

COMMONWEALTH OF MASSACHUSETTS

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

October 1, 2013
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

AGENDA

Time	#	Item	Exhibits	Staff Contact
8:30	I.	CALL TO ORDER		
8:30	II.	APPROVAL OF AGENDA		
8:45	III.	M.G.L. c. 112, § 65C SESSION	CLOSED SESSION	
9:00	IV.	<p>EXECUTIVE SESSION</p> <p>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.</p> <p>Specifically, the Board will discuss and evaluate the <u>Good Moral Character</u> as required for registration for the following applicants:</p> <p>a. Derek J. Hiett, applicant for pharmacy internship registration and NAPLEX/MPJE examination and licensure;</p> <p>b. Lauren A. Sibley, applicant for pharmacy internship registration and NAPLEX/MPJE examination and licensure</p> <p>2. Specifically, the Board will discuss and evaluate the reputation, character, physical condition or mental health, rather than professional competence, of the following individual:</p> <p>a. John O'Sullivan, PH18979, Request for Pharmacist Reinstatement</p> <p>b. Lidia Ramos, PH25003, Request for Termination of Probation</p> <p>c. Daniel S. Bugajski, PH20363, Request for Termination of Probation</p> <p>3. Approval of prior executive session minutes in accordance with M.G.L. ch.30A, § 22(f) for sessions held during the September 10, 2013 meeting.</p>	CLOSED SESSION	

9:30	V.	APPROVAL OF BOARD MINUTES <ol style="list-style-type: none"> 1. June 4, 2013 Regularly Scheduled Meeting 2. July 2, 2013 Regularly Scheduled Meeting 3. September 10, 2013 Regularly Scheduled Meeting 	Minutes	V. Berg
9:45	VI.	REPORTS <ol style="list-style-type: none"> 1. Applications approved pursuant to Licensure Policy 13-01 2. Plans of Correction reviewed pursuant to Enforcement Policy 13-02 	Reports	M. Cittadino H.Engman
10:00	VII.	FILE REVIEW <ol style="list-style-type: none"> 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. CVS #751, DS89718, SA-INV-3303 8. Janet Mary Robert, PH22670, PHA-2013-0026 9. Walgreens #3469, DS2593, PHA-2012-0083 10. Adam Deletetsky, PH27726, PHA-2012-0175 11. Matthew Shea, PH27752, PHA-2012-0176 12. Courtney Torres, PT6162, PHA-2012-0177 13. Elizabeth Murphy, PT6241, SA-INV-3275 14. Yenesh Groom, PT5355, PHA-2012-0224 15. Donald Montigny, PH22029, PHA-2013-0055 16. Freedom Fertility Pharmacy, DS89717, SA-INV-4069 17. Freedom Fertility Pharmacy, DS89717, SA-INV-2818 18. Freedom Fertility Pharmacy, DS89717, SA-INV-3257 19. Brian Marquis, PH23304, SA-INV-4124 20. Dung Nguyen, PH21900, PHA-2013-0057 21. Angela Burnham, PH25973, PHA-2013-0056 22. Care Point Partners, DS89801, PHA-2012-0256 23. Richard Wagner, Jr, PH22708, PHA-2013-0065 24. Sullivan's Healthcare, DS3335, PHA-2012-0240 25. Timothy Fensky, PH22090, PHA-2013-0041 26. The Whittier Pharmacist, DS2587, PHA-2012-0238 27. Ralph Luciano, PH18388, PHA-2013-0044 28. Oncomed, DS89702, PHA-2012-0236 29. Pamela Mortland, PH18776, PHA-2013-0043 30. Kimberly Gould, PH27266, PHA-2013-0067 31. North Shore Pharmacy Services, DS3458, PHA-2012-0250 32. Frederick L. Rowe, JR, PH16931, PHA-2013-0069 33. Boston Home Infusion, DS2623, SA-INV-4190 34. Melinna Cepeda, PT11631, SA-INV-3176 35. Eaton Apothecary #2080, DS3511, SA-INV-3172 36. Henry Pelletier, PH15436, PHA-2012-0151 37. Michael Graham, PH232447, PHA-2013-0003 	Investigation Reports	S. Penta W. Frisch L. McKenna C. Lathum V. Berg
12:00	X.	LUNCH		

4:00	XI.	APPLICATIONS 1. 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 795) Compounding Room 2. 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 Rooms 3. Fox's Drug Store 416 Watertown Street, Newton Application for new community pharmacy	Applications and supporting documents	M. Cittadino
4:30	XII.	FLEX SESSION 1. 2014 Board Calendar 2. Introduction to Secure Email 3. Items for the next meeting		
5:00	XIII.	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, October 1, 2013

Board Members Present

Karen Ryle, RPh, President-Elect
Anita Young, RPh, EdD, Secretary
Jane F. Franke, RN, MHA
Patrick M. Gannon, RPh, MS, FABC (8:45)
Anthony Perrone, RPh, MD, MBA
Edmund Taglieri, RPh, MSM, NHA
Richard Tinsley, MBA, MEd
Joanne Trifone, RPh

Board Members Not Present

James T. DeVita, RPh, President

Board Staff Present

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

Board Staff Not Present

TOPIC:

I. CALL TO ORDER

DISCUSSION: A quorum of the Board was present. 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. J.

LAVERY welcomed the new executive director of the Board, D. SENCABAUGH.

ACTION: At 8:35 a.m. K. RYLE, President-elect, called the October 1, 2013, meeting of the Board of Registration in Pharmacy to order.

TOPIC:

II. APPROVAL OF AGENDA

DISCUSSION: Board members reviewed the tentative agenda. V. BERG announced that certain items will be deferred to the November Meeting, including File Review 2 & 3 (CVS 1871 and Bhandari). There were no items added to the Flex Session.

ACTION: Motion by, J. TRIFONE, 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

ACTION: Motion by E. TAGLIERI seconded by J. FRANKE and passed by unanimous roll call vote to enter into M.G.L. c. 112, § 65C Session at 8:38 a.m. K. RYLE: yes; J. TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; J. FRANKE: yes; A. PERRONE: yes; R. TINSLEY: yes.

M.G.L. c. 112, § 65C SESSION (8:38 – 9:18 a.m.)

TOPIC:

IV. EXECUTIVE SESSION

DISCUSSION: None

ACTION: Motion by E. TAGLIERI seconded by P. GANNON and passed by unanimous roll call vote to enter into the Executive Session at 9:20 a.m. K. RYLE: yes; J. TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; J. FRANKE: yes; P. GANNON: yes; A. PERRONE: yes; R. TINSLEY: yes.

EXECUTIVE SESSION (9:20 – 10:10 a.m.)

BREAK (10:10 – 10:23 a.m.)

CONTINUED EXECUTIVE SESSION (10:23 – 10:32 a.m.)

RE-ENTER OPEN SESSION 10:32 a.m.

TOPIC:

V. APPROVAL OF BOARD MINUTES

A. June 4, 2013 Regularly Scheduled Meeting

DISCUSSION: V. BERG presented the minutes of the June 4, 2013 Regularly Scheduled Meeting.

ACTIONS: Motion by P. GANNON, seconded by J. TRIFONE, and voted unanimously, to approve the minutes of the June 4, 2013 Regularly Scheduled Meeting, with no changes.

B. July 2, 2013 Regularly Scheduled Meeting

DISCUSSION: V. BERG presented the minutes of the July 2, 2013 Regularly Scheduled Meeting.

ACTIONS: Motion by J. TRIFONE, seconded by E. TAGLIERI, and voted unanimously, to approve the minutes of the July 2, 2013 Regularly Scheduled Meeting, with changes to correct typographical errors as noted.

C. September 10, 2013 Regularly Scheduled Meeting

DISCUSSION: V. BERG presented the minutes of the September 10, 2013 Regularly Scheduled Meeting.

ACTIONS: Motion by P. GANNON, seconded by J. TRIFONE, and voted unanimously, to approve the minutes of the June 4, 2013 Regularly Scheduled Meeting, with no changes.

TOPIC:

VI. REPORTS

1. Applications approved pursuant to Licensure Policy 13-01

DISCUSSION: M. CITTADINO noted that there were four (4) new community pharmacies, two (2) community pharmacy relocations, one (1) certificate of fitness, forty-nine (49) changes of manager, six (6) renovations or expansions, and five (5) store closing applications which were approved, as documented in her report.

ACTION: So noted.

VI. REPORTS

2. Plans of Correction reviewed pursuant to Enforcement Policy 13-02

DISCUSSION: H. ENGMAN indicated that four (4) Plans of Correction had been submitted and approved as documented in her report.

ACTION: So noted.

TOPIC:

VII. FILE REVIEW

1. Michael Dubay (PH16047), PHA-2012-0129

DISCUSSION:

V. BERG presented the above-referenced matter to the Board. This is a new complaint for failure to comply with a 2009 consent agreement (resolving a prior complaint). A letter was sent by the Board in May, 2012 with no response from the licensee.

ACTION: Motion by J. TRIFONE, seconded by A. YOUNG, and voted unanimously, 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, to accept a voluntary surrender of license until such time as the respondent meets the requirements in the 2009 agreement and submits evidence demonstrating that he is otherwise up to date on continuing education requirements.

TOPIC:

VII. FILE REVIEW

4. CVS 1861 (DS2078), PHA-2012-0220

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. This complaint involves a Pharmacy Services Associate (sales associate) who was allowed behind the counter as a "technician-in-training" where she had access to and diverted controlled substances. In fact, the individual was a previously registered technician with an expired registration. The store self-reported the incident.

ACTION: Motion by K. RYLE, seconded by A. YOUNG, and voted unanimously, 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, resolution with a consent agreement for stayed probation, whose terms require the drug store to provide the board with (1) a job description for its PSAs, (2) a policy that ensures PSAs do not provide pharmacy services and have access to controlled substances, and (3) a policy to check the registration status for persons hired as PSAs and/or as technicians in training.

TOPIC:

VII. FILE REVIEW

5. CVS 8437 (DS3549), PHA-2012-0244

DISCUSSION:

This complaint alleged a confidentiality violation by the pharmacy for sharing patient information with Brigham and Women's Hospital as part of a study. Upon investigation it was determined that no patient data was supplied by the pharmacy.

ACTION: Motion by A. YOUNG, seconded by J. FRANKE, and voted unanimously, to dismiss this complaint with no violation.

TOPIC:

VII. FILE REVIEW

6. **Ashley Lanzisera** (PT7549), PHA-2012-0260

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. During a biannual inventory it was discovered that over 1,500 tablets of buprenorphine, a CIII controlled substance, were missing. The licensee voluntarily admitted to taking approximately 500 tablets.

ACTION: Motion by J. TRIFONE, seconded by A. YOUNG, and voted unanimously, 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, resolution via a consent agreement for surrender of the respondent's registration. The motion further directed the Executive Director of the Board will write a letter to the pharmacy concerning the burden of responsibility to better control inventory.

TOPIC:

VII. FILE REVIEW

7. **CVS 751** (DS89718), SA-INV-3303

DISCUSSION:

C. LATHUM presented the above-referenced matter to the Board. A front-store supervisor, on receipt of deliveries, would place controlled substances into inventory. Over 3,000 hydrocodone a CIII controlled substance, were found to be missing. The supervisor was observed diverting (security camera). The relatively new MOR terminated the employee and appropriately reported the loss. The plan of correction involved the CVS Loss Prevention Manager, implemented a weekly inventory of hydrocodone, are reaffirmed the policy to not allow non-licensed personnel access to any medication.

ACTION: Motion by P. GANNON, seconded by J. FRANKE, and voted unanimously, to convert the staff assignment to an open complaint and then to dismiss this complaint with no violation on the part of the drug store.

TOPIC:

VII. FILE REVIEW

8. **Janet May Robert** (PH22670), PHA-2013-0026

DISCUSSION:

V. BERG presented the above-referenced matter to the Board. This individual entered into a consent agreement for a reprimand in 2009 that included the requirement that she retake the MPJE. She has not submitted documentation to the Board that she has completed this requirement.

ACTION: Motion by P. GANNON, seconded by J. FRANKE, and voted unanimously, 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, to accept a surrender of license until such time as the licensee can demonstrate compliance with the original consent agreement and is up-to-date with CE requirements.

TOPIC:

VII. FILE REVIEW

9. **Walgreens 3469** (DS2593), PHA-2012-0083

DISCUSSION:

B. FRISCH presented the above-referenced matter to the Board. A prescription for the 250 mg strength of divalproex (Depakote) was incorrectly entered into the pharmacy computer system as 500 mg by a pharmacy technician (see File Review #12), order entry checked by a data review pharmacist (see File Review #10), and the finished prescription checked by a product review pharmacist (see File Review #11). The patient reported no adverse effects. The inspector indicated that the pharmacy implemented a good corrective action plan.

RECUSAL: J. TRIFONE

ACTION: Motion by K. RYLE, seconded by P. GANNON, and voted unanimously, to dismiss this complaint with no violation by the drug store.

TOPIC:

VII. FILE REVIEW

10. Adam Deletesky (PH27726), PHA-2012-0175

DISCUSSION:

The Board discussed the facts of this complaint about this data review pharmacist whose duty it is to check the order entry of the pharmacy technician (see File Review #9 & #12). The technician's order entry mistake was not caught by this data review pharmacist.

RECUSAL: J. TRIFONE

ACTION: Motion by K. RYLE, seconded by A. YOUNG, and voted unanimously 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, to authorize resolution with a consent agreement for a 3 month stayed probation, requiring that he take two CE contact hours in medication error prevention and report the error to ISMP.

TOPIC:

VII. FILE REVIEW

11. Matthew Shea (PH27752), PHA-2012-0176

DISCUSSION:

The Board discussed the facts of this complaint about this product review pharmacist who checked the final prescription (see File Review #9). The responsibility of this position is to compare the contents of the prescription to the prescription label. At this point in the process the product review pharmacist does not have immediate access to the prescription and would be unable to catch the order entry error.

RECUSAL: J. TRIFONE

ACTION: Motion by E. TAGLIERI, seconded by P. GANNON, and voted unanimously, to dismiss this complaint for no violation.

TOPIC:

VII. FILE REVIEW

12. Courtney Torres (PT6162), PHA-2012-0177

DISCUSSION:

The Board discussed the facts of this complaint about this pharmacy data entry technician who incorrectly entered a prescription order into the pharmacy computer system (see File Review #9).

RECUSAL: J. TRIFONE

ACTION: Motion by A. YOUNG, seconded by P. GANNON, and voted 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, to authorize resolution with a consent agreement for a 3 month stayed probation, requiring that she take two CE contact hours in medication error prevention. Motion opposed by E. TAGLIERI.

TOPIC:

VII. FILE REVIEW

13. Elizabeth Murphy (PT6241), SA-INV-3275

DISCUSSION:

A patient had been filling prescriptions at Alexander's Pharmacy for many years. Alexander's Pharmacy did not stock prescribed supplies. The pharmacy technician at Walgreens refused to fill supplies unless the patient transferred their prescriptions to Walgreen, indicating that Walgreens would take the chance of Medicare non-reimbursement if the prescriptions were transferred. The Board was cognizant that the filling of prescriptions for durable medical equipment and supplies is not within its jurisdiction. In addition, the Board noted that the

MOR for the pharmacy was aware of this interaction. The complaint was opened against this technician because she was the individual named by the patient-complainant.

RECUSAL: J. TRIFONE

ACTION: Motion by P. GANNON, seconded by E. TAGLIERI, and voted unanimously, to close the staff assignment and refer to the Office of the Attorney General for review of any potential unfair business practices.

TOPIC:

VII. FILE REVIEW

14. Yenesh Groom (PT5355), PHA-2012-0224

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. This individual has been a pharmacy technician for 8 years and self-reported that she had worked 8 shifts with a lapsed license. She indicated that she did not receive the Board generated reminder (mailed 90 days prior to a birthday). The Board credited the self-report, noting that it might not have otherwise learned of the unlicensed practice.

ACTION: Motion by A. YOUNG, seconded by P. GANNON, and voted unanimously, to dismiss the complaint with no violation.

TOPIC:

VII. FILE REVIEW

15. Donald Montigny (PH22029), PHA-2013-0055

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. This individual was the new Manager of Record at West River Pharmacy at the time of the board's inspection that resulted in a cease and desist order. He was not the MOR at the time that the attestation was signed, but had only been at the pharmacy for a matter of weeks. He has been instrumental in implementing the pharmacy's Plan of Correction.

ACTION: Motion by J. TRIFONE, seconded by P. GANNON, and voted unanimously, to dismiss the complaint with no violation.

TOPIC:

VII. FILE REVIEW

16. Freedom Fertility (DS89717), SA-INV-4069

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. On May 1, 2013, Freedom Fertility self-reported an abnormal result of particulate found in parenteral progesterone in ethyl oleate. The patient and prescriber were notified; there were no reports of adverse reactions. All lots of progesterone in ethyl oleate were quarantined; prescribers were notified and samples sent to an outside testing laboratory. The particulate appears to be bits of stopper material that may have broken off.

Freedom Fertility has voluntarily discontinued production of progesterone in oil. The MOR was aggressive in quarantining and testing, and stopped high-risk compounding. The product in question passed the USP standard test for particulate matter. No regulatory or USP violations were observed during the site visit by Board investigators that occurred following the report.

ACTION: Motion by E. TAGLIERI, seconded by A. YOUNG, and voted unanimously, to close this staff assignment with no violation noted.

TOPIC:

VII. FILE REVIEW

17. Freedom Fertility (DS89717), SA-INV-2818

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. This staff assignment arose when an inspection revealed the use of shared space for clerical/billing activities for this drug store and the related discount drug store. The pharmacy implemented a satisfactory plan of correction; the shared space no longer exists. The pharmacy is a separate and secured space.

ACTION: Motion by J. TRIFONE, seconded by E. TAGLIERI, and voted unanimously, to close this staff assignment with discipline not warranted.

TOPIC:

VII. FILE REVIEW

18. Freedom Fertility (DS89717), SA-INV-3257

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. This staff assignment related to a November 27, 2012 unannounced sterile compounding inspection. No violations were observed during the inspection.

ACTION: Motion by _____, seconded by _____, and voted unanimously, to close this staff assignment with no violation noted.

TOPIC:

VII. FILE REVIEW

19. Brian Marquis (PH23304), SA-INV-4124

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. This pharmacist was the Manager of Record at the time of the November 27, 2012 unannounced sterile compounding inspection described in File Review #18. No violations were observed during the inspection.

ACTION: Motion by E. TAGLIERI, seconded by A. YOUNG, and voted unanimously, to close this staff assignment with no violation noted.

LUNCH (12:10 – 1:14)

TOPIC:

VII. FILE REVIEW

20. Dung Nguyen (PH21900), PHA-2013-0057

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. This individual was a pharmacist at Infusion Resources, a sterile compounding pharmacy that has since voluntarily surrendered their license due to grossly unsanitary conditions. H. ENGMAN noted that the Board has not taken action against pharmacists other than the MORs at other sterile compounding pharmacies and that Mr. Nguyen was not employed on a full time basis. However, the inspector noted that the unsanitary conditions were so overt that Mr. Nguyen should have known that the facility was not compliant with USP <797> criteria.

ACTION: Motion by P. GANNON, seconded by A. YOUNG, and voted unanimously, to refer this complaint to the Office of Prosecution with authorization in the alternative to resolve the complaint with a consent agreement for a 3 month stayed probation requiring 5 contact hours of continuing education on the topic of sterile compounding.

TOPIC:

VII. FILE REVIEW

21. Angela Burnham (PH25973), PHA-2013-0056

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. This individual was on the roster of staff pharmacists at Infusion Resources, a sterile compounding pharmacy that has since voluntarily surrendered their license (see File Review #20). However, further investigation revealed that this individual had ceased her employment with the pharmacy several months prior to the inspection.

ACTION: Motion by P. GANNON, seconded by J. FRANKE, and voted unanimously, to dismiss the complaint with no violation.

TOPIC:

VII. FILE REVIEW

22. Care Point Partners (DS89801), PHA-2012-0256

BORP Regularly Scheduled Session

Preliminary Agenda

October 1, 2013

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. This pharmacy was not operational when inspected and never dispensed a sterile compounded prescription. The Board inspection revealed that the pharmacy, although it never dispensed a sterile compounded product, was not compliant. They installed a temporary, modular clean room and completed a Plan of Correction. The facility was sold to NE Home Therapies.

ACTION: Motion by J. TRIFONE, seconded by A. YOUNG, and voted unanimously, to dismiss the complaint with no violation.

TOPIC:

VII. FILE REVIEW

23. Richard Wagner, Jr. (PH22708), PHA-2013-0065

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. Mr. Wagner was the Manager of Record at Care Point Partners Pharmacy (see File Review #22) and signed an attestation that indicated the pharmacy was compliant with USP <797> criteria. The Board inspection revealed that the pharmacy, although it never dispensed a sterile compounded product, was not compliant.

ACTION: Motion by J. TRIFONE, seconded by J. FRANKE, and voted unanimously, to refer this complaint to the Office of Prosecution with authorization in the alternative to resolve the complaint with a consent agreement for stayed probation requiring that the registrant complete 5 contact hours of continuing education on the topic of sterile compounding within 90 days.

TOPIC:

VII. FILE REVIEW

24. Sullivan's Healthcare (DS3335), PHA-2012-0240

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. This pharmacy was inspected on 12/11/12 and raised concerns about containment and storage of hazardous substances. The pharmacy voluntarily ceased production of high-risk level sterile products (hydroxyprogesterone). A follow-up inspection on 6/27/13 confirmed that no high-risk level sterile compounding was occurring. The pharmacy implemented a plan of correction for low and medium risk sterile compounding, and negative pressure storage for hazardous <795> materials.

ACTION: Motion by A. YOUNG, seconded by J. TRIFONE, and voted unanimously, to dismiss the complaint with no disciplinary action warranted.

TOPIC:

VII. FILE REVIEW

25. Timothy Fensky (PH22090), PHA-2013-0041

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. Mr. Fensky is the Manager of Record at Sullivan's Healthcare (see File Review #24) and determined that the pharmacy could not safely compound high-risk level sterile products. He successfully transitioned those patients to obtain their prescriptions at an approved sterile compounding pharmacy.

ACTION: Motion by A. YOUNG, seconded by E. TAGLIERI, and voted unanimously, to dismiss the complaint with no disciplinary action warranted.

TOPIC:

VII. FILE REVIEW

26. The Whittier Pharmacist (DS2587), PHA-2012-0238

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. A Board inspection on November 28 & 29, 2012 indicated that the pharmacy was not in compliance with USP <797> criteria. An order to cease and desist was issued. Consistent with the Plan of Correction (POC) the room has been reengineered. 2 large

scale containment hoods have been installed for low and medium risk level products, standard operating procedures (SOPs) have been written and implemented.

ACTION: Motion by P. GANNON, seconded by J. FRANKE, and voted unanimously, to refer this complaint to the Office of Prosecution with authorization in the alternative to resolve the complaint with a consent agreement for a one year probation with the requirement that all staff pharmacists and pharmacy technicians complete 5 CEUs on the topic of compounding sterile products.

TOPIC:

VII. FILE REVIEW

27. Ralph Luciano (PH18388), PHA-2013-0044

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. Mr. Luciano is the Manager of Record at The Whittier Pharmacist (see File Review #26) and signed an attestation indicating that the pharmacy complied with USP <797> criteria. A Board inspection on November 28 & 29, 2012 showed that the pharmacy was not compliant. An order to cease and desist from sterile compounding was issued.

He successfully transitioned prescriptions to an approved sterile compounding pharmacy (CAPS) and coordinated implementation of the POC.

ACTION: Motion by P. GANNON, seconded by A. PERRONE, and voted unanimously, to refer this complaint to the Office of Prosecution with authorization in the alternative to resolve the complaint with a consent agreement for a one year probation with the requirement that Mr. Luciano also complete 5 CEUs in compounding sterile products.

TOPIC:

VII. FILE REVIEW

28. Oncomed (DS89702), PHA-2012-0236

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. The complaint raised an employee safety issue arising numerous safety hazards pertaining to the storage and handling of hazardous medications. The hazardous medications were not segregated, contained, or stored under negative pressure. A cease and desist order was issued. The pharmacy implemented a plan of correction that addressed the storage and safe handling issues. The cease and desist order was subsequently lifted.

ACTION: Motion by J. FRANKE, seconded by P. GANNON, and voted unanimously, to dismiss the complaint with no disciplinary action warranted.

TOPIC:

VII. FILE REVIEW

29. Pamela Mortland (PH18776), PHA-2013-0043

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. Ms. Mortland is the Manager of Record at Oncomed (see File Review #28) and was unfamiliar with the USP <797> requirements for storage of hazardous medications to protect employees from unintended exposure.

ACTION: Motion by P. GANNON, seconded by A. YOUNG, and voted unanimously to refer this complaint to the Office of Prosecution with authorization in the alternative to resolve the complaint with a consent agreement for three months stayed probation with the requirement that she take five CE contact hours in USP <797> compounding sterile products.

TOPIC:

VII. FILE REVIEW

30. Kimberly Gould (PH27266), PHA-2013-0067

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. Ms. Gould was the Manager of Record at New England Home Therapies at the time of the unannounced sterile compounding inspection on December

17 & 18, 2012. While some violations were observed during the inspection, the violations did not present an immediate threat to public health or safety and were remedied in a timely manner through a plan of correction.
ACTION: Motion by K. RYLE, seconded by E. TAGLIERI, and voted unanimously to dismiss the complaint with no disciplinary action warranted.

TOPIC:

VII. FILE REVIEW

31. North Shore Pharmacy Services (DS3458), PHA-2012-0250

DISCUSSION:

C. LATHUM and W. FRISCH presented the above-referenced matter to the Board. The complaint was the result of a December 2012 Board inspection that identified multiple issues related to USP <797> as well as unverified medication kits and vaccine storage requirements. The pharmacy's plan of correction was developed in conjunction with ISMP consultants and approved on 4/9/13. Re-inspections on 8/23/13 and 9/6/13 identified that the plan of correction was implemented.

ACTION: Motion by J. TRIFONE, seconded by E. TAGLIERI, and voted unanimously, to refer this complaint to the Office of Prosecution with authorization in the alternative to resolve the complaint with a consent agreement for 3 months stayed probation, and requiring all staff pharmacists and pharmacy technicians to complete five CE contact hours in compounding sterile products (USP <797>), to be completed in 90 days.

TOPIC:

VII. FILE REVIEW

32. Frederick Rowe, Jr. (PH16931), PHA-2013-0069

DISCUSSION:

C. LATHUM and W. FRISCH presented the above-referenced matter to the Board. Mr. Rowe is the Manager of Record at North Shore Pharmacy Services (see File Review #31) and was unfamiliar with some of the USP <797> requirements.

ACTION: Motion by K. RYLE, seconded by A. YOUNG, and voted unanimously to refer this complaint to the Office of Prosecution with authorization in the alternative to resolve the complaint with a consent agreement for 3 months stayed probation, and require that Mr. Rowe to complete five CE contact hours in USP <797> compounding sterile products.

TOPIC:

VII. FILE REVIEW

33. Boston Home Infusion (DS2623), SA-INV-4190

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. This pharmacy self-reported abnormal test results. The testing company sent a microbiologist; the infusion pump and hood were replaced, and a corrective action plan implemented.

ACTION: Motion by J. TRIFONE, seconded by A. YOUNG, and voted unanimously, to close this staff assignment with no violation noted.

TOPIC:

VII. FILE REVIEW

34. Melinna Cepeda (PT11631), SA-INV-3176

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. A Walmart pharmacy reported the termination of a pharmacy technician for gross misconduct and refusal to submit to a drug screen.

ACTION: Motion by P. GANNON, seconded by A. YOUNG, and voted unanimously, to close this staff assignment with no violation noted.

TOPIC:

VII. FILE REVIEW

35. Eaton Apothecary #2080 (DS3511), SA-INV-3172

DISCUSSION:

W. FRISCH presented the above-referenced matter to the Board. This pharmacy self-reported to the DEA that a prescriber's DEA number had expired and that 17 prescriptions had been filled before the expiration was noted. The Board did not feel that the pharmacy had responsibility to confirm the status of a prescriber's DEA.

ACTION: Motion by J. TRIFONE, seconded by A. YOUNG, and voted unanimously, to close this staff assignment with no disciplinary action warranted.

TOPIC:

VII. FILE REVIEW

36. Henry Pelletier (PH15436), PHA-2012-0051

DISCUSSION:

Mr. Pelletier is a pharmacist who is registered in multiple states. He was disciplined in one state (CT) and did not disclose this to another state (ME) which led to discipline in the second state.

ACTION: Motion by P. GANNON, seconded by J. FRANKE, and voted unanimously, to refer this complaint to the Office of Prosecution with authorization in the alternative to resolve the complaint with a consent agreement for a reprimand with the precondition that Mr. Pelletier shows that he is in compliance with the requirements in all states in which he is registered.

TOPIC:

VII. FILE REVIEW

37. Michael Graham (PH232447), PHA-2013-0003

DISCUSSION:

Mr. Graham is a pharmacist who is registered in multiple states, and received a letter of caution from North Carolina related to the checking the preparation of chemotherapy. He failed to verify that the actual ingredients were correct. Mr. Graham self-reported to the MA Board within 60 days.

ACTION: Motion by K. RYLE, seconded by P. GANNON, and voted unanimously, and voted unanimously to dismiss the complaint with no disciplinary action warranted.

BREAK (2:52 – 3:00 p.m.)

TOPIC:

VIII. APPLICATIONS

A. Applications for Expansion

1. Acton Compounding Pharmacy (DS2731), 563 Mass Ave, Acton, MA 01720

DISCUSSION: Owner and MOR Saad Dino appeared and presented his application for expansion requests approval to build a non-sterile (USP <795>) compounding area, expanding the space from 470 to 800 ft². The pharmacy prepares specialty products for hospital patients (CH, MGH, TMC), pediatric autistic patients, and ships to patients in ME, NH, and RI. The only controlled substance is lorazepam gel. The MOR is a member of PCCA and has taken over 20 hours of CE on non-sterile compounding. Plans have been approved by the Town of Acton.

ACTION: Motion by K. RYLE, seconded by P. GANNON, and voted unanimously to approve the application, pending a successful inspection.

TOPIC:

VIII. APPLICATIONS

A. Applications for Expansion

- 2. Boulevard Pharmaceutical Compounding Center (DS2943), 149 Shrewsbury Street, Worcester, MA**

DISCUSSION: Mr. Joseph Rosetti (MOR) and pharmacist Gene Svirskiy presented an application for expansion and approval to build a non-sterile (USP <795>) and sterile (USP <797>) compounding areas. The plans call for four rooms; 1) a negative pressure room for non-sterile, low, medium, and high-risk level hazardous products, 2) a positive pressure room for non-sterile, low, medium, and high-risk level non-hazardous products, 3) a negative pressure room for sterile, low, medium, and high-risk level hazardous products, 4) a positive pressure room for sterile, low, medium, and high-risk level non-hazardous products. He indicated that the pharmacy wants to meet the needs of patients from local hospitals. Sterile compounding had ceased prior to the USP <797> attestations. Mr. Rosetti has extensive compounding experiences; is a member of PCCA; will be attending Baxter training, and has contracted for staff training through Medisca. Plans have been approved by the City of Worcester.

ACTION: Motion by J. TRIFONE, seconded by A. YOUNG, and voted unanimously to approve the application, pending a successful inspection.

TOPIC:

VIII. APPLICATIONS

B. Applications for a New Store

- 1. Fox's Drug Store, 120 Forbes Boulevard, Suite 400, Mansfield, MA**

RECUSAL: A. YOUNG

DISCUSSION: Rany Zaky (MOR); owners, Jon Cincotta, Mark Foskin, and Kenneth Minty, and legal counsel, Paul Garbarini, Esq. presented this application for a new store. The pharmacy is located in a free-standing building with motion detectors, contacts on the doors and glass-break sensors. CII's and hydrocodone are under lock.

The pharmacy would be open 7 days/week and is the only pharmacy in a 5-mile radius. Plans are to compound non-sterile "simple" preparations and package combination medications for the elderly. The pharmacy would service group homes in the area and include DME products.

ACTION: Motion by J. TRIFONE, seconded by J. FRANKE, to approve this application, pending a successful inspection.

TOPIC:

IX. FLEX SESSION

1. 2014 Board Calendar: A list of tentative dates was distributed.
2. Secure email was discussed. Since SFED is in transition, more details will be provided. Some members voiced preference for hard copies.
3. Deferred items will be placed on the agenda of the November meeting. A discussion of deferring item at an upcoming meeting.
4. ACPE providers are no longer providing statements of attendance. Documentation is available on the NABP CPE Monitor. The Board would like to phase out approval of CE programs.
5. An NABP taskforce is investigating virtual wholesalers.
6. M. CITTADINO and D. SENCABAUGH will report on the status of FAQs.
7. Members requested a summary of the pharmacy bill, once it is signed into law.
8. Creation of a Board of Registration in Pharmacy *Strategic Plan* was suggested.

TOPIC:

XVI. ADJOURNMENT

DISCUSSION: None

ACTION: Motion by J. FRANKE, seconded by A. PERRONE, and voted unanimously to adjourn at 4:00 p.m.

LIST OF EXHIBITS USED DURING THE MEETING

1. Preliminary Agenda for the October 1, 2013 Regularly Scheduled Meeting.
2. Draft Minutes of the June 4, 2013 Regularly Scheduled Meeting
3. Draft Minutes of the July 2, 2013 Regularly Scheduled Meeting
4. Draft Minutes of the September 10, 2013 Regularly Scheduled Meeting
5. Report of Applications approved pursuant to Licensure Policy 13-01
6. Report of Plans of Correction reviewed pursuant to Enforcement Policy 13-02
7. Investigative Report in the Matter of Michael Dubay, PH16047, PHA-2012-0129
8. Investigative Report in the Matter of CVS #1861, DS2078, PHA-2012-0220
9. Investigative Report in the Matter of CVS #8437, DS3549, PHA-2012-0244
10. Investigative Report in the Matter of Ashley Lanzisera, PT7549, PHA-2012-0260
11. Investigative Report in the Matter of CVS #751, DS89718, SA-INV-3303
12. Investigative Report in the Matter of Janet Mary Robert, PH22670, PHA-2013-0026
13. Investigative Report in the Matters of Walgreens #3469, DS2593, PHA-2012-0083, Adam Deletetsky, PH27726, PHA-2012-0175, Matthew Shea, PH27752, PHA-2012-0176 and Courtney Torres, PT6162, PHA-2012-0177
14. Investigative Report in the Matter of Elizabeth Murphy, PT6241, SA-INV-3275
15. Investigative Report in the Matter of Yenesh Groom, PT5355, PHA-2012-0224
16. Investigative Report in the Matter of Donald Montigny, PH22029, PHA-2013-0055
17. Investigative Report in the Matter of Freedom Fertility Pharmacy, DS89717, SA-INV-4069
18. Investigative Report in the Matter of Freedom Fertility Pharmacy, DS89717, SA-INV-2818
19. Investigative Report in the Matters of Freedom Fertility Pharmacy, DS89717, SA-INV-3257 and Brian Marquis, PH23304, SA-INV-4124
20. Investigative Report in the Matter of Dung Nguyen, PH21900, PHA-2013-0057
21. Investigative Report in the Matter of Angela Burnham, PH25973, PHA-2013-0056
22. Investigative Report in the Matter of Care Point Partners, DS89801, PHA-2012-0256

23. Investigative Report in the Matter of Richard Wagner, Jr, PH22708, PHA-2013-0065
24. Investigative Report in the Matters of Sullivan's Healthcare, DS3335, PHA-2012-0240 and Timothy Fensky, PH22090, PHA-2013-0041
25. Investigative Report in the Matters of the Whittier Pharmacist, DS2587, PHA-2012-0238 and Ralph Luciano, PH18388, PHA-2013-0044
26. Investigative Report in the Matters of Oncomed, DS89702, PHA-2012-0236 and Pamela Mortland, PH18776, PHA-2013-0043
27. Investigative Report in the Matter of Kimberly Gould, PH27266, PHA-2013-0067
28. Investigative Report in the Matters of North Shore Pharmacy Services, DS3458, PHA-2012-0250 and Frederick L. Rowe, JR, PH16931, PHA-2013-0069
29. Investigative Report in the Matter of Boston Home Infusion, DS2623, SA-INV-4190
30. Investigative Report in the Matter of Melinna Cepeda, PT11631, SA-INV-3176
31. Investigative Report in the Matter of Eaton Apothecary #2080, DS3511, SA-INV-3172
32. Investigative Report in the Matter of Henry Pelletier, PH15436, PHA-2012-0151
33. Investigative Report in the Matter of Michael Graham, PH232447, PHA-2013-0003
34. Application for approval of expansion: Acton Compounding Pharmacy, DS2731
35. Application for approval of expansion: Boulevard Pharmaceutical Compounding Company, DS2943
36. Application for new community pharmacy: Fox's Drug Store
37. 2014 Board meeting calendar

Respectfully submitted,

Vita Palazzolo Berg, Board Counsel