

COMMONWEALTH OF MASSACHUSETTS

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

June 4, 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.	ADJUDICATORY SESSION	CLOSED SESSION	
9:30	IV.	M.G.L. c. 112, § 65C SESSION	CLOSED SESSION	
9:40	V.	APPROVAL OF BOARD MINUTES May 7, 2013 Regularly Scheduled Meeting	Minutes	V. Berg
9:45	VI.	REPORTS 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

9:50.	VII.	<b>APPLICATIONS</b>  <i>A. Applications for New Stores</i> 1. <b>Caring Pharmacy</b> (Appearance) 2288 Dorchester Avenue, Dorchester, MA 02124  2. <b>Home Care Pharmacy</b> (Appearance) 104 Newbury Street Peabody, MA. 01960  3. <b>Harbor Community Health Center Hyannis Pharmacy</b> (Appearance) 123 Summer Street, Suite 365, Worcester, MA. 01608  4. <b>IVG Veterinary Compounding Pharmacy</b> (Appearance) 25 Armory Street, Boston  5. <b>SJ Medsav Solutions</b> (Wholesale Distributor Appearance) 121 Brick Kiln Road, Suite 235, Chelmsford, MA 02184  <i>B. Application for Relocation of Wholesale Distributor</i> 1. <b>Safecor Health, LLC</b> 317 New Boston Street, Suite 100 Woburn, MA 01801  <i>C. Application for Transfer of Ownership</i> 1. <b>Compare Quality Pharmacy Inc. (DS89761)</b> 664 Main Street, Worcester, MA 01610 (new owner: <b>Compare Quality Pharmacy Corp.</b> )	Applications	M. Cittadino
11:40	VIII.	<b>LICENSE STATUS CHANGE REQUESTS</b>  1. Mona-Lissa (Frain) Mathews (PH2522) Reinstatement 2. Michelle McCrea, (PH20675) Termination of Probation	Applications	M. Cittadino
11:40	IX.	<b>LUNCH</b>		

12:40	X.	<b>FILE REVIEW</b> <ol style="list-style-type: none"> <li>1. Prescription Shoppe, Inc., DS6654, PHA-2012-0092</li> <li>2. A. LaMonica, PH12804, PHA-2012-0168</li> <li>3. E. Varkonyi, PH20141, PHA-2013-0033</li> <li>4. Pawtucket, DS789, PHA-2013-0045</li> <li>5. J. Floria, PH19594, PHA-2013-0046</li> <li>6. R. Audet, PH13088, PHA-2013-0047</li> <li>7. Infusion Resource, DS89704, PHA-2012-0217</li> <li>8. L. Yacubian, PH26457, PHA-2012-0216</li> <li>9. A. Burnham, PH25973, PHA-2013-0056</li> <li>10. D. Nguyen, PH21900, PHA-2013-0057</li> <li>11. M. Scott, PH23306, PHA-2013-0058</li> <li>12. J. Pace, PT4707, PHA-2013-0059</li> <li>13. Village Fertility, DS89658, PHA-2013-0020</li> <li>14. S. Levine, PH16082, PHA-2013-0051</li> <li>15. Baystate Home Infusion Resp. Services, DS3300, PHA-2012-0247</li> <li>16. W. Loomis, PH18751, PHA-2012-0049</li> <li>17. The Whittier Pharmacist, DS3587, PHA-2012-0238</li> <li>18. R. Luciano, PH18388, PHA-2013-0044</li> <li>19. West River Pharmacy, DS3572, PHA-2012-0251</li> <li>20. D. Montigny, PH22029, PHA-2013-0055</li> <li>21. OncoMed, DS89702, PHA-2012-0236</li> <li>22. P. Mortland, PH18776, PHA-2013-0043</li> <li>23. Medi-Son Solutions, DS89749, PHA-2013-0032</li> <li>24. Christopher Le, PH233115, PHA-2013-0034</li> <li>25. CarePro Pharmacy, DS89838, PHA-2013-0052</li> <li>26. Son Dinh, PH26530, PHA-2013-0053</li> <li>27. Randolph New Store Application</li> <li>28. M. Dubay, PH16047, PHA-2012-0129</li> <li>29. CVS #1871, DS3286, PHA-2012-0041</li> <li>30. G. Bhandari, PT12190, PHA-2012-0166</li> <li>31. K. Morgan, PH23952, PHA-2012-0162</li> <li>32. K. Morgan, PH23952, PHA-2013-0006</li> <li>33. CVS #140, DS2729, PHA-2012-0188</li> <li>34. CVS #1861, DS2078, PHA-2012-0220</li> <li>35. CVS #8437, DS3549, PHA-2012-0244</li> <li>36. A. Lanzisera, PT7549, PHA-2012-0260</li> <li>37. Y. Groom, PT5355, PHA-2012-0224</li> <li>38. Walgreens #3469, DS2593, PHA-2012-0083</li> <li>39. A. Deletetsky, PH27726, PHA-2012-0175</li> <li>40. M. Shea, PH27752, PHA-2012-0176</li> <li>41. C. Torres, PT6162, PHA-2012-0177</li> <li>42. Walgreens #4393, DS2882, PHA-2012-0172</li> <li>43. C. Sloltish, PH24826, PHA-2012-0223</li> <li>44. D. Gonzalez, PT7710, PHA-2013-0014</li> </ol>	Investigation Reports for all complaints listed	S. Penta W. Frisch L. McKenna C. Lathum
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4:30	XI.	<b>FLEX SESSION</b> <ol style="list-style-type: none"> <li>1. NABP Election Announcements</li> <li>2. Items for the next meeting</li> <li>3. Scheduling of additional meetings prior to next regularly scheduled meeting <ol style="list-style-type: none"> <li>a. Board Delegated Complaint Review</li> <li>b. Plan of Correction Approval</li> </ol> </li> </ol>		
5:00	XII.	<b>ADJOURNMENT</b>		

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, June 4, 2013

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**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

**Board Members Not Present**

Patrick Gannon, RPh, MS

**Board Staff Present**

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

**Board Staff Not Present**

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**TOPIC:**

**I. CALL TO ORDER**

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

**ACTION:** At 8:35 a.m. J. DEVITA, President, called the June 4, 2013, meeting of the Board of Registration in Pharmacy to order.

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**TOPIC:**

**II. APPROVAL OF AGENDA**

**DISCUSSION:** Board members reviewed the tentative agenda. Items IX.1-2, XI.1-2, and XI.17-44 are deferred to a subsequent meeting because they require recusal by at least one board member which will bring members present to discuss and vote below quorum. Items XI.17-22 and XI.51-54 are deferred to a subsequent meeting. The upcoming District 1 & 2 Boards of Pharmacy meeting was added to the Flex Session.

ACTION: Motion by, E. TAGLIERI, seconded by A. YOUNG, and voted unanimously to approve the agenda with changes.

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TOPIC:

**III. ADJUDICATORY SESSION**

DISCUSSION: None

ACTION: Motion by A. YOUNG seconded by J. FRANKE and passed by unanimous roll call vote to enter into Adjudicatory Session at 8:39 a.m.

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ADJUDICATORY SESSION (8:40 – 9:03 a.m.)

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TOPIC:

**IV. M.G.L. c. 112, § 65C SESSION**

DISCUSSION: None

ACTION: Motion by \_\_\_\_\_ seconded by \_\_\_\_\_ and passed by unanimous roll call vote to enter into M.G.L. c. 112, § 65C Session at 9:03 a.m.

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M.G.L. c. 112, § 65C SESSION (9:04 – 9:15 a.m.)

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TOPIC:

**V. APPROVAL OF BOARD MINUTES**

1. May 7, 2013 Regularly Scheduled Meeting

DISCUSSION: V. BERG presented the minutes of the May 7, 2013 Regularly Scheduled Meeting.

ACTION: Motion by J. TRIFONE, seconded by E. TAGLIERI, and voted unanimously, to approve the minutes of the May 7, 2013 Regularly Scheduled Meeting with no changes.

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TOPIC:

**VI. REPORTS**

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

DISCUSSION: M. CITTADINO noted that there was one (1) new community pharmacy, one (1) community pharmacy relocation, seventeen (17) changes of manager, four (4) renovation or expansion, and six (6) store closing applications which were approved.

ACTION: So noted.

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TOPIC:

**VI. REPORTS**

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

DISCUSSION: H. ENGMAN indicated that no Plans of Correction had been approved pursuant to Enforcement Policy 13-02.

ACTION: So noted.

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TOPIC:

**VII. POLICIES**

**1. Proposed amendments to Enforcement Policy 13-02**

DISCUSSION: V. BERG presented proposed revisions to Implementation of Plans of Correction, Enforcement Policy 13-02. Proposed changes included (1) aligning the policy with existing regulatory provisions concerning time limit for registrant's submission of a plan of correction; (2) adapting review team and process depending on whether the plan of correction is directly related to a cease and desist or order of summary suspension; and (3) allowing for review team to request registrant to resubmit plan of correction where appropriate.

ACTION: Motion by J. TRIFONE, seconded by J. FRANKE and voted unanimously to adopt proposed amendments to Enforcement Policy 13-02, Implementation of Plans of Correction.

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TOPIC:

**VIII. APPLICATIONS**

**A. Applications for a New Store**

**1. Caring Pharmacy**

**2288 Dorchester Avenue, Dorchester, MA 02124**

DISCUSSION: Tuan Dang, proposed Manager of Record, and Christine Phan, proposed owner, presented the pharmacy's application for a new store and answered the questions of the Board. The proposed MOR provided the board with a brief history of his prior experience. He is a 2007 graduate and has worked as a pharmacist at the outpatient pharmacy at the Boston Medical Center and at Caring Pharmacy, Springfield, MA, which is also owned by Christine Phan. The proposed pharmacy intends to offer prescription delivery services and blister packaging at no extra charge to customers. The pharmacy does not intend to perform sterile compounding. They plan to offer immunizations eventually but not initially. Tuan Dang and Christine Phan are not currently enrolled in the Prescription Monitoring Program; Board members recommended that each immediately register. The proposed pharmacy does not require regulatory waivers.

ACTION: Motion by E. TAGLIERI, seconded by J. FRANKE, and voted unanimously to conditionally approve the application subject to a successful inspection and demonstration of enrollment in PMP.

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TOPIC:

**VIII. APPLICATIONS**

**A. Applications for a New Store**

**2. Home Care Pharmacy**

**104 Newbury Street, Peabody, MA 01960**

DISCUSSION: Neil Welch, proposed Manager of Record, presented the pharmacy's application for a new store and answered the questions of the Board. The proposed MOR has previous experience as a pharmacist in retail pharmacy and with selling medical equipment. This proposed pharmacy would specialize in clients requiring home care and would display medical equipment products it can offer to clients. The proposed pharmacy does not require regulatory waivers and does not plan to perform sterile compounding.

ACTION: Motion by K. RYLE, seconded by E. TAGLIERI, and voted unanimously to conditionally approve the application subject to a successful inspection.

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TOPIC:

**VIII. APPLICATIONS**

**A. Applications for a New Store**

**3. Harbor Community Health Center Hyannis Pharmacy**

**123 Summer Street, Suite 365, Worcester, MA 01608**

DISCUSSION: Benjamin Sturm, proposed Manager of Record, and Victor Fournier, consultant, presented the pharmacy's application for a new store and answered questions of the Board. This will be the third pharmacy within Harbor Health Services, Inc. Mr. Fournier has served as a consultant performing pharmacy compliance audits using 247 CMR for 21 other locations. Mr. Sturm is a 2012 graduate and does not have prior experience as an MOR. The proposed pharmacy intends to dispense 340B medications to Health Center patients and will maintain a separate inventory. While the other two Harbor Health pharmacies maintain a virtual separation, this location may implement a physical separation. The pharmacy does not plan to perform sterile or non-sterile compounding and does not require regulatory waivers.

ACTION: Motion by E. TAGLIERI, seconded by J. FRANKE, and voted unanimously to conditionally approve the application, pending a successful inspection.

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TOPIC:

**VIII. APPLICATIONS**

**A. Applications for a New Store**

**4. IVG Veterinary Compounding Pharmacy**

**25 Armor Street, Boston**

DISCUSSION: Justin McDowell, proposed Manager of Record, Patrick Welch, Medical Director at the co-owned clinic in Woburn, and Nick Capone, from Springer Architects, presented the pharmacy's application for a new store and answered the questions of the Board. The proposed MOR described his training and experience, which includes over ten years of experience practicing sterile and non-sterile compounding. This proposed pharmacy intends to perform both sterile (primarily eye drops) and non-sterile compounding for veterinary patients only; the pharmacy does not intend to compound medications for humans. The proposed pharmacy is associated with IVG Hospitals, Inc., McDowell and Welch advised that the pharmacy would compound and dispense strictly on the basis of a prescription, and would not provide the veterinary hospitals with stock. The pharmacy will also not stock commercially available medications. Board members could not ascertain whether ownership of the pharmacy would be in compliance with 247 CMR 6.01(3), specifically, whether any of the current shareholders hold prescriptive privileges pursuant to current controlled substance and DEA registrations.

ACTION: Motion by E. TAGLIERI, seconded by A. YOUNG, and voted unanimously to conditionally approve the application, pending a successful inspection and pending the Board's receipt of documentation that ownership of the pharmacy will be in compliance with 247 CMR 6.01(3).



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**BREAK (10:05-10:15)**

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TOPIC:

**VIII. APPLICATIONS**

**A. Applications for a New Store**

**5. SJ Medsav Solutions (Wholesale Distributor)**

**121 Brick Kiln Road, Suite 235, Chelmsford, MA 02184**

DISCUSSION: Scot Finn and Melvin Sparkman, two of the proposed owners, presented a license application for a wholesale distributor and answered questions from the Board. SJ Medsav Solutions intends to operate as a virtual wholesaler. SJ Medsav would not hold any inventory itself, but would drop ship inventory held by other manufacturers or distributors to its customers. SJ Medsav indicated that its customers would be primarily the federal government (Department of Defense, Veterans Affairs) and hospitals. SJ Medsav Solutions intends to distribute primarily medical devices, Schedule VI medications and over the counter medications.

ACTION: Motion by J. DEVITA, seconded by E. TAGLIERI, and voted unanimously to take this application under advisement.

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TOPIC:

**VIII. APPLICATIONS**

**B. Applications for Relocation of Wholesale Distributor**

**1. Safecor Health, LLC (WD475)**

DISCUSSION: M. CITTADINO presented the application of Safecor Health, LLC for relocation to a new building in Woburn, MA.

ACTION: Motion by E. TAGLIERI, seconded by J. TRIFONE, and voted unanimously to conditionally approve the application for relocation, pending a successful inspection.

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**IX. LUNCH (11:41-12:40)**

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TOPIC:

**VIII. APPLICATIONS**

**C. Applications for Transfer of Ownership**

**1. Compare Quality Pharmacy Inc. (DS89761)**

DISCUSSION: M. CITTADINO presented the application for the transfer of ownership of "Compare Quality Pharmacy" from Compare Quality Pharmacy, Inc. (d/b/a Compare Quality Pharmacy) to Quality Pharmacy Corp. (also d/b/a Compare Quality Pharmacy). The MOR would remain the same, Olga Ozhovan.

ACTION: Motion by J. DEVITA, seconded by J. FRANKE, and voted unanimously to conditionally approve the application, pending a successful inspection.

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TOPIC:

**VIII. LICENSE STATUS CHANGE REQUESTS**

1. **Mona-Lissa (Frain) Mathews** (PH2522) Reinstatement

DISCUSSION: None.

ACTION: Deferred to subsequent Board meeting.

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TOPIC:

2. **Michelle McCrea** (PH20675) Termination of Probation

DISCUSSION: None.

ACTION: Deferred to subsequent Board meeting.

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TOPIC:

**X. FILE REVIEW**

1. Prescription Shoppe, Inc., DS6654, PHA-2012-0092
2. A. LaMonica, PH12804, PHA-2012-0168
23. Medi-Son Solutions, DS89749, PHA-2013-0032
24. Christopher Le, PH233115, PHA-2013-0034
25. CarePro Pharmacy, DS89838, PHA-2013-0052
26. Son Dinh, PH26530, PHA-2013-0053
27. CarePro, 1167 North Main Street, Randolph, MA New Store Application
28. M. Dubay, PH16047, PHA-2012-0129
29. CVS #1871, DS3286, PHA-2012-0041
30. G. Bhandari, PT12190, PHA-2012-0166
31. K. Morgan, PH23952, PHA-2012-0162
32. K. Morgan, PH23952, PHA-2013-0006
33. CVS #140, DS2729, PHA-2012-0188
34. CVS #1861, DS2078, PHA-2012-0220
35. CVS #8437, DS3549, PHA-2012-0244
36. A. Lanzisera, PT7549, PHA-2012-0260
37. Y. Groom, PT5355, PHA-2012-0224
38. Walgreens #3469, DS2593, PHA-2012-0083
39. A. Deletetsky, PH27726, PHA-2012-0175
40. M. Shea, PH27752, PHA-2012-0176
41. C. Torres, PT6162, PHA-2012-0177
42. Walgreens #4393, DS2882, PHA-2012-0172
43. C. Sloltish, PH24826, PHA-2012-0223
44. D. Gonzalez, PT7710, PHA-2013-0014

RECUSAL: Recusal by at least one Board member was appropriate in each of these matters, but recusal would have left the Board without a quorum.

ACTION: Discussion and action deferred to a subsequent Board meeting.

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TOPIC:

**X. FILE REVIEW**

17. The Whittier Pharmacist, DS3587, PHA-2012-0238
18. R. Luciano, PH18388, PHA-2013-0044
19. West River Pharmacy, DS3572, PHA-2012-0251
20. D. Montigny, PH22029, PHA-2013-0055
21. OncoMed, DS89702, PHA-2012-0236

- 22. P. Mortland, PH18776, PHA-2013-0043
- 51. IntegriScript, Inc., DS89726, SA-INV-3273
- 52. Jeanne M. Szwajkowski, PH27446, SA-INV-3980
- 53. Partners of Massachusetts LLC, DS3419, SA-INV-3281
- 54. David H. Huang, PH20989, SA-INV-3982

DISCUSSION: None.

ACTION: Discussion and action deferred to subsequent Board meeting.

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TOPIC:

**X. FILE REVIEW**

- 1. **E. Varkonyi**, PH20141, PHA-2013-0033

DISCUSSION: V. BERG presented the above-referenced matter. E. Varkonyi entered into a consent agreement with the Rhode Island Board of Pharmacy following a summary suspension of her license in that state. The summary suspension was based in part on the routine practice by Varkonyi, while acting in the capacity of MOR at a Rhode Island pharmacy, of accepting medications compounded by Massachusetts registrant Village Fertility which does not hold a non-resident registration in Rhode Island and then relabeling those medications and dispensing them such that they appeared to have been compounded in the Rhode Island pharmacy.

ACTION 2: Motion by J. DEVITA, seconded by A. YOUNG, to refer to office of prosecution for the issuance of an order to show cause. The motion further authorized, in the alternative, commencement of settlement negotiations for resolution of the complaint with a consent agreement for minimum of one year voluntary surrender, with conditions of reinstatement to include restoration of Varkonyi's Rhode Island license to good standing. Motion passed with all members in favor.

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TOPIC:

**X. FILE REVIEW**

- 2. **Pawtucket Pharmacy**, (DS789), PHA-2013-0045
- 3. **J. Floria**, (DS19594), PHA-2013-0046
- 4. **R. Audet**, (PH19594), PHA-2013-0047

DISCUSSION: These complaints arise from a single set of facts and were presented jointly to the Board by C. LATHUM. An inspection was initiated due to the probation monitor's concerns that the pharmacy and Mr. Audet were non-compliant with their probation agreement. Per the terms of that agreement, the pharmacy was prohibited from compounding practice and was required to complete appropriate disposal of certain hazardous substances on its premises. Investigators observed that the pharmacy was continuing to engage in compounding and had not followed through with disposal requirements. J. Floria, the MOR, indicated that the pharmacy owner, R. Audet, advised him that the pharmacy was permitted to engage in compounding. The Board recognized the influence of an owner over an MOR in a small retail pharmacy setting, but noted that it is still the professional responsibility of an MOR to ensure compliance.

ACTION 1: Motion by J. TRIFONE, seconded by A. YOUNG, and voted unanimously for Board to refer the complaint to the Office of Prosecution for issuance of an order to show cause, with authorization to settle with a consent agreement for permanent surrender of the pharmacy license.

ACTION 2: Motion by A. YOUNG seconded by E. TAGLIERI, and voted unanimously to refer the J. Floria matter to the Office of Prosecution for the issuance

of an order to show cause. The motion further authorized, in the alternative, commencement of settlement negotiations for resolution of the complaint by a consent agreement for probation for a minimum of one year with the terms to re-take the MPJE with a passing grade of 75% or higher, by the end of probation.

ACTION 3: Motion by E. TAGLIERI, seconded by J. FRANKE, and voted unanimously to refer the R. Audet matter to the Office of Prosecution for the issuance of an order to show cause and, in the alternative, authorization to settle the complaint with a consent agreement for voluntary surrender of license for a minimum of one year with the terms to re-take the MPJE with a passing grade of 75% or higher, as a condition of reinstatement.

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TOPIC:

**X. FILE REVIEW**

5. **Infusion Resource**, DS89704, PHA-2012-0217
6. **L. Yacubian**, (PH26457), PHA-2012-0216
7. **A. Burnham**, (PH25973), PHA-2013-0056
8. **D. Nguyen**, (PH21900), PHA-2013-0057
9. **M. Scott**, (PH23306), PHA-2013-0058
10. **J. Pace**, (PT4707), PHA-2013-0059

DISCUSSION: S. PENTA and L. MCKENNA presented the above-referenced matters to the Board. All six complaints arise from a single set of facts and were considered together. In October 2012, Board investigators conducted an unannounced sterile compounding inspection of Infusion Resources. The inspection revealed numerous USP 797 violations, including but not limited to, multiple surfaces in the clean room that were visible dirty. Additionally, investigators observed the HVAC system located directly above the clean room was malfunctioning and leaking water. The ceiling tiles in the clean room and below the HVAC system were covered in what appeared to be mold. Investigators noted that the conditions at Infusion Resources were the most unsanitary of any of the sterile compounding pharmacies that were inspected by Board Investigators in October, November, and December 2012. Investigators also observed other deficiencies, including, but not limited to, refrigeration, handwashing, training, and security. Following the inspection, the pharmacy voluntarily surrendered its Pharmacy Registration No. DS89704. H. ENGMAN advised the Board that the voluntary surrender agreement did not directly address the conditions, if any, under which Infusion Resources may be permitted to reinstate its license. Infusion Resources is currently closed. Pharmacist L. Yacubian was the Infusion Resources manager of record. That Board noted that, as MOR, L. Yacubian was responsible for the conditions of the pharmacy and the sterile compounding operations and expressed alarm that the MOR did not take actions to remedy unsanitary conditions that were clearly visible. Pharmacist M. Scott signed an attestation in October 2012 (prior to the inspection) stating that Infusion Resources was fully compliant with USP 797 sterile compounding standards. The Board expressed alarm that M. Scott signed the attestation of compliance when the conditions at the pharmacy were visibly unsanitary and out of compliance. Pharmacy technician J. Pace performed sterile compounding; the Board noted that, as a technician, she was supervised and directed by pharmacists. Pharmacists A. Burnham and D. Nguyen were *per diem* and/or part time employees at the pharmacy. The Board noted that A. Burnham's and D. Nguyen's roles and responsibilities with regard to sterile compounding operations at Infusion Resources are not presently known.

ACTION 1: Motion by J. DEVITA, seconded by E. TAGLIERI, and voted unanimously to accept the voluntary surrender of Infusion Resources' pharmacy license, per the terms of the voluntary surrender agreement. The motion further stated the Board could not envision any circumstances under which it would approve reinstatement and/or an application by the same owners to manage and operate a new community pharmacy. Motion passed with all members in favor.

ACTION 2: Motion by J. DEVITA, seconded by K. RYLE, to refer the matter of Y. Yacubian to the Office of Prosecution for the issuance of an order to show cause. The motion further authorized resolution of the complaint with a consent agreement including the following terms (1) one year voluntary surrender followed by a three years probation; (2) completion of a Board-approved, certificate continuing education program on sterile compounding and retaking the MPJE with a passing score of 75% prior to reinstatement; and (3) L. Yacubian may not serve as MOR while on probation. Motion passed with all members in favor.

ACTION 3: Motion by J. DEVITA, seconded by A. YOUNG, and voted unanimously to request further investigation regarding the roles and responsibilities, including the dates of employment, for A. Burnham.

ACTION 4: Motion by J. DEVITA, seconded by A. YOUNG, and voted unanimously to request further investigation regarding the roles and responsibilities, including the dates of employment, for D. Nguyen.

ACTION 5: Motion by E. TAGLIERI, seconded by J. FRANKE, to refer the matter of M. Scott to the Office of Prosecution for the issuance of an order to show cause. The motion further authorized resolution of the complaint with a consent agreement including the following terms (1) one year voluntary surrender followed by a three years probation; (2) completion of a Board-approved, certificate continuing education program on sterile compounding and retaking the MPJE with a passing score of 75% prior to reinstatement; and (3) M. Scott may not serve as MOR while on probation. Motion passed with all members in favor.

ACTION 6: Motion by K. RYLE, seconded by A. YOUNG and voted unanimously to refer the matter of J. Pace to the Office of Prosecution for the issuance of an order to show cause, or in the alternative, to approve settlement with a consent agreement for stayed probation for six months with the condition that, during the time of probation, that the licensee completes one continuing education unit in Sterile Compounding that is within the scope of practice for a pharmacy technician.

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TOPIC:

**X. FILE REVIEW**

11. **Village Fertility**, (DS89658), PHA-2013-0020

12. **S. Levine**, (PH16082), PHA-2013-0051

DISCUSSION: S. PENTA and L. MCKENNA presented the above-referenced matters to the Board. Both complaints were considered together. S. Levine is the MOR for the Village Fertility Pharmacy. Village Fertility received an unannounced sterile compounding inspection in December 2012. Violations were noted and the pharmacy was required to submit a plan of correction. In February 2013, the Board received a report from Village Fertility regarding possible contamination of sterile compounded products. The pharmacy was directed to cease and desist all sterile compounding and to quarantine all sterile compounded products. Board investigators, along with an FDA investigator, inspected the pharmacy and observed particulate matter in multiple vials of sterile compounded products as well as USP 797 violations.

Notably, the contaminated products involved high risk sterile compounding. Village Fertility recalled several lots of affected products, which had been shipped into many states. The pharmacy did not hold a required non-resident pharmacy license in some of the state into which it shipped product. The Board expressed dismay that some of the violations cited during the December 2012 inspection had not been corrected by the time of the February 2013 inspection. H. ENGMAN advised the Board that the pharmacy's plan of correction was approved and the cease and desist notice was rescinded. The pharmacy advised the board that it would refrain from all high risk sterile compounding.

ACTION 1: Motion by J. DEVITA, seconded by E. TAGLIERI, and voted unanimously to refer the matter of Village Fertility to the Office of Prosecution for the issuance of an order to show cause. The motion further authorized, in the alternative, commencement of settlement negotiations for resolution of the complaint by a consent agreement for three years probation with terms to include an agreement to refrain from any and all high-risk sterile compounding, unless and until the pharmacy receives written approval from the Board and that the pharmacy provide documentation of additional training and education for all employees regarding sterile compounding and USP <797> annually during the probationary period.

ACTION 2: Motion by E. TAGLIERI, seconded by A. YOUNG, and voted unanimously to refer the matter of S. Levine to the Office of Prosecution for the issuance of an order to show cause. The motion further authorized, in the alternative, commencement of settlement negotiations for resolution of the complaint by a consent agreement for three years probation with terms to include completion of a Board-approved, certificate continuing education program on sterile compounding.

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TOPIC:

**X. FILE REVIEW**

**13. Baystate Home Infusion Respiratory Services, (DS3300), PHA-2012-0247**

DISCUSSION: C. LATHUM presented the above-referenced matter to the Board. Baystate Home Infusion received an unannounced sterile compounding inspection in December 2012. Numerous UPS 797 violations were observed; as a result, Baystate was directed to cease and desist all sterile compounding. H. ENGMAN and J. SCEPPA advised the Board the Baystate submitted a thorough, detailed, and comprehensive written plan of correction, which in some cases went above and beyond the minimum requirements of USP 797. The written plan of correction was approved. The pharmacy was re-inspected in May 2013 and noted to have satisfactorily implemented its plan of correction which included substantial reconstruction of the facility and implementation of robust documentation systems. The cease and desist notice was rescinded shortly thereafter.

ACTION: Motion by J. DEVITA, seconded by E. TAGLIERI, and voted unanimously to refer the matter to the Office of Prosecution for issuance of an order to show cause. The motion further authorized, in the alternative, commencement of settlement negotiations for resolution of the complaint by a consent agreement for one year probation and the condition that the pharmacy refrains from any and all high risk sterile compounding, unless and until the pharmacy receives written approval from the Board to perform high risk sterile compounding.

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**BREAK (2:39 – 2:54)**

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**TOPIC:**

**X. FILE REVIEW**

14. **W. Loomis**, (PH18751), PHA-2012-0049

DISCUSSION: C. LATHUM presented the above-referenced matter to the Board. W. Loomis is the MOR at Baystate Home Infusion and signed the attestation stating the facility was in compliance with USP <797>. As described above, during the December 2012 unannounced inspection of Baystate, investigators observed this pharmacy to be non-compliant with USP <797>. The Board noted that as MOR, W. Loomis was responsible for the conditions of the pharmacy and the sterile compounding operations. J. DEVITA stated that pharmacists on probation are generally not permitted to serve as MOR during the probation. K. RYLE noted that Baystate's plan of correction was very good and that it would be undesirable if W. Loomis was no longer the MOR, as he has played a role in implementing the plan of correction and bringing the pharmacy into compliance.

ACTION: Motion by E. TAGLIERI, and seconded by J. FRANKE, and voted unanimously to refer the matter to the Office of Prosecution for issuance of an order to show cause. The motion further authorized, in the alternative, commencement of settlement negotiations for resolution of the complaint by a consent agreement for one year probation with the condition that W. Loomis may not serve as MOR during the probationary period.

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**TOPIC:**

**X. FILE REVIEW**

15. **Diamoto Medical, Inc.**, (DS89700), SA-INV-3265

16. **Eve M. Lopriore**, (PH25758), SA-INV-3981

DISCUSSION: S. PENTA presented the above-referenced matter to the Board. Both staff assignments were considered together. Diamoto Medical, Inc. received an unannounced sterile compounding inspection in December 2012. Eve M. Lopriore was the MOR of the pharmacy. The pharmacy had very few USP 797 violations, and the violations that were cited were remedied during the inspection.

ACTION 1: Motion by J. DEVITA, and seconded by J. FRANKE, and voted unanimously to close the Diamoto staff assignment with discipline not warranted.

ACTION 2: Motion by J. DEVITA, and seconded by J. FRANKE, and voted unanimously to close the Eve M. Lopriore staff assignment with discipline not warranted.

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**TOPIC:**

**X. FILE REVIEW**

17. **Cape Cod Home Infusion Services**, (DS89832), SA-INV-3272

18. **Joseph M. Ferraro**, (PH26968), SA-INV-3983

DISCUSSION: C. LATHUM presented the above-referenced matters to the Board. Both staff assignments were considered together. Cape Cod Home Infusion received an unannounced sterile compounding inspection in December 2012. Joseph M. Ferraro was the MOR of the pharmacy. The pharmacy had very few USP 797 violations and the violations that were cited were remedied in an expeditious manner.

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**BREAK (2:39 – 2:54)**

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TOPIC:

**X. FILE REVIEW**

**14. W. Loomis, (PH18751), PHA-2012-0049**

DISCUSSION: C. LATHUM presented the above-referenced matter to the Board. W. Loomis is the MOR at Baystate Home Infusion and signed the attestation stating the facility was in compliance with USP <797>. As described above, during the December 2012 unannounced inspection of Baystate, investigators observed this pharmacy to be non-compliant with USP <797>. The Board noted that as MOR, W. Loomis was responsible for the conditions of the pharmacy and the sterile compounding operations. J. DEVITA stated that pharmacists on probation are generally not permitted to serve as MOR during the probation. K. RYLE noted that Baystate's plan of correction was very good and that it would be undesirable if W. Loomis was no longer the MOR, as he has played a role in implementing the plan of correction and bringing the pharmacy into compliance.

ACTION: Motion by E. TAGLIERI, and seconded by J. FRANKE, and voted unanimously to refer the matter to the Office of Prosecution for issuance of an order to show cause. The motion further authorized, in the alternative, commencement of settlement negotiations for resolution of the complaint by a consent agreement for one year probation with the condition that W. Loomis may not serve as MOR during the probationary period.

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TOPIC:

**X. FILE REVIEW**

**15. Diamoto Medical, Inc., (DS89700), SA-INV-3265**

**16. Eve M. Lopriore, (PH25758), SA-INV-3981**

DISCUSSION: S. PENTA presented the above-referenced matter to the Board. Both staff assignments were considered together. Diamoto Medical, Inc. received an unannounced sterile compounding inspection in December 2012. Eve M. Lopriore was the MOR of the pharmacy. The pharmacy had very few USP 797 violations, and the violations that were cited were remedied during the inspection.

ACTION 1: Motion by J. DEVITA, and seconded by J. FRANKE, and voted unanimously to close the Diamoto staff assignment with discipline not warranted.

ACTION 2: Motion by J. DEVITA, and seconded by J. FRANKE, and voted unanimously to close the Eve M. Lopriore staff assignment with discipline not warranted.

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TOPIC:

**X. FILE REVIEW**

**17. Cape Cod Home Infusion Services, (DS89832), SA-INV-3272**

**18. Joseph M. Ferraro, (PH26968), SA-INV-3983**

DISCUSSION: C. LATHUM presented the above-referenced matters to the Board. Both staff assignments were considered together. Cape Cod Home Infusion received an unannounced sterile compounding inspection in December 2012. Joseph M. Ferraro was the MOR of the pharmacy. The pharmacy had very few USP 797 violations and the violations that were cited were remedied in an expeditious manner.



ACTION 1: Motion by J. FRANKE, and seconded by A. YOUNG, and voted unanimously to close the Cape Cod Home Infusion staff assignment with discipline not warranted.

ACTION 2: Motion by E. TAGLIERI, and seconded by A. YOUNG, and voted Unanimously to close the Joseph M. Ferraro staff assignment with discipline not warranted.

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TOPIC:

**X. FILE REVIEW**

19. **Bio RX**, (DS89763), SA-INV-3231

20. **Gita Jafarzadeh-Hosseini**, (PH23416), SA-INV- 3983

DISCUSSION: L. MCKENNA presented the above-referenced matters to the Board. Both staff assignments were considered together. BioRX received an unannounced sterile compounding inspection in December 2012. Gita Jafarzadeh-Hosseini was the MOR of the pharmacy. Investigators presented the matters to the Board, noting that there were no USP 797 violations.

ACTION 1: Motion by A. YOUNG, and seconded by J. FRANKE, and voted unanimously to close the BioRX staff assignment with no violation noted.

ACTION 2: Motion by A. YOUNG, and seconded by E. TAGLIERI, and voted unanimously to close the Gita Jafarzadeh-Hosseini staff assignment with no violation noted.

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TOPIC:

**X. FILE REVIEW**

21. **Coram Specialty Infusion**, (DS3601), SA-INV-3232

22. **John. M. Consolettii**, (PH16527), SA-INV-3984

DISCUSSION: L. MCKENNA and S. PENTA presented the above-referenced matters to the Board. Both staff assignments were considered together. Coram Specialty Infusion received an unannounced sterile compounding inspection in December 2012. John M. Consolettii was the MOR of the pharmacy. Investigators presented the matters to the Board, noting that there were no USP 797 violations.

ACTION 1: Motion by J. DEVITA, and seconded by A. YOUNG, and voted unanimously to close the Coram Specialty Infusion staff assignment with no violation noted.

ACTION 2: Motion by A. YOUNG, and seconded by E. TAGLIERI and voted unanimously to close the John M. Consolettii staff assignment with no violation noted.

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**XI. FLEX SESSION**

1. The next NABP District 1 (New England) meeting will be held from October 17-19, 2013 in Bar Harbor, Maine. This meeting is being hosted by Maine. The position for Secretary/Treasurer is available due the retirement of individuals holding these positions. K. RYLE offered to distribute a preliminary agenda. It was suggested by a few Board members that the district consider combining these positions and that A. YOUNG be considered for this position.
2. Items for Next Meeting: none
3. Scheduling of additional meetings prior to next regularly scheduled meeting:
  - a. Board Delegated Complaint Review: A. YOUNG volunteered for June (J. TRIFONE will participate and J. FRANKE will observe) E. TAGLIERI will

- participate for July.
- b. Plan of Correction Approval: Board staff will send board members out the dates of meeting for a time when the investigators are available.

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TOPIC:

**XII. ADJOURNMENT**

DISCUSSION: None

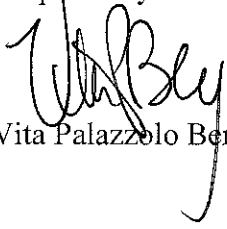
ACTION: Motion by K. RYLE, seconded by J. DEVITA, and voted unanimously to adjourn at 3:32 p.m.

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LIST OF EXHIBITS USED DURING THE MEETING

1. Preliminary Agenda for the June 4, 2013 Regularly Scheduled Meeting.
2. Proposed Minutes of the May 7, 2013 Regularly Scheduled Meeting.
3. Report of Applications approved pursuant to Licensure Policy 13-01
4. Proposed revision to Enforcement Policy 13-02
5. Application to Manage and Operate a New Community Pharmacy: Caring Pharmacy.
6. Application to Manage and Operate a New Community Pharmacy: Home Care Pharmacy.
7. Application to Manage and Operate a New Community Pharmacy: Harbor Community Health Center Hyannis Pharmacy.
8. Application to Manage and Operate a New Community Pharmacy: IVG Veterinary Compounding Pharmacy.
9. Curriculum Vitae of Justin McDowell
10. IVG Veterinary Group Compounding Pharmacy Introduction
11. Application for License as a Wholesale Distributor: SJ Medsav Solutions.
12. Application for Relocation of Wholesale Distributor: Safecor Health, LLC.
13. Application for Transfer of Ownership: Compare Quality Pharmacy.
14. Rhode Island Board of Pharmacy Summary Suspension Order: E. Varkonyi, PH20141, PHA-2013-0033
15. Inspection Report: Pawtucket Pharmacy, (DS789), PHA-2013-0045; J. Floria, (DS19594), PHA-2013-0046; and R. Audet, (PH19594), PHA-2013-0046.
16. Inspection Report: Infusion Resource, DS89704, PHA-2012-0217; L. Yacubian, (PH26457), PHA-2012-0216; A. Burnham, (PH25973), PHA-2013-0056; D. Nguyen, (PH21900), PHA-2013-0057; M. Scott, (PH23306), PHA-2013-0058; and J. Pace, (PT4707), PHA-2013-0059 (materials include Attestation of Compliance and Voluntary Surrender Agreement)
17. Inspection Report: Village Fertility, (DS89658), PHA-2013-0020 and S. Levine, (PH16082), PHA-2013-0051.
18. Inspection Report: Baystate Home Infusion Respiratory Services, (DS3300), PHA-2012-0247 and W. Loomis, (PH18751), PHA-2012-0049.
19. Inspection Report: Diamoto Medical, Inc., (DS89700), SA-INV-3265 and Eve M. Lopriore, (PH25758), SA-INV-3981.
20. Inspection Report: Cape Cod Home Infusion Services, (DS89832), SA-INV-3272 and Joseph M. Ferraro, (PH26968), SA-INV-3983.
21. Inspection Report: Bio RX, (DS89763), SA-INV-3231 and Gita Jafarzadeh-Hosseini, (PH23416), SA-INV-3983.
22. Inspection Report: Coram Specialty Infusion, (DS3601), SA-INV-3232 and John. M. Consoletti, (PH16527), SA-INV-3984.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Vita Berg", written over the printed name.

Vita Palazzolo Berg, Assisting Board Counsel