

# COMMONWEALTH OF MASSACHUSETTS

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

May 5, 2015  
239 Causeway Street ~ Room 417 A&B  
Boston, Massachusetts 02114

### Agenda

Time	#	Item	Exhibits	Contact
8:30	I	<b>CALL TO ORDER</b>		
8:35	II	<b>APPROVAL OF AGENDA</b>		
8:40	III	<b>APPROVAL OF BOARD MINUTES</b> 1. Draft April 7, 2015 Regular Session Minutes 2. Draft April 28, 2015 Regular Session Minutes		
8:45	IV	<b>APPLICATIONS</b> 1. Genoa, A QoL Healthcare Co – New Community Pharmacy 2. Cardinal Health 414 – Renovation/Expansion 3. Highpoint Pharmacy – New Community Pharmacy 4. Skenderian Apothecary – Renovation/Expansion		
9:45	V	<b>REPORTS</b> <ul style="list-style-type: none"><li>• Applications approved pursuant to Licensure Policy 13-01</li><li>• Plans of Correction Associated with Compliance Inspections Reviewed Pursuant to Enforcement Policy 13-02.</li></ul>	Reports	R. Harris W. Frisch

9:45	VI	<p><b>FLEX SESSION</b></p> <ol style="list-style-type: none"> <li>1. Introduction of new Board Members: <ol style="list-style-type: none"> <li>a. Andrew Stein, PharmD, R.Ph.</li> <li>b. Phillippe Bouvier, BS, R.Ph</li> </ol> </li> <li>2. Guidelines for pharmacist continuing education: sterile and non-sterile compounding</li> <li>3. Advisory Committee / Sub-committee on abnormal results: update and summary of discussion following May 1, 2015 sub-committee meeting</li> <li>4. Pharmacy Advisory Committee meeting 5/29</li> <li>5. Inspector Training- FDA</li> <li>6. Additional Meetings</li> </ol>	OPEN SESSION	<p>D. Sencabaugh</p> <p>K. Barnes</p> <p>W. Frisch</p>
10:00	VII	<p><b>REGULATIONS:</b></p> <ol style="list-style-type: none"> <li>1. Proposed amendments to 247 CMR 9.00: Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies and Pharmacy Departments ;</li> <li>2. Proposed new regulation – 247 CMR 17.00: Sterile Compounding; introduction.</li> </ol>		<p>H. Engman</p> <p>W. Frisch K. Barnes</p>
12:00		<b>LUNCH BREAK</b>		

1:00	VIII	<p><b>FILE REVIEW</b></p> <ol style="list-style-type: none"> <li>1. PHA-2014-0164, Walgreens Infusion Services, DS3584</li> <li>2. PHA-2014-0245, Walgreens 2063, DS1741</li> <li>3. PHA-2014-0223, CVS 2878, DS3092</li> <li>4. PHA-2014-0270, Stacey St. Yves, PH24515.</li> <li>5. SA-INV-3396, Animal Pharmacy, DS3066</li> <li>6. SA-INV-6174, Village Fertility, DS89658</li> <li>7. SA-INV-6445, Kabafusion, DS89700</li> <li>8. SA-INV-6649, Home Solutions, DS89639</li> <li>9. PHA-2014-0209, BioRX, (DS89763)</li> <li>10. SA-INV-5040, Park Avenue Pharmacy, DS247</li> </ol>		
2:30	IX	<p><b>EXECUTIVE SESSION</b></p> <p>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 pending applicants.</p>	CLOSED SESSION	
3:30	X	<b>M.G.L. c. 112, § 65C SESSION</b>	<b>CLOSED SESSION</b>	
5:00	XI	<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**

**May 5, 2015**

**Board Members Present**

Patrick Gannon, RPh, MS, President  
Edmund Taglieri Jr., RPh, MSM, NHA  
President-elect  
Richard Tinsley, MBA, MEd., Secretary  
Timothy Fensky, RPh, FACA  
Garrett Cavanaugh, RPh  
Karen Conley, RN, DNP (arrived 9:15 AM)  
Susan Cornacchio, JD, RN.  
William Cox CPht  
Michael Godek, RPh  
Andrew Stein, Pharm D, R.Ph.  
Phillippe Bouvier, R.Ph.

**Board Members Not Present**

Catherine Basile, Pharm D, RPh

**Board Staff Present**

David Sencabaugh, RPh, Executive Director  
David Dunn, RPh, Associate Executive Director  
Heather Engman, JD, MPH Board Counsel  
Kelly Ann Barnes, JD, RPh, Director of Pharmacy  
Quality Assurance  
William Frisch, RPh, Director of Pharmacy Compliance  
Richard Harris, Program Analyst  
Monica Vasquez, Compliance Officer  
Colleen Collins, PharmD, RPh. Contract Investigator  
(James Lavery, JD, DHPL Director present through Cardinal renovation/expansion  
application vote)

**TOPIC: I**

**CALL TO ORDER**

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

**ACTION:** AT 8:30AM P.GANNON, called the May 5, 2015, meeting of the Board of Registration in Pharmacy to order. Quorum was established by roll call, P. GANNON;

Page 1 of 11

Minutes of the Regularly Scheduled Meeting held on May 5, 2015

Approved on June 2, 2015



yes, E.TAGLIERI; yes, R.TINSLEY; yes, P. BOUVIER; yes, G. CAVANAUGH; yes, S.CORNACCHIO; yes, W. COX; yes; T.FENSKY; yes; M. GODEK; yes, A. STEIN: yes. K.CONLEY was not present at roll call.

TOPIC II.

**APPROVAL OF AGENDA**

DISCUSSION: W. FRISCH noted that pharmacy complaint PHA-2014-0245, scheduled to be heard during File Review, against Walgreens 2063 would be deferred to a future meeting.

ACTION: Motion by T.FENSKY, seconded by R.TINSLEY, and voted unanimously to approval the agenda with the noted change.

TOPIC III.

**APPROVAL OF BOARD MINUTES**

1. Draft April 7, 2015, Regular Session Minutes

DISCUSSION: P. GANNON noted that the minutes of the Community Care Pharmacy motion to approve the application needed to include approval letter HCQ and policy and procedures for bed-side delivery to reflect the Board decision.

ACTION: Motion by M.GODEK, seconded by E.TAGLIERI, and voted unanimously to approve the Draft April 7, 2015, Regular Session Minutes with the noted change. R. TINSLEY, P. BOUVIER, and A.STEIN abstained from the vote on this matter. K.CONLEY was not present for the discussion or vote on this matter.

2. 1. Draft April 28, 2015, Regular Session Minutes

DISCUSSION: None

ACTION: Motion by E.TAGLIERI, seconded by T.FENSKY and voted unanimously to approve the Draft April 28, 2015, Regular Session Minutes. R.TISLEY, S. CORNACCHIO.P.BOUVIER and A.STEIN abstained from the vote of this matter. K.CONLEY was not present for the discussion or vote on this matter.

TOPIC IV.

**IV. APPLICATIONS**

8:35

**1. Genoa, a QoL Healthcare Co New Community Pharmacy 340 Maple Street, Suite 450, Marlborough, MA.**

DISCUSSION: Genoa was represented by pharmacist Jason Kan. Genoa is a closed door pharmacy, and will deliver to residential and group homes. They waived compounding, but neglected to submit a waiver request for 9.01(16), and will do so.

They will use traditional vials and "bingo cards" and plan to offer immunizations. Although closed on weekends, a phone number will be posted at the entrance, and patients and caregivers will be able to be covered for services off-hours. Patients have freedom of choice. Security was explained, and there will be a separate alarm system (separate from adjacent clinic),and security cameras.

Page 2 of 11

Minutes of the Regularly Scheduled Meeting held on May 5, 2015

Approved on June 2, 2015



ACTION: Motion by M. GODEK, seconded by, T. FENSKY, and voted unanimously to approve the license for this community pharmacy, pending successful inspection, and submission of proper waiver. K. CONLEY was not present for the discussion or vote of this matter.

TOPIC IV.:  
**APPLICATIONS**

**2. Cardinal Health 414, LLC. Renovation / Expansion** **TIME:8:46AM**  
**27 Sixth Road, Woburn**

DISCUSSION: Cardinal 414 is a nuclear pharmacy, represented by MOR Ann Marie Shea, R.Ph. and nuclear pharmacist Richard Green, who is from their Dublin, OH office. Cardinal wants to improve their resources to match their growing business, and were applying for approval to start construction on new inter-locking pass-throughs, and also adding hepa filters and additional return ducts. Work had not commenced as of Board time.

During a recent conference call with Cardinal 414, Director of Pharmacy Compliance William Frisch and Director of Quality Assurance Kelly Barnes, had been given an overview as to the plan for construction. While Frisch applauded the efforts of Cardinal to improve its space, he also had concerns about their intent to perform construction on weekends (up to 3 weekends), and resume compounding during the weekdays while construction was occurring. Frisch had several concerns, not the least of which involved the potential for particulate matter in the ISO 5 PEC. Green and Shea both spoke about coverage during the weekends handled by their Rhode Island and Connecticut facilities. Board Executive Director Sencabaugh suggested that they needed to have a continuity of care plan regardless, and if it is the CT and RI facilities, then they should consider using them for the entire process during construction and retesting.

Other concerns mentioned by Frisch and echoed by Barnes included the negative pressure issue involved with hazardous drugs, a refrigerator located in the ante room, and pass-throughs into unclassified space. Green and Shea explained the ultra-short BUDs and need for refrigerators in closest possible proximity to compounding areas. There was also discussion about compliance before, and after, USP 800 is finalized.

The outcome of the discussion left the Board requesting that Cardinal produce a written explanation of possible waiver requests, as well as responses to the board's concerns including the pass through to unclassified space, renovations, negative pressure, continuity of care, and the refrigerator in the anteroom. The plan would be to bring the matter back to the Board at the earliest possible time, and that would be the June 2<sup>nd</sup> Board meeting, all of this in the interest of patient safety.



**ACTION:** Motion by M. GODEK, seconded by E. TAGLIERI, and voted yes by all present for the entire discussion, to defer this application to the June 2<sup>nd</sup> meeting. K. CONLEY arrived just prior to the vote, but did not participate in the vote on this matter.

**TOPIC IV:  
APPLICATIONS**

**3. High Point Pharmacy New Community Pharmacy** **TIME: 9:15AM**  
**52 Oak Street, Middleboro**

**DISCUSSION:** High Point was represented by MOR Lila Lizotte, Management Consultant Ben Sturm of Integrated Pharmacy Services (IPS), Michael Tocco, CEO of IPS, and Mary Ann Frose Nursing Director of High Point.

Highpoint recently purchased a hospital in Middleboro, where they expect to have 72 inpatient beds and a hospital pharmacy. Located in the same building separated by a wall, they applied for a license to operate a retail pharmacy which would provide services to approximately 400 patients who are in “step-down” programs, and located throughout the State. The pharmacy will be 310 sq. ft. and have separate staff, security, and inventory. The pharmacy had originally applied for a compounding waiver, but since they anticipated the use of “compounding kits”, they withdrew the waiver and were reminded that a new scale would need to be NTEP compliant. There is a 24 hour phone service available for emergency after-hours needs. Patients would have freedom of choice.

**ACTION:** Motion by R. TINSLEY, seconded by G. CAVANAUGH, and voted unanimously, to approve the application for a new community drugstore, pending successful inspection, and appropriate waiver adjustments.

**TOPIC IV.:**  
**APPLICATIONS**

**4. Skenderian Apothecary Renovation / Expansion** **TIME:9:30AM**  
**1613 Cambridge St, Cambridge**

**DISCUSSION:** MOR Robert Skenderian, <795> Compounding consultant David Trinx, and Atty. Paul Garbarini, represented Skenderian. R. Skenderian explained that the purpose of the renovation was to “get back on track” with <795> (non-sterile) compounding. The renovation consists of several improvements, including 3 powder containment hoods; 1 dedicated to NIOSH drugs storage, 1 dedicated to NIOSH drugs compounding, and 1 for non-NIOSH drug compounding. Skenderian ceased compounding last year, in response to deficiencies found during inspection. Director of Pharmacy Compliance Frisch spoke about the substantial plan of correction action steps taken by the pharmacy since, and explained that the pharmacy has cooperated fully. There was a follow-up inspection performed by BOP Investigators last week, and it was determined that Skenderian is now in compliance. One concern that was brought up by Board staff and highlighted by member T. FENSKY, was the venting of the hoods when



compounding with NIOSH drugs, away from the room, and the fact that proposed regulations, if adopted, could possibly put the pharmacy out of compliance. The pharmacy was advised to consider that now, when it may be easier to plan.

**ACTION:** Motion by T. FENSKY, seconded by K. CONLEY, and voted unanimously, to approve the renovation, pending venting away from the room, and successful inspection.

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**BREAK**

**TIME: 9:37AM- 9:45AM**

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**TOPIC V.**  
**REPORTS**

**Applications Approved Pursuant to Licensure Policy 13-01** **9:45AM**

**DISCUSSION:** R HARRIS noted that during the past month there have been twenty nine (29) Change of Managers, seven (7) renovation/expansions and one (1) nuclear pharmacist..

**ACTION:** So noted

**Plans of Correction Associated With Compliance Inspections Reviewed Pursuant to Enforcement Policy 13-02** **9:47AM**

**DISCUSSION:** W. FRISCH reviewed the report informing the Board that seven hundred and eight (708) Plans of Corrections had been received and reviewed resulting from routine compliance inspections. The report summarized the top categories of regulatory deficiencies that were noted by compliance investigators. The Board was pleased to receive the report and appreciative of the information along with the number of inspections conducted.

**ACTION:** So noted

**TOPIC VI: FLEX SESSION**

**9:48AM**

1. Introduction of new Board of Registration in Pharmacy Members Andrew Stein and Philippe Bouvier, D.SENCABAUGH formerly introduced the new Board Members to the Board and the audience. D.SENCABAUGH informed all that each would be occupying the two (2) independent seats.

2. Guidelines for Pharmacist Continuing Education: Sterile and Non-Sterile Complex compounding: D SENCABAUGH re-introduced the Policy 2015-02 document to assist pharmacists with questions if the continuing education requirements for compounding specific continuing education pertains to their work environment. K.BARNES reviewed and explained the Policy to the Board, which was introduced at the March 3, 2015 meeting, and deferred to allow board staff to seek legislative intent for the policy. The revised Policy document sets forth in bullet point fashion the critical information that would require a pharmacist to obtain the specific contact hours related to compounding as

Page 5 of 11

Minutes of the Regularly Scheduled Meeting held on May 5, 2015

Approved on June 2, 2015





required by c. 159. D.SENCABAUGH indicated that if approved by the board that the policy would be posted to the Board's website and sent to the distribution list.  
ACTION: Motion by T.FENSKY, seconded by K.CONLEY and voted unanimously to approve Policy 15-02: Guidelines for Pharmacist Continuing Education Requirement: Sterile and Complex Non-Sterile Compounding.

3. Advisory Committee / Sub-committee on abnormal results; update and summary of discussion following the May 1, 2015 sub-committee meeting:  
K. BARNES and W FRISCH provided a recap of the Pharmacy Advisory Sub-committee meeting on abnormal results. K.BARNES indicated that it was a productive discussion in which the work group was able to come to a consensus regarding the environmental monitoring of an ISO 5 primary engineering control, and when it would be prudent to cease compounding.

4. Pharmacy Advisory Committee meeting 5/29  
D SENCABAUGH informed the Board on the upcoming Pharmacy Advisory Committee meeting scheduled for 5/29. D. SENCABAUGH indicated that the Pharmacy Advisory Committee will meet the last Friday of each month.

5. Inspector Training  
W.FRISCH reported to the Board that pharmacy investigators C.MOGNI and J. MURRAY were attending the FDA 2 week training course on compounding compliance. W. FRISCH was appreciative for the funding for the training for the new investigators and the collaboration of the FDA for providing the opportunity.

6. Additional Meeting Dates  
D.DUNN reminded the Board of the upcoming meeting schedule of June 2, 2015, and June 30, 2015 in place of the July meeting. D. DUNN informed Board members in order to keep on track with day to day business and the continued need to devote time to the regulations that he would be seeking feedback for a July meeting date and that the Board would meet on Tuesday August 4, 2015.

**TOPIC VII:**  
**REGULATIONS**

**TIME: 10:20AM-11:30AM**

Draft Proposed Amendments to 247 CMR 9.00: Code of Professional Conduct; Professional Standards for Registered Pharmacist, Pharmacies, and Pharmacy Departments.

**DISCUSSION:** The final draft of the proposed amendments to 247 CMR 9.00 was presented to the Board for final review. The document was displayed on the screen for the Board members and audience to see. H.ENGSMAN captured the Board requests via track changes. W.FRISCH had recommended final inclusion with the most notable being the requirement that Pharmacist and Pharmacies must comply with the current standards



of USP. After the final review and the incorporation of changes D.DUNN reviewed with the Board the memo summarizing the proposed changes to 247 CMR 9.00.

**ACTION:** Motion by P.GANNON, seconded by K Conley, and voted unanimously to approve the proposed amendments to 247 CMR 9.00 with incorporated changes made on May 5, 2015, (2) proceed with the administrative review process, and (3) if substantive changes are not required by the administrative review process, send the proposed amendments to 247 CMR 9.00 out for public comment and hearing.

247 CMR 17:00 Sterile Compounding; Introduction: **11:30AM- 11:59AM**  
**DISCUSSION:** W FRISCH via a PowerPoint presentation provided an outline of 247 CMR 17:00 Sterile Compounding, this new section is a result of c 159 of the Act of 2014. W FRISCH set for the road map and overarching themes that will be incorporated in this new section to protect the citizen of the Commonwealth.

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**LUNCH BREAK**

**TIME: 11:59AM-1:00PM**

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**TOPIC VIII.**

**OPEN FILE REVIEW**

**1. PHA-2014-0164, Walgreens Infusion Services, DS3584** **1:00PM**  
**RECUSAL:** M. GODEK recused himself and was not present for the discussion or vote.  
**DISCUSSION:** W.FRISCH presented and summarized the investigation report pertaining to this matter. On June 6, 2014, Pharmacy Compliance Investigators cited inspectional deficiencies during a <797> compliance audit. Walgreens Infusion installed a new laminar flow hood without conducting viable air testing as required by USP <797>. Walgreens Infusion Services voluntarily cease compounding on June 9, 2014. Environmental monitoring yielded highly pathogenic organisms and all sterile compounded products were directed back to Walgreens Infusion Services. Walgreens Infusion Service submitted a POC to make modification to its facility and procedures, relative to clean procedures for the facility and equipment. Based on a implemented POC improved environmental monitoring Walgreens Infusion Services had substantially remediated. W. Frisch noted the pharmacy successfully remediated.  
**ACTION:** Motion by E.TAGLIERI, seconded by R.TINSLEY, and voted unanimously to dismiss the complaint with discipline not warranted.

**2. PHA-2014-0245, Walgreens 2063, DS1741**  
**DISCUSSION:** This matter was differed to a future meeting

**3. PHA-2014-0223, CVS / Pharmacy 2878, DS3092**

**1:05PM**

**4. PHA-2014-0270, Stacey St. Yves, PH24515**

**1:16PM**

Page 7 of 11

Minutes of the Regularly Scheduled Meeting held on May 5, 2015

Approved on June 2, 2015



**RECUSAL:** S. CORNACCHIO recused herself and was not present for the discussion or vote.

**DISCUSSION:** Investigators C. COLLINS and MONICA VASQUEZ, presented and summarized the investigation report pertaining to these complaints. Evidence indicates that OPP investigators on multiple compliance inspections cited deficiencies in: maintaining proper pharmacist to technician ratios, perpetual inventory reconciliations and the proper recording of refrigerator temperatures. Of concern to the Board was the fact that the plans of correction were not acted upon by the Manager of Record resulting in the same deficiencies on multiple compliance inspections.

**ACTION:** In the matter of PHA-2014-0223, motion by M. GODEK, seconded by T. FENSKY and voted unanimously to refer the matter to the Office of the Prosecution for issuance of an Order to Show Cause, and to authorize resolution of this matter with a Consent Agreement for 1 year probation with terms to include, (1) MOR complete and sign a self-inspection form, (2) the pharmacy refrain for hosting any Initial Pharmacy Practice Externs or Advance Pharmacy Practice Interns for the term of the probation, (3) the pharmacy submit copies of the staffing schedules monthly during probation; and (4) the pharmacy submit a plan of correction pertaining to staffing ratios within 90 days of the effective date.

**ACTION:** In the matter of PHA-2014-0270 (St. Yves), motion by T. FENSKY, seconded by G. Cavanaugh, and voted unanimously to refer the complaint to the office of prosecution for the issuance of an order to show cause and to authorization resolution of the matter with a consent agreement for stayed probation requiring the licensee to complete 4 contact hours of continuing education in the area of law and to submit an attestation that she read and reviewed 247 CMR 2.00 et seq.

**5. SA-INV-3396; Animal Pharmacy, DS3066**

**1:20PM**

**DISCUSSION:** C. COLLINS presented and summarized the investigation report pertaining to this complaint. This staff assignment was opened in response to notification by the FDA that it had received a complaint from a former Animal Pharmacy employee reporting that they had concerns about handling diethylstilbestrol. The employee also indicated that they were improperly trained, did not have appropriate personal protective equipment, and the air flow in the compounding facility was inadequate. In March of 2014 a routine USP <795> compliance inspection was performed with multiple deficiencies cited. The MOR submitted a comprehensive plan of correction (POC) and retained the services of a consultant. On January 6, 2015, the facility was re-inspected for <795> compliance and it was determined that the POC had been substantially implemented with addition of a powder hood and an improved facility.

**ACTION:** Motion by E. TAGLIERI, seconded by W. COX and voted unanimously to close the Staff Assignment with discipline not warranted because the pharmacy already remediated.

**6. SA-INV-6174, Village Fertility, DS89658**

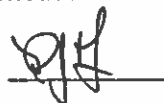
**1:24PM**

**DISCUSSION:** M. VASQUEZ presented and summarized the investigation report pertaining to this matter. The Staff Assignment was opened as the result of a self-reported

Page 8 of 11

Minutes of the Regularly Scheduled Meeting held on May 5, 2015

Approved on June 2, 2015



Abnormal Result. On November 2, 2014, environmental monitoring revealed an actionable result in the ISO 7 Buffer Room. The root cause was determined to be a crack in the ceiling of the clean room which was repaired. The pharmacy properly remediated. Environmental monitoring conducted on January 5, 2015, by an external vendor yielded no actionable levels. A USP <797> compliance audit was conducted on February 3, 2015, with no noted deficiencies.

**ACTION:** Motion by T.FENSKY, seconded by E.TAGLIERI, and voted unanimously to close the Staff Assignment with discipline not warranted.

**7. SA-INV-6445; Kabafusion, DS89700**

**1:26PM**

**DISCUSSION:** C.COLLINS presented and summarized the investigation report pertaining to this matter. The Staff Assignment was opened as the result of a <797> inspection that note the use of a vertical laminar airflow workbench in the buffer room without a Lexan shield. Compliance Inspectors recommended a smoke study to assess air-flow with in the compounding space. The smoke study revealed abnormal turbulence. The licensees voluntarily cease compounding a renovated the facility keeping Board staff updated throughout the process. A <797> audit performed on October 16, 2014, revealed a minor cleaning deficiency with the POC adequately implemented.

**ACTION:** Motion by G.CAVANAUGH, seconded by M.GODEK, and voted unanimously to close the Staff Assignment with no discipline warranted. P.GANNON was not present for the discussion and did not participate in the vote of this matter.

**8. SA-INV-6649, Home Solutions, DS89639**

**1:28PM**

**DISCUSSION:** Patrick Gannon returned to the room for the start of this discussion. Director of Pharmacy Compliance W. FRISCH presented and summarized the investigative report. The Staff Assignment was opened as a result of abnormal results reported by Home Solutions on a 11/7 final report showing fungus. Home Solutions voluntarily cease compounding on 10/ 24 and remained closed until 2/13/15, during which time they made a substantial upgrade to their HVAC system, and major improvements to their ante room. A follow up inspection, conducted by BOP Investigators on 2/13/2015 was successful, at which time Home Solutions re-engaged.

**ACTION:** A motion was made by T. FENSKY, seconded by K. CONLEY, and voted unanimously to close the Staff Assignment with “no discipline warranted”.

**9. PHA-2014-0209, BioRX, DS89763**


**1:30PM**

**DISCUSSION:** This file was presented by Contract Investigator Colleen Collins. In July of 2014, BOP Investigators, during a site visit, noted several deficiencies, including the fact that a new hood had been introduced in the classified space without EM (environmental monitoring), and abnormal results from 1/2014 had not been properly reported. On 7/1, the pharmacy ceased compounding. On 7/2, sampling and EM.....led to a plexi-glass installation around an anteroom sink. On 7/21 /15, a complete <797> audit was done by BOP Investigators, and no deficiencies were noted, so BioRx resumed compounding. From 7/21 thru 1/2015, the firm conducted monthly EM, and no actionable levels were reported. BioRx has successfully implemented their POC.

Page 9 of 11

Minutes of the Regularly Scheduled Meeting held on May 5, 2015

Approved on June 2, 2015



Director Frisch pointed out that most of the compounders have been going through a learning curve when it comes to moving things and changing out filters in clean rooms. **ACTION:** A motion was made by M. GODEK, seconded by T. FENSKY, and voted unanimously to dismiss the Complaint with “no discipline warranted”.

**10. SA-INV-5040 Park Avenue Pharmacy, DS247**

**1:34PM**

**DISCUSSION:** C. COLLINS presented. In December of 2013, BOP Investigators cited multiple deficiencies during an audit done with DEA. Deficiencies included perpetual inventories, outdated pharmaceuticals, extended BUDs without documented support, signage issues and sanitation violations. A POC (plan of correction) was submitted on 12/10/2013). The DEA issue closed their case without findings. A re-inspection on 7/9/14 found issues with CQI and refrigeration, and an additional POC was submitted by Park Avenue. The pharmacy no longer engages in compounding and will be filing a waiver. **ACTION:** Motion by W. COX, seconded by G.CAVANAUGH, and voted unanimously to close the staff assignment with “Discipline Not Warranted”.

**TOPIC IX.**

**EXECUTIVE SESSION:**

**DISCUSSION:** None

**ACTION:** At 1:35PM, motion by R.TINSLEY, seconded by T.FENSKY, and voted unanimously by roll call to enter into Executive Session. P.GANNON; yes, E.TAGLIERI; yes, R.TINSLEY; yes, P. BOUVIER; yes, G.CAVANAGH; yes, K.CONLEY; yes, S. CORNACCHIO; yes, W.COX; yes, T.FENSKY; yes, M.GODEK; yes, A.STIEN; yes

**TOPIC X.**

**M.G.L. c. 65C Session**

**DISCUSSION:** None

**ACTION:** At 1:56PM, motion by T.FENSKY, seconded by A.STIEN, and voted unanimously to enter into M.G.L. c 112 §65C Session.

**TOPIC XI.**

**ADJOURNMENT OF MEETING**

**DISCUSSION:** None

**ACTION:** At 2:57PM, motion by K.CONLEY, seconded by G.CAVANAUGH, and voted unanimously to adjourn the meeting

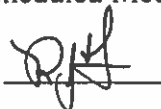
**LIST OF EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING**

1. Agenda for the May 5, 2015, Board of Registration in Pharmacy meeting.
2. Draft April 7, 2015, General Session Minutes.
3. Draft April 28, 2015, General Session Minutes.
4. Application to Manager and Operate a New Community Pharmacy: Genoa, a QoL Healthcare Company, LLC.

Page 10 of 11

Minutes of the Regularly Scheduled Meeting held on May 5, 2015

Approved on June 2, 2015



5. Application for Renovation / Expansion Request for Board Approval: Cardinal Health 414, LLC.
6. Application to Manager and Operate a New Community Pharmacy: High Point Treatment Center, Inc.
7. Application for Renovation / Expansion Request for Board Approval: Skenderian Apothecary.
8. Report of Applications approved pursuant to Licensure Policy 13-01
9. Report of Plans of Correction received associated with Compliance Inspections Reviewed Pursuant to Enforcement policy 13-02.
10. Draft Policy 2015-02 Guidelines for Pharmacist Continuing Education Requirements: Sterile and Complex Non-Sterile Compounding.
11. Draft proposed amendments to 247 CMR 9.00 Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies, and Pharmacy Departments.
12. Draft proposed amendments to 247 CMR 9.00 Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies, and Pharmacy Departments with track changes.
13. Powerpoint presentation introduction of proposed new regulation, 247 CMR 17.00: Sterile Compounding.
14. Investigative report in the matter of Walgreens Infusion Services, DS3584, PHA-2014-0164.
15. Investigative report in the matter of Walgreens 2063, DS1741, PHA-2014-0245.
16. Investigative report in the matter of CVS / pharmacy 2878, DS3092, PHA-2014-0223
17. Investigative report in the matter of Stacey St. Yves, PH24515, PHA-2014-0270.
18. Investigative report in the matter of Animal Pharmacy, DS3066, SA-INV-3396.
19. Investigative report in the matter of Village Fertility, DS 89658, SA-INV-6174.
20. Investigative report in the matter of Kabafusion, DS89700, SA-INV-6445.
21. Investigative report in the matter of Home Solutions, DS 89639, SA-INV-6649.
22. Investigative report in the matter of BioRx, DS89763, PHA-2014-0209.
23. Investigative report in the matter of Park Avenue Pharmacy, DS247, SA-INV-5040.

Respectfully submitted by:  
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