharmacy Services, DS3458, PHA-2012-0250 40. Frederick L. Rowe, JR, PH16931, PHA-2013-0069 41. Western Mass Pharmacy, DS89799, PHA-2012-0239 42. John F. Horan, PH16180, PHA-2013-0042 43. Michael Dubay, PH16047, PHA-2012-0129 44. CVS #1871, DS3286, PHA-2012-0041 45. G. Bhandari, PT12190, PHA-2012-0166 46. Kathi Morgan, PH23952, PHA-2012-0162 47. Kathi Morgan, PH23952, PHA-2013-0006 	Investigation Reports for all complaints listed	S. Penta W. Frisch L. McKenna C. Latham

12:30	X.	FILE REVIEW continued 48. CVS #1861, DS2078, PHA-2012-0220 49. CVS #8437, DS3549, PHA-2012-0244 50. Ashley Lanzisera, PT7549, PHA-2012-0260 51. Yenenesh Groom, PT5355, PHA-2012-0224 52. Walgreens #3469, DS2593, PHA-2012-0083 53. Adam Deletetsky, PH27726, PHA-2012-0175 54. Matthew Shea, PH27752, PHA-2012-0176 55. Ccourtney Torres, PT6162, PHA-2012-0177 56. Walgreens #4393, DS2882, PHA-2012-0172 57. Christopher. Softish, PH24826, PHA-2012-0223 58. Deliluz Gonzalez, PT7710, PHA-2013-001456 59. Prescription Shoppe, Inc, DS6654, PHA-2012-0092 60. Anthony LaMonica, PH12804, PHA-2012-0168 61. CVS #1026, DS2824, SA-INV-2958 62. CVS #2138, DS2815, SA-INV-2274 63. CVS #751, DS89718, SA-INV-3303 64. DANIEL RICHARD, PH17676, PHA-2013-0011 65. FRANK PALLARIA, PH 18787, PHA-2013-0012 66. Melinna Cepeda, PT11631, SA-INV-3176 67. Jessica Elliott, PT8627, SA-INV-2951 68. CVS #1026, DS2824, SA-INV-2958 69. Eaton Apothecary #2080, DS3511, SA-INV-3172 70. Elizabeth Murphy, PT6241, SA-INV-3275	Investigation Reports for all complaints listed	S. Penta W. Frisch L. McKenna C. Lathum
4:30		FLEX SESSION 1. Items for the next meeting 2. September MPJE Review at NABP 3. Board Delegated Complaint Review 4. Recommendations of the Special Commission on the Oversight of Compounding Pharmacies <ul style="list-style-type: none"> a. #2f: formation of Advisory Group tasked with developing a model to license out of state pharmacies; b. #2c: formation of Advisory Group tasked with evaluating the policy and operational implications of establishing a single regulatory authority for all pharmacy practice in the Commonwealth (including freestanding, hospital and physician office) 		
5:00	XI.	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, July 2, 2013

Board Members Present

James T. DeVita, RPh
Karen Ryle, RPh, MS
Joanne Trifone, RPh
Anita Young, RPh, EdD
Jane Franke, RN, MHA
Edmund Taglieri, RPh, MSM, NHA
Patrick Gannon, RPh, MS

Board Members Not Present

Board Staff Present

James Lavery, Division Director, DHPL
Margaret Cittadino, MEd, Associate Director
Heather Engman JD, MPH, Board Counsel
Vita P. Berg, Board Counsel
Leo McKenna, RPh, PharmD, QA Coordinator
Samuel Penta, RPh, Investigator Supervisor
William E. Frisch, Jr., RPh, Investigator
Cheryl Lathum, RPh, PharmD, Investigator

Board Staff Not Present

Joseph Sceppa, RPh, Consultant

TOPIC:

I. CALL TO ORDER

DISCUSSION: A quorum of the Board was present.

ACTION: At 8:41 a.m. J. DEVITA, President, called the July 2, 2013, meeting of the Board of Registration in Pharmacy to order.

TOPIC:

II. APPROVAL OF AGENDA

DISCUSSION: Board members reviewed the tentative agenda and discussed deferring item V (minutes) and reordering items III (65C session) and IV (executive session).

ACTION: Motion by P. GANNON, seconded by A. YOUNG and voted unanimously to approve the agenda with the foregoing changes.

TOPIC:

III. EXECUTIVE SESSION

DISCUSSION: None.

ACTION: Motion by E. TAGLIERI, seconded by J. FRANKE and passed by unanimous roll call vote to enter into Executive Session at 8:45 a.m. J. DEVITA: yes; K. RYLE: yes; J. TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; J. FRANKE: yes; P. GANNON: yes.

EXECUTIVE SESSION (8:45 – 9:08 a.m.)

TOPIC:

IV. M.G.L. c. 112, § 65C SESSION

DISCUSSION: None.

ACTION: Motion by J. FRANKE, seconded by E. TAGLIERI and passed by unanimous roll call vote to enter into M.G.L. c. 112, § 65C Session at 9:09am. J. DEVITA: yes; K. RYLE: yes; J. TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; J. FRANKE: yes; P. GANNON: yes.

M.G.L. c. 112, § 65C SESSION (9:09 – 11:33 a.m.)

TOPIC:

V. APPROVAL OF BOARD MINUTES

A. June 4, 2013 Regularly Scheduled Meeting

DISCUSSION: Defer the minutes from the June 4, 2013 meeting.

ACTIONS: Motion by J. FRANKE, seconded by E. TAGLIERI and voted unanimously to defer approval of the minutes for the June 4, 2013 Regularly Scheduled Meeting.

TOPIC:

VI. REPORTS

1. Applications approved pursuant to Licensure Policy 13-01

DISCUSSION: M. CITTADINO noted that there was one (1) new certificate of fitness, thirty-seven (37) changes of manager, two (2) renovation or expansion, and two (2) store closing applications which were approved.

ACTION: So noted.

TOPIC:

VII. LICENSE STATUS CHANGE REQUESTS

1. Mona-Lissa Frain Matthews, PH25272, PHA-2011-0193

RECUSALS: J. DEVITA recused himself and was not present during the discussion or vote of this matter.

DISCUSSION: H. ENGMAN presented the petition for reinstatement. Ms. Matthews has submitted all documentation required by Reinstatement Policy 2011-02 and has met all requirements set forth in the consent agreement for suspension, including retaking the MPJE with a passing score.

ACTION: Motion by J. TRIFONE, seconded by E. TAGLIERI and voted unanimously to reinstate Ms. Matthew's license with probation for three years.

TOPIC:

III. EXECUTIVE SESSION

DISCUSSION: None.

ACTION: Motion by E. TAGLIERI, seconded by J. FRANKE and passed by unanimous roll call vote to enter into Executive Session at 8:45 a.m. J. DEVITA: yes; K. RYLE: yes; J. TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; J. FRANKE: yes; P. GANNON: yes.

EXECUTIVE SESSION (8:45 – 9:08 a.m.)

TOPIC:

IV. M.G.L. c. 112, § 65C SESSION

DISCUSSION: None.

ACTION: Motion by J. FRANKE, seconded by E. TAGLIERI and passed by unanimous roll call vote to enter into M.G.L. c. 112, § 65C Session at 9:09am. J. DEVITA: yes; K. RYLE: yes; J. TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; J. FRANKE: yes; P. GANNON: yes.

M.G.L. c. 112, § 65C SESSION (9:09 – 11:33 a.m.)

TOPIC:

V. APPROVAL OF BOARD MINUTES

A. June 4, 2013 Regularly Scheduled Meeting

DISCUSSION: Defer the minutes from the June 4, 2013 meeting.

ACTIONS: Motion by J. FRANKE, seconded by E. TAGLIERI and voted unanimously to defer approval of the minutes for the June 4, 2013 Regularly Scheduled Meeting.

TOPIC:

VI. REPORTS

1. **Applications approved pursuant to Licensure Policy 13-01**

DISCUSSION: M. CITTADINO noted that there was one (1) new certificate of fitness, thirty-seven (37) changes of manager, two (2) renovation or expansion, and two (2) store closing applications which were approved.

ACTION: So noted.

TOPIC:

VII. LICENSE STATUS CHANGE REQUESTS

1. **Mona-Lissa Frain Matthews, PH25272, PHA-2011-0193**

RECUSALS: J. DEVITA recused himself and was not present during the discussion or vote of this matter.

DISCUSSION: H. ENGMAN presented the petition for reinstatement. Ms. Matthews has submitted all documentation required by Reinstatement Policy 2011-02 and has met all requirements set forth in the consent agreement for suspension, including retaking the MPJE with a passing score.

ACTION: Motion by J. TRIFONE, seconded by E. TAGLIERI and voted unanimously to reinstate Ms. Matthew's license with probation for three years.

TOPIC:

VII. LICENSE STATUS CHANGE REQUESTS

2. Michelle McCrea, PH-25272, PH-08-023

RECUSALS: K. RYLE recused herself and was not present during the discussion or vote of this matter.

DISCUSSION: K. FISHMAN presented request for termination of probation. Ms. McCrea has successfully completed MPRS and complied with the terms of her probation.

ACTION: Motion by J. TRIFONE, seconded by P. GANNON and voted unanimously to terminate probation.

TOPIC:

VII. LICENSE STATUS CHANGE REQUESTS

3. John C. Carey III, PH17893, PHA-2011-0062

RECUSALS: J. TRIFONE recused herself and was not present during the discussion or vote of this matter.

DISCUSSION: K. FISHMAN presented the petition for reinstatement. Mr. Carey has submitted all documentation required by Reinstatement Policy 2011-02 and has met requirements set forth in the consent agreement for suspension. These included random drug screens which were mostly negative but include two instances where he failed to call in to the screening center (one of those two occasions was a major holiday). He has taken the MPJE and obtained a passing score.

ACTION: Motion by K. RYLE, seconded by J. FRANK and voted unanimously to reinstate Mr. Carey's license with probation for 3 years. The specific terms of probation include continued random drug screens during the probationary period and the requirement that he work under the supervision of a preceptor for a minimum of 300 hours for the first three months that he returns to practice – prior to working independently. The preceptor must submit a report at the conclusion of the three month period.

LUNCH (11:50– 12:43)

TOPIC:

IX. FILE REVIEW

1. Medi-Son Solutions, DS89749, PHA-2013-0032

2. Christopher Le, PH233115, PHA-2013-0034

3. CarePro Pharmacy, DS89838, PHA-2013-0052

4. Son Dinh, PH26530, PHA-2013-0053

RECUSALS: J. TRIFONE recused herself and was not present during the discussion or vote of these matters.

DISCUSSION: These complaints arise from a single set of facts and were presented jointly to the Board by W. FRISCH. An inspection was conducted to investigate the dispensing of prescriptions for federally-controlled substances generated from out-of-state prescribers. Investigators C. Lathum and L. McKenna conducted a site visit to Medi-Son on April 2, 2013 accompanied by DEA Investigators and Norwood Police Detective Sergeant Robert W. Rinn. Observations raised concerns about the pharmacy filling

prescriptions for out of state patients, without verifying the out of state's practitioner's prescriptive authority and the validity of the prescriber-patient relationship. In inspectors noted multiple instances where prescriptions from out of state bearing false DEA numbers were paid for in cash. The inspectors also observed non-compliant refrigeration, expired medications on shelves; possibly used in compounding medications, failure of registrant to maintain required records and perform required inventories of controlled substances, failure to comply with USP 797 and 795 compounding standards, and failure to conduct pharmacy operations in accordance with different areas of 247 CMR. On April 2, the Board issued a *Cease and Desist and Quarantine Notice* to Medi-Son Solutions to

"immediately cease ALL pharmacy operations." Thereafter, on May 8, 2012, the Board conducted a follow up inspection. Inspectors found evidence that Medi-Son was continuing to operate in violation of its cease and desist notice in that it was continuing to fill prescriptions and dispense to patients, with the collaboration of CarePro Pharmacy in Quincy. Managers of Record Son Dinh (CarePro) and Christopher Le (Medi-Son) hold ownership interests in Medi-Son; Son Dinh holds ownership interests in CarePro. The Board issued a *Cease and Desist and Quarantine Notice* to CarePro Pharmacy.

ACTION 1: Motion by J. FRANKE, seconded by E. TAGLIERI and voted unanimously to summarily suspend the pharmacy license of MediSon Solutions pending final resolution of the complaint.

ACTION 2: Motion by E. TAGLIERI, seconded by A. YOUNG and voted unanimously to the refer the complaint against Medi-Son Solutions to the office of prosecutions for issuance of an order to show cause with authority to resolve the complaint with a consent agreement for voluntary surrender.

ACTION 3: Motion by K. RYLE, seconded by A. YOUNG and voted unanimously to summarily suspend the pharmacist license of Christopher Le pending final resolution of the complaint.

ACTION 4: Motion by K. RYLE, seconded by P. GANNON and voted unanimously to the refer the complaint against Christopher Le to the office of prosecutions for issuance of an order to show cause with authority to resolve the complaint with a consent agreement for voluntary surrender.

ACTION 5: Motion by J. FRANKE, seconded by E. TAGLIERI and voted unanimously to summarily suspend the pharmacy license of CarePro Pharmacy pending final resolution of the complaint.

ACTION 6: Motion by J. FRANKE, seconded by E. TAGLIERI and voted unanimously to the refer the complaint against CarePro Pharmacy to the office of prosecutions for issuance of an order to show cause with authority to resolve the complaint with a consent agreement for voluntary surrender.

ACTION 7: Motion by K. RYLE, seconded by A. YOUNG and voted unanimously to summarily suspend the pharmacist license of Son Dinh pending final resolution of the complaint.

ACTION 8: Motion by K. RYLE, seconded by P. GANNON and voted unanimously to the refer the complaint against Son Dinh to the office of prosecutions for issuance of an order to show cause with authority to resolve the complaint with a consent agreement for voluntary surrender.

TOPIC:

IX. FILE REVIEW

5. CarePro, 1167 North Main St, Randolph, MA, New Store Application

RECUSALS: J. TRIFONE recused herself and was not present during the discussion or vote of the matter.

DISCUSSION: This application was reviewed by the Board on March 19, 2013 and approved pending successful inspection. Son Dinh holds an ownership interest in this pharmacy and had presented the application to Board in March. An inspection has not yet occurred. Due to the issues surrounding the other two pharmacies and Son Dinh, and since the license for this pharmacy has not yet issued, H. ENGMAN recommended that the Board reconsider whether it is in the best interests of the public health, safety and welfare to issue this license.

ACTION: Motion by A. YOUNG, seconded by E. TAGLIERI and voted unanimously to deny license to open new a store in Randolph.

TOPIC:

IX. FILE REVIEW

6. West River Pharmacy, DS3572, PHA-2012-0251

7. West River Pharmacy, DS3572, SA-INV-2356

8. Donald Montigny, PH22029, PHA-2013-0055

62. CVS #2138, DS2815, SA-INV-2274

RECUSALS: J. DEVITA recused himself and was not present during the discussion or vote of these matters.

DISCUSSION: These complaints are interrelated and were presented jointly to the Board by S. PENTA. Board staff inspected West River Pharmacy during the series of unannounced inspections of sterile compounding pharmacies that occurred between November 2012 and January 2013. The observations at West River Pharmacy included the absence of an ante room. Donald Montigny was the Manager of Record at the time of the inspection, but had only been there for a short period of time. The prior Manager of Record was Jessica Pauline. The Board issued an immediate cease and desist notice during the inspection. Since that time, West River Pharmacy has submitted a plan of correction which was approved under the Board's policy;

following a successful reinspection, the Cease and Desist was rescinded on April 10, 2013. Board investigators opened a new, separate staff assignment against West River with respect to observations concerning after-hours prescription processing for long term care clients requiring medications that are not available through emergency kits. West River utilizes a backup pharmacy network in which the prescription is reviewed by an e-pharmacy located in Pennsylvania, but filled and delivered by retail pharmacy in MA (CVS #2138).

ACTION 1: Motion by E. TAGLIERI, seconded by P.GANNON and voted unanimously to open a complaint on the staff assignment against West River (after hours processing), to consolidate that complaint with the complaint based on the sterile compounding inspection and to refer both matters to prosecution for the issuance of an Order to Show Cause. The vote also authorized resolution of the complaints with a consent agreement for probation for one year with probation terms including the submission of a plan of correction concerning after-hours processing within thirty days.

ACTION 2: Motion by E. TAGLIERI, seconded by P. GANNON and voted unanimously to defer the complaint against Mr. Montigny, and to open a complaint against Ms. Pauline, for review of both matters by the Board in September concerning their respective roles as Manager of Record for West River Pharmacy.

ACTION 3: Motion by K. RYLE, seconded by E. TAGLIERI and voted unanimously to open a complaint against CVS #2138 and to refer to the complaint to prosecution for the issuance of an Order to Show Cause, with authority to resolve the complaint with a consent agreement for Stayed Probation for 3 months during which time the pharmacy is required to submit a Plan of Correction which includes appropriate re-education for staff.

TOPIC:

IX. FILE REVIEW

9. **Boston Home Infusion**, DS2623, PHA-2012-0248
10. **Boston Home Infusion**, DS2623, SA-INV-4190
11. **Rachel E. Gallagher**, PH25323, PHA-2013-0050

DISCUSSION: These complaints are interrelated and were presented jointly to the Board by S. PENTA. Board staff inspected Boston Home Infusion during the series of unannounced inspections of sterile compounding pharmacies that occurred between November 2012 and January 2013. During the inspection the pharmacy was found to have an inappropriate buffer room and the ante room was unclassified. This deficiency would have warranted a cease and desist but for the fact that the pharmacy was able to submit an appropriate plan of correction and implement the corrections within 17 hours. The investigators also observed additional deficiencies, however, that were also addressed by an appropriate plan of correction. Rachel Gallagher was the Manager of Record for Boston Home Infusion at the time of inspection.

ACTION 1: Motion by K. RYLE, seconded by A. YOUNG and voted unanimously to dismiss the complaint against the pharmacy on the grounds that the inspectional deficiencies have been corrected and further discipline is not warranted.

ACTION 2: Motion by K. RYLE, seconded by A. YOUNG and voted unanimously to dismiss the complaint against the Manager of Record on the grounds that the inspectional deficiencies have been corrected and further discipline is not warranted.

FURTHER DISCUSSION: S. PENTA also provided the Board with an update on staff assignment against Boston Home Infusion was opened due to the pharmacy's self report concerning contamination found when testing a hood for recertification. The pharmacy has taken appropriate actions and additional retest results are pending.

ACTION 3: So noted.

TOPIC:

IX. FILE REVIEW

12. **Critical Care Systems (Braintree)**, DS3327, SA-INV-3252
13. **Kelvin P. Ma**, PH23996, SA-INV-4130

RECUSALS: E. TAGLIERI recused himself and was not present during the discussion or vote of these matters.

DISCUSSION: These complaints arise from a single set of facts and were presented jointly to the Board by L. MCKENNA. Board staff inspected the Braintree facility during the series of unannounced inspections of sterile compounding pharmacies that occurred between November 2012 and January 2013. This pharmacy, which performs

low to medium risk compounding, had few noted deficiencies which have since been corrected. Kelvin Ma was the Manager of Record at the time of inspection.

ACTION 1: Motion by A. YOUNG seconded by P. GANNON and voted unanimously to close the staff assignment and take no further action against the pharmacy.

ACTION 2: Motion by A. YOUNG seconded by P. GANNON and voted unanimously to close the staff assignment and take no further action against the pharmacist Manager of Record, Kelvin Ma.

TOPIC:

IX. FILE REVIEW

14. **Critical Care Systems (Burlington)**, DS3328, PHA-2012-0249

15. **Charles Airhart**, PH21738, PHA-2013-0066

RECUSALS: E. TAGLIERI recused himself and was not present during the discussion or vote of these matters.

DISCUSSION: These complaints arise from a single set of facts and were presented jointly to the Board by L. MCKENNA. Board staff inspected the Burlington facility during the series of unannounced inspections of sterile compounding pharmacies that occurred between November 2012 and January 2013. This pharmacy had improper air quality control in one of their clean rooms (air conditioner blowing against the HEPA filter). The pharmacy has since shut down that clean room. Charles Airhart was the Manager of Record at the time of inspection.

ACTION 1: Motion by P. GANNON seconded by A. YOUNG and voted unanimously to close the complaint against the pharmacy, discipline not warranted.

ACTION 2: Motion by A. YOUNG seconded by P. GANNON and voted unanimously to close the complaint against the pharmacist Manager of Record, Charles Airhart, discipline not warranted.

IX. FILE REVIEW

16. **Critical Care Systems (Shrewsbury)**, DS3330, SA-INV-3280

17. **Matthew J. McLoughlin**, PH23310, SA-INV-4131

RECUSALS: E. TAGLIERI recused himself and was not present during the discussion or vote of these matters.

DISCUSSION: These complaints arise from a single set of facts and were presented jointly to the Board by L. MCKENNA. Board staff inspected the Shrewsbury facility during the series of unannounced inspections of sterile compounding pharmacies that occurred between November 2012 and January 2013. This pharmacy utilized a sink that was not in compliance with <797>. The pharmacy has corrected this issue. Matthew McLoughlin was the Manager of Record at the time of inspection.

ACTION 1: Motion by A. YOUNG seconded by P. GANNON and voted unanimously to close the staff assignment and take no further action against the pharmacy..

ACTION 2: Motion by A. YOUNG seconded by P. GANNON and voted unanimously to close the staff assignment and take no further action against the pharmacist Manager of Record, Matthew McLoughlin.

IX. FILE REVIEW

18. Home Infusion Solutions (Falmouth), DS3592, PHA-2012-0255

19. James E. Hermansen, PH17587, PHA-2013-0064

DISCUSSION: These complaints arise from a single set of facts and were presented jointly to the Board by S. PENTA. Board staff inspected the Falmouth facility during the series of unannounced inspections of sterile compounding pharmacies that occurred between November 2012 and January 2013. The Board issued a cease and desist to this pharmacy where a sink was installed in the buffer room. The pharmacy has corrected this issue. James Hermansen was the Manager of Record at the time of inspection.

ACTION 1: Motion by E. TAGLIERI, seconded by J. FRANKE and voted unanimously to refer to prosecution for the issuance of an Order to Show Cause, with authority to resolve the complaint with a consent agreement for probation of one year.

ACTION 2: Motion by E. TAGLIERI, seconded by P. GANNON and voted unanimously to refer to prosecution for the issuance of an Order to Show Cause, with authority to resolve the complaint with a consent agreement for probation of one year, providing however that this individual may remain as MOR during the probation period.

TOPIC:

IX. FILE REVIEW

20. Home Solutions (Canton), DS89639, SA-INV-3251

21. John D. Norcross, PH27663, SA-INV-4128

DISCUSSION: These complaints arise from a single set of facts and were presented jointly to the Board by S. PENTA. Board staff inspected the Canton facility during the series of unannounced inspections of sterile compounding pharmacies that occurred between November 2012 and January 2013. John Norcross was the Manager of Record at the time of inspection.

ACTION 1: Motion by A. YOUNG, seconded by E. TAGLIERI and voted unanimously to close staff assignment and take no further action against the pharmacy.

ACTION 2: Motion by A. YOUNG, seconded E. TAGLIERI and voted unanimously to close staff assignment and take no further action against the pharmacist Manager of Record, John Norcross.

TOPIC:

IX. FILE REVIEW

22. Lenox Village Pharmacy, DS3344, PHA-2012-0241

23. Richard P. Mole, PH15360, PHA-2013-0048

DISCUSSION: These complaints arise from a single set of facts and were presented jointly to the Board by W. FRISCH. Board staff inspected this pharmacy during the series of unannounced inspections of sterile compounding pharmacies that occurred between November 2012 and January 2013. Investigators observed that the clean room was in non-compliance with USP 797 and the sink was not within the ante room. In addition the pharmacy lacked a quality assurance program and had other noted deficiencies. A cease and desist notice was issued on December 12, 2012 for all sterile compounding. This pharmacy has not submitted a formal plan of corrections and have not decided if they will resume sterile compounding. Richard Mole, the Manager of Record, had signed an attestation in October averring that the pharmacy was in compliance with sterile compounding regulations.

ACTION 1: Motion by K. RYLE, seconded by A. YOUNG, to refer the complaint to prosecution for the issuance of an Order to Show Cause, with authority to resolve the

complaint with a consent agreement for one year probation with a specific provision that the cease and desist be rescinded and in its' place a provision in the agreement that the pharmacy will discontinue all sterile compounding until and unless they receive prior written approval from the Board. No vote was taken on this initial motion. K. RYLE amended her motion, seconded by A. YOUNG, to refer the complaint to prosecution for the issuance of an Order to Show Cause, with authority to resolve the complaint with a consent agreement for *reprimand* with a specific provision that the cease and desist be rescinded and in its' place a provision in the agreement that the pharmacy will discontinue all sterile compounding until and unless they receive prior written approval from the Board. The amended motion passed unanimously.

ACTION 2: Motion by A. YOUNG, seconded by E. TAGLIERI, to refer the complaint to prosecution for the issuance of an Order to Show Cause, with authority to resolve the complaint with a consent agreement for one year stayed probation with the requirement that the licensee take 5 CE hours in sterile and non-sterile compounding during the probationary period. No vote was taken on this initial motion. A. YOUNG amended her motion, seconded by E. TAGLIERI, to refer the complaint to prosecution for the issuance of an Order to Show Cause, with authority to resolve the complaint with a consent agreement for a formal reprimand, provided that the licensee first complete, as a precondition to entering into the agreement, 5 CE hours in sterile and non-sterile compounding. The amended motion passed unanimously.

TOPIC:

IX. FILE REVIEW

24. **Long Term Pharmacy Solution, Inc.**, DS3184, SA-INV-3279

25. **Steven D. Geoffroy**, PH18181, SA-INV-4125

DISCUSSION: These complaints arise from a single set of facts and were presented jointly to the Board by S. PENTA. Board staff inspected this pharmacy during the series of unannounced inspections of sterile compounding pharmacies that occurred between November 2012 and January 2013. Steven Geoffroy was the Manager of Record at the time of inspection.

ACTION 1: Motion by E. TAGLIERI, seconded by P. GANNON and voted unanimously to close staff assignment and take no further action against the pharmacy.

ACTION 2: Motion by E. TAGLIERI, seconded by P. GANNON and voted unanimously to close staff assignment and take no further action against the pharmacist Manager of Record, Steven Geoffroy.

TOPIC:

IX. FILE REVIEW

26. **New England Life Care**, DS3513, SA-INV-3260

27. **William J. Silva**, PH21534, SA-INV-4129

DISCUSSION: These complaints arise from a single set of facts and were presented jointly to the Board by L. MCKENNA. Board staff inspected this pharmacy during the series of unannounced inspections of sterile compounding pharmacies that occurred between November 2012 and January 2013. William Silva was the Manager of Record at the time of inspection.

ACTION 1: Motion by J. TRIFONE, seconded by P. GANNON and voted unanimously to close staff assignment and take no further action against the pharmacy.

ACTION 2: Motion by J. TRIFONE, seconded by P. GANNON and voted unanimously to close staff assignment and take no further action against the pharmacist Manager of

TOPIC:

IX. FILE REVIEW

28. **Partners of Massachusetts LLC**, DS3419, SA-INV-3281

29. **David H. Huang**, PH20989, SA-INV-3982

RECUSAL: E. TAGLIERI recused himself and was not present during the discussion or vote of these matters

DISCUSSION: These complaints arise from a single set of facts and were presented jointly to the Board by S. PENTA. Board staff inspected this pharmacy during the series of unannounced inspections of sterile compounding pharmacies that occurred between November 2012 and January 2013. Board members inquired about a reference in the inspection audit indicating that an iso-class room was "not applicable" to this facility. Investigators clarified that this pharmacy utilized a certified glove box and conducted only low risk compounding. David Huang was the Manager of Record at the time of inspection.

ACTION 1: Motion by P. GANNON, seconded by J. FRANKE and voted unanimously to close staff assignment and take no further action against the pharmacy.

ACTION 2: Motion by P. GANNON, seconded by J. FRANKE and voted unanimously to close staff assignment and take no further action against the pharmacist Manager of Record, David Huang.

TOPIC:

IX. FILE REVIEW

30. **Preferred Pharmacy Solutions**, DS3542, SA-INV-3266

31. **Anthony Rozzi**, PH17821, SA-INV-4132

DISCUSSION: These complaints arise from a single set of facts and were presented jointly to the Board by W. FRISCH. Board staff inspected this pharmacy during the series of unannounced inspections of sterile compounding pharmacies that occurred between November 2012 and January 2013. Investigators observed that this pharmacy had deficiencies associated with their quality assurance plan, a technician was found to be wearing nail polish and the ratio of pharmacists to pharmacy technicians appeared to be out of compliance with regulations among other deficiencies. The plan of correction has been approved. When reviewing the ratio of pharmacy staff, it appears that one pharmacy technician may have worked in excess of a 1000 hours without registration.

ACTION 1: Motion by J. TRIFONE, seconded by E. TAGLIERI and voted unanimously to close staff assignment but to conduct a re-inspection of this facility as a priority matter.

ACTION 2: Motion by J. DEVITA, seconded by E. TAGLIERI and voted unanimously to defer staff assignment on the pharmacist Manager of Record, Anthony Rozzi, in order to gather additional information concerning whether a pharmacy technician worked unlicensed in excess of 1000 hours.

TOPIC:

IX. FILE REVIEW

32. **Walgreens Infusions Services**, DS3584, PHA-2012-0253

33. **Scott N. Shepard**, PH26048, PHA-2013-0062

Re-ordered to facilitate recusal.

TOPIC:

IX. FILE REVIEW

34. **Apothecare South Shore**, DS89820, PHA-2012-0252

35. **Geoffrey D. Peterson**, PH27443, PHA-2013-0063

DISCUSSION: These complaints arise from a single set of facts and were presented jointly to the Board by W. FRISCH. Board staff inspected this pharmacy during the series of unannounced inspections of sterile compounding pharmacies that occurred between November 2012 and January 2013. Investigators noted several deficiencies in the compounding area, dust was observed in clean room environment, air returns were non-compliant with USP 797 regulations among observed deficiencies. A cease and desist notice was issued on December 20, 2012 for all sterile and non-sterile compounding. A plan of correction was approved with respect to non-sterile compounding activities, and the cease and desist was rescinded on May 31, 2013 conditioned upon the pharmacy's agreement to abstain from sterile compounding. Geoffrey Peterson was Manager of Record at the time of the inspection, but had been in that role for only two to three weeks. David Young was the prior Manager of Record.

ACTION 1: Motion by J. FRANKE, seconded by P. GANNON and voted unanimously to refer the complaint against the pharmacy to office of prosecution for order to show cause with authority to resolve the complaint by a consent agreement for reprimand that preserves the prior agreement to cease all sterile compounding activity.

ACTION 2: Motion by J. DEVITA, seconded by P. GANNON and voted unanimously to dismiss complaint the pharmacist Manager of Record, Geoffrey Peterson, discipline not warranted.

ACTION 3: Motion by J. DEVITA, seconded by E. TAGLIERI and voted unanimously to open a staff assignment to investigate the role of the prior Manager of Record, David Young, in the pharmacy's deficiencies.

TOPIC:

IX. FILE REVIEW

36. **Johnson Compounding and Wellness Center**

37. **John Walczyk**, PH26796, SA-INV-4119

RECUSAL: J. TRIFONE recused herself and was not present during the discussion or vote of these matters

DISCUSSION: These complaints arise from a single set of facts and were presented jointly to the Board by L. MCKENNA and S. PENTA. Board staff inspected this pharmacy during the series of unannounced inspections of sterile compounding pharmacies that occurred between November 2012 and January 2013. John Walczyk was the Manager of Record at the time of inspection.

ACTION: Motion by P. GANNON, seconded by J. FRANKE and voted unanimously to close the staff assignment and take no further action against the pharmacy.

ACTION: Motion by P. GANNON, seconded by J. FRANKE and voted unanimously to close the staff assignment and take no further action against the pharmacist Manager of Record, John Walczyk.

TOPIC:

IX. FILE REVIEW

32. **Walgreens Infusions Services**, DS3584, PHA-2012-0253

33. **Scott N. Shepard**, PH26048, PHA-2013-0062

RECUSAL: J. TRIFONE recused herself and was not present during the discussion or vote of these matters

DISCUSSION: These complaints arise from a single set of facts and were presented jointly to the Board by S. PENTA. Board staff inspected this pharmacy during the series of unannounced inspections of sterile compounding pharmacies that occurred between November 2012 and January 2013. Scott Shepard was the Manager of Record at the time of inspection.

ACTION: Motion by A. YOUNG, seconded by E. TAGLIERI and voted unanimously to dismiss complaint against the pharmacy with discipline not warranted.

ACTION: Motion by A. YOUNG, seconded by P. GANNON and voted unanimously to dismiss complaint against the pharmacist Manager of Record, Scott Shepard, with discipline not warranted

TOPIC:

IX. FILE REVIEW

38. **Freedom Fertility Pharmacy**, DS89717, SA-INV-4069

39. **North Shore Pharmacy Services**, DS3458, PHA-2012-0250

40. **Frederick L. Rowe, Jr**, PH16931, PHA-2013-0069

DISCUSSION: None

ACTION: Deferred to September

TOPIC:

IX. FILE REVIEW

41. **Western Mass Pharmacy**, DS89799, PHA-2012-0239

42. **John F. Horan**

DISCUSSION: These complaints arise from a single set of facts and were presented jointly to the Board by W. FRISCH. Board staff inspected this pharmacy during the series of unannounced inspections of sterile compounding pharmacies that occurred between November 2012 and January 2013. During the inspection there were multiple deficiencies observed and a cease and desist notice was issued on December 6, 2012. In addition, investigators observed that the owner counseled patients on numerous occasions even though he is not a pharmacist or physician. The pharmacy worked with consultant to bring the facility up to standards for sterile compounding and submitted a gap analysis. The plan of correction was approved and, following a satisfactory re-inspection the cease and desist for *non-sterile* compounding was rescinded on March 12, 2013. John Horan was the Manager of Record. Investigators noted that correspondence from the MOR to the owner demonstrated that the MOR had knowledge the pharmacy was not in full compliance with sterile compounding regulations and continued working as the MOR.

ACTION 1: Motion by J. DEVITA, seconded by P. GANNON and voted unanimously to refer the complaint against the pharmacy to the office of prosecution for the issuance of an order to show cause with authority to resolve the complaint with a consent agreement for one year probation that specifically reinforces the pharmacy's responsibility to disallow individuals from engaging in any activity that requires a pharmacist's license except for individuals who have a current pharmacist license.

ACTION 2: Motion by A. YOUNG, seconded by E. TAGLIERI and voted unanimously to refer complaint against the pharmacist Manager or Record, John Horan, to the office of prosecution for the issuance of an order to show cause with authority to resolve the complaint with a consent agreement of one year probation, including the requirement that he complete 10 additional CE hours in the area of sterile and non-sterile compounding during the probation period.

TOPIC:

IX. FILE REVIEW

- 43. **Michael Dubay**, PH16047, PHA-2012-0129
- 44. **CVS #1871**, DS3286, PHA-2012-0041
- 45. **G. Bhandari**, PT12190, PHA-2012-0166
- 46. **Kathi Morgan**, PH23952, PHA-2012-0162
- 47. **Kathi Morgan**, PH23952, PHA-2013-0006
- 48. **CVS #1861**, DS2078, PHA-2012-0220
- 49. **CVS #8437**, DS3549, PHA-2012-0244
- 50. **Ashley Lanzisera**, PT7549, PHA-2012-0260
- 51. **Yenenesh Groom**, PT5355, PHA-2012-0224
- 52. **Walgreens #3469**, DS2593, PHA-2012-0083
- 53. **Adam Deletetsky**, PH27726, PHA-2012-0175
- 54. **Matthew Shea**, PH27752, PHA-2012-0176
- 55. **Courtney Torres**, PT6162, PHA-2012-0177
- 56. **Walgreens #4393**, DS2882, PHA-2012-0172
- 57. **Christopher. Soltish**, PH24826, PHA-2012-0223
- 58 **Deliluz Gonzalez**

DISCUSSION: None

ACTION: Deferred due to time constraints

TOPIC:

IX. FILE REVIEW

- 59. **Prescription Shoppe, Inc.**
- 60. **Anthony LaMonica**, PH12804, PHA-2012-0168

DISCUSSION: Board members had previously reviewed this matter on May 7, 2013. V. BERG updated the Board members that while the complaints were pending, the Board received a notice of closing by the Prescription Shoppe. Mr. LaMonica was the prior owner and prior manager of record. The premises were sold and a new license number was issued to the new owner who has hired a new manager of record.

ACTION 1: Motion by P. GANNON, seconded by J. DEVITA and voted unanimously to dismiss the complaint against the now closed pharmacy without prejudice.

ACTION 2: Motion by K. RYLE seconded by A. YOUNG to refer the complaint against Mr. LaMonica to the office of prosecution for the issuance of an order to show cause with authority to resolve the complaint with a consent agreement for Stayed Probation with the condition that he is required to complete 2 hours of additional CE in pharmacy law by December 31, 2013.

TOPIC:

IX. FILE REVIEW

- 61. **CVS #1026**, DS2824, SA-INV-2958
- 63. **CVS #751**, DS89718, SA-INV-3303

- 64. **Daniel Richard**, PH17676, PHA-2013-0011
- 65. **Frank Pallaria**, PH 18787, PHA-2013-0012
- 66. **Melinna Cepeda**, PT11631, SA-INV-3176 Daniel Richard
- 67. **Jessica Elliott**, PT8627, SA-INV-2951
- 68. **CVS #1026**, DS2824, SA-INV-2958
- 69. **Eaton Apothecary #2080**, DS3511, SA-INV-3172
- 70. **Elizabeth Murphy**, PT6241, SA-INV-3275

DISCUSSION: None

ACTION: Deferred due to time constraints

TOPIC:

X. FLEX SESSION

1. September MPJE Review at NABP

DISCUSSION: J. TRIFONE will go to Chicago and attend. There will be an item writing workshop in the Spring. K. RYLE will learn more and update the board.

ACTION: None.

TOPIC:

X. FLEX SESSION

2. Board Delegated Complaint Review

DISCUSSION: A. YOUNG will be serve as the Board member on the review team on July 10, 2013.

ACTION: None.

TOPIC:

X. FLEX SESSION

3. Recommendations of the Special Commission on the Oversight of Compounding Pharmacies

DISCUSSION: J.DEVITA started this discussion.

- a. #2f: J.DEVITA noted that per the recommendations, the Board should form advisory groups on the topic of developing a model for licensing out of state pharmacies. The group should consist of Board members and community members (stakeholders), sub specialty license (nuclear, long term care, veterinary). J. DEVITA asked Board members to identify anyone they know who would be interested on serving on these advisory groups.
- b. #2c: J.DEVITA noted that per the recommendations, the Board should form a separate advisory group to think about what one regulatory authority for all pharmacy practice (freestanding, hospital and physician's office settings) in the Commonwealth.

ACTION: None.

TOPIC:

X. FLEX SESSION

4. Discussion for next meeting

DISCUSSION: A. YOUNG recommended that the October NABP district meeting be addressed at the Board's September meeting and further suggested that the Board host a speaker on Veterinary pharmacy practice.

ACTION: None.

TOPIC:

XI. ADJOURNMENT

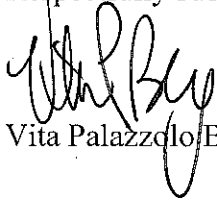
DISCUSSION: None

ACTION: Motion by E.TAGLIERI, seconded by P.GANNON, and voted unanimously to adjourn at 5:06 p.m.

LIST OF EXHIBITS USED DURING THE MEETING

1. Preliminary Agenda for the July 2, 2013 Regularly Scheduled Meeting.
2. Report of Applications approved pursuant to Licensure Policy 13-01
3. License Status Change Request: Mona Lissa Frain
4. License Status Change Request: Michelle McCrea
5. License Status Change Request: John C. Carey, III
6. Investigative Report in the Matters of Medi-Son Solutions Pharmacy (PHA-2013-0032), Christopher Le (PHA-2013-0034), Son H. Dinh (PHA-2013-0053)
7. Inspection Report, CarePro Pharmacy (DS89838)
8. Investigative Report in the Matters of West River Pharmacy (PHA-2012-0251) and Donald Montigny (PHA-2013-0055)
9. Investigative Report in the Matter of West River Pharmacy (SA-INV-2356)
10. Investigative Report in the Matter of Boston Home Infusion (PHA-2012-0248)
11. Investigative Report in the Matter of Critical Care Systems – Braintree (SA-INV-3252)
12. Investigative Report in the Matter of Critical Care Systems – Burlington (PHA-2012-0249)
13. Investigative Report in the Matter of Critical Care Systems – Shrewsbury (SA-INV-3280)
14. Investigative Report in the Matter of Home Infusion Solutions (PHA-2012-0255)
15. Investigative Report in the Matter of Home Solutions (SA-INV-3251)
16. Investigative Report in the Matters of Lenox Village Pharmacy (PHA-2012-0241) and Richard Mole (PHA-2013-0048)
17. Investigative Report in the Matter of Long Term Pharmacy Solutions, Inc. (SA-INV-3279)
18. Investigative Report in the Matter of New England Life Care (SA-INV-3260)
19. Investigative Report in the Matter of Partners of Massachusetts, LLC. (SA-INV-3281)
20. Investigative Report in the Matter of Preferred Pharmacy Solutions (SA-INV-3266)
21. Investigative Report in the Matter of Walgreens Infusion Services (PHA-2012-0253)
22. Investigative Report in the Matters of Apothecare of South Shore (PHA-2012-0252) and Geoffrey Peterson (PHA-2013-0063)
23. Investigative Report in the Matter of Johnson Compounding and Wellness Center (SA-INV-3262)
24. Investigative Report in the Matter of North Shore Pharmacy Services (PHA-2012-0250)
25. Investigative Report in the Matter of North Shore Pharmacy Services (SA-INV-3050)
26. Investigative Report in the Matters of Western Massachusetts Compounding Center (PHA-2012-0239) and John Horan (PHA-2013-0042)
27. Investigative Report in the Matter of Prescription Shoppe, Inc. (SA-INV-2718)
28. Investigative Report in the Matter of CVS Pharmacy #2138 (SA-INV-2274)
29. Power Point, Report of Office of Investigations, July 2, 2013

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Vita Palazzolo Berg". The signature is stylized with a large, looped initial "V" and a prominent "B" at the end.

Vita Palazzolo Berg, Assisting Board Counsel