

**COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy**

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

June 7, 2016
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

Agenda

Time	#	Item	Exhibits	Contact
8:30	I	CALL TO ORDER		E. Taglieri
8:35	II	APPROVAL OF AGENDA <ul style="list-style-type: none"> • Introductions: Vishtal Thacker, Liann Chan, Ananya Shah, Joanne Trifone, Joe Santoro 		
8:40	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none"> • Draft of May 3, 2016 Regular Session Minutes 		
8:45	IV	APPLICATIONS <ul style="list-style-type: none"> • Charles River Community Health – New Community Pharmacy • Shire Inc. – Wholesale Distributor • Southwick Pharma LLC- New Community Pharmacy • Southcoast Pharmacies- Petition for waivers • Long Term Pharmacy Solutions- Waivers 		
9:45	V	REPORTS <ul style="list-style-type: none"> • Applications approved pursuant to Licensure Policies 13-01 & 16-01 • Monthly Report from Probation • Board Delegated Complaint Review Pursuant to Policy 14-02 	Reports	R. Harris K. Fishman
9:50	VI	POLICIES <ul style="list-style-type: none"> • Amendments to Licensure Policy 13-01: Staff Action on Licensure Applications and Notices 		
10:00	VII	REGULATIONS <ul style="list-style-type: none"> • Proposed new regulations, 247 CMR 19.00: Hazardous Drugs 		W. Frisch M. Chan

11:00	VIII	FLEX SESSION <ul style="list-style-type: none"> • Board Meeting Schedule • Controlled Substance Advisory • Update on NABP Annual Meeting • POC Review • Discussion: Advisory Committee to study the role of the Pharmacy Technician. 	T. Fensky W. Frisch
11:15	IX	FILE REVIEW <ol style="list-style-type: none"> 1. SA-INV-7664, Boulevard Pharmacy, DS2973 2. SA-INV-8754, Freedom Fertility Pharmacy, DS89717 3. SA-INV-8781, Johnsons Compounding Center, DS3549 4. SA-INV-7945, Critical Care Systems, DS3327 5. SA-INV-7895, Baystate Home Infusion, DS3300 6. SA-INV-7493, Pentec Health, DS89913 7. SA-INV-8308, Pentec Health, DS89913 8. SA-INV-8780, Pentec Health, DS89913 9. SA-INV-8117, Omnicare Northern MA, DS89931 10. SA-INV-7946, Omnicare Northern MA, DS89931 11. SA-INV-8309, Amherst Pharmacy LLC, DS89775 12. SA-INV-8621, Coram/CVS Specialty Infusion Services, DS3601 13. SA-INV-8513, Alexander's Pharmacy, DS6349 	
12:00		LUNCH BREAK	
1:00	X	M.G.L. c. 112, § 65C SESSION	CLOSED SESSION

<p>3:00</p>	<p>XII</p>	<p>EXECUTIVE SESSION</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 Good Moral Character as required for registration for pending applicants.</p>	<p>CLOSED SESSION</p>
<p>5:00</p>	<p>XIV</p>	<p>ADJOURNMENT</p>	

**COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY**

**MINUTES OF THE REGULARLY SCHEDULED MEETING
239 Causeway Street, Fourth Floor Room 417A
Boston Massachusetts, 02114**

June 7, 2016

Board Members Present

Edmund Taglieri Jr., R.Ph, MSM, NHA
President
Timothy Fensky, R.Ph, FACA
President –elect
Michael Godek, R.Ph, Secretary
Garrett Cavanaugh, R.Ph.
Karen Conley, RN, DNP
Ali Raja, MD, M.B.A., M.P.H.(arrived at 8:37)
Patrick Gannon, RPh, MS
Richard Tinsley, MBA, M.Ed.
Catherine Basile, Pharm D, R.Ph.
Susan Cornacchio, JD
William Cox CPhT (arrived at 8:37)
Andrew Stein, Pharm D, R.Ph.

Board Members Not Present

Phillippe Bouvier, R.Ph.

Board Staff Present

David Sencabaugh, RPh, Executive Director
William Frisch, Director of Pharmacy Compliance
Michelle Chan, R.Ph., Quality Assurance Pharmacist
Heather Engman, JD, MPH Board Counsel
Sam Leadholm, JD, Board Counsel
Richard Harris, Program Analyst
Julienne Tran, PharmD, RPh. Pharmacy Investigator
Greg Melton, JD, R.Ph., Pharmacy Investigator
Vita Palazzolo Berg, JD, Chief Board Counsel
Joanne Trifone, R.Ph. Director of Pharmacy Investigations
Joe Santoro, R.Ph. Contract Investigator

TOPIC: I

CALL TO ORDER 8:30 AM

DISCUSSION: A quorum of the Board was present, established by roll call. President E. TAGLIERI chaired the meeting and asked if anyone was recording. Hearing “no”, he explained that the Board of Pharmacy was recording the meeting.

TOPIC II.

APPROVAL OF AGENDA

DISCUSSION: The petition for Waiver from Southcoast was withdrawn. Shire was deferred.

ACTION:

1. Motion by P. GANNON, seconded by, C. BASILE, and voted unanimously to approve the agenda (W. COX and A. RAJA had not yet arrived).
2. Executive Director D. SENCABAUGH introduced APPE students A. SHAH, and L. CHAN, Contract Investigator J. SANTORO, Contract Consultant V. THACKER, and newest Investigator N. VAN ALLEN, while Board Counsel H. ENGMAN introduced Legal Intern M. DIFRANCESCO

TOPIC III.

APPROVAL OF BOARD MINUTES

1. Draft May 3, 2016, Regular Session Minutes

DISCUSSION: Need to correct motions made to adjourn the meeting.

ACTION:

3. Motion by T. FENSKY, seconded by, K. CONLEY, and voted unanimously to approve the minutes of the General Session from May 3, 2016, with noted changes.

TOPIC IV:

APPLICATIONS

TIME: 8:39-9:25AM

1. Charles River Community Health – New Community Pharmacy

DISCUSSION: Charles River Community Health was represented by Ms. Hinal Patel (proposed MOR) and Dr. Elizabeth Molina, Medical Director. Charles River plans to convert their current clinic pharmacy to a retail location. Although they had expressed a desire to petition the Board to waive the 795 compounding requirement, they changed their request based on the conversation with Board Members, who expressed concern relative to patient access. Also, Director of Compliance W. FRISCH reminded Charles River that they could not use existing inventory, (purchased at clinic prices), in their retail operation, and they would need to come up with a plan, and make DCP aware of that plan as part of approval.

ACTION: Motion by R. TINSLEY, seconded by, A. STEIN, and voted unanimously in the affirmative to approve the application for a new community pharmacy for Charles River Community Health, pending submission of a plan to return inventory, and a successful inspection.

2. SOUTHWICK PHARMA New Community Pharmacy

RECUSAL: G. CAVANAUGH and W. COX recused when they heard current MOR applicant associated with Rite Aid.

DISCUSSION: Southwick Pharma was represented by Sivagama Sundari Dorairaj (Managing Member) and Sreenivas Athuluri (proposed MOR) in this matter. Initially, they requested to petition the Board to waive compounding requirements for 795, but the Board members made it clear that it was a concern of reduced access to medications in a location the applicants described as in “need “ of their services. The applicants decided to withdraw the waiver petition and perform simple and moderate compounding as needed.

ACTION: Motion by P. GANNON, seconded by C. BASILE, and voted in the affirmative by E. TAGLIERI, S. CORNACCHIO, A. STEIN, A. RAJA, P. GANNON, R. TINSLEY and C. BASILE to approve the application for a new community pharmacy for SOUTHWICK PHARMA, with waiver petition withdrawn, and pending successful inspection by the Board. The motion was voted in the negative by T. FENSKY, M. GODEK, and K. CONLEY, therefore the motion passed 7-3, with 2 recused, and 1 absent.

3. LONGTERM PHARMACY SOLUTIONS Waiver of Signage Requirements.

RECUSAL: T. FENSKY recused and was not present for the discussion or vote on this matter.

DISCUSSION: based on provisions of 247 CMR section 14.01, Longterm Pharmacy Solutions of Lowell, petitioned the Board to waive the requirement to post a sign in public view, indicating the presence of a pharmacy within the premises. They are a Long Term Care Pharmacy, servicing nursing homes and other LTC facilities, and not “walk-ins”, and the existence of a methadone clinic in the same parking lot, caused them concern about the safety of their employees. This was a waiver originally granted in 2014, updated by the current Board.

ACTION: Motion by M. GODEK, seconded by R. TINSLEY, and voted unanimously by those present to approve the signage waiver for LongTerm Pharmacy Solutions.

TOPIC V. REPORTS

Applications Approved Pursuant to Licensure Policy 13-01

DISCUSSION: R. HARRIS noted that during the past month there have been thirty-nine (39) change-of-managers, and two (2) renovation/expansions.

Pursuant to Licensure Policy 16-01

There were 4 denials of non-resident outsourcing facility applications.

ACTION: So noted

Report of activities Probation Monitor

DISCUSSION: D. SENCABAUGH, (for K. FISHMAN) provided the April 27, 2016 – May 26, 2016, Board of Pharmacy Statistics Report for the Probation monitor, which noted that: there are fifty (50) licensees on probation, twenty-four (24) satisfactorily completed probation, three (3) licensee did not cure within 30 days, five (5) given the opportunity to cure, and two (2) notices of further discipline.

ACTION: So noted

Board Delegated Compliant Review March 31, 2016 and April 29, 2016

DISCUSSION: D. SENCABAUGH provided the Board with statistics of 24 cases heard at Board Delegated Complaint Review on March 3, 2016, and 4 cases on April 29, 2016.

A total of 28 cases were heard and dismissed during the two sessions, both of which were attended by E.TAGLIERI as the Board Member, H. ENGMAN as Board Counsel, W. FRISCH as Director of Pharmacy Compliance, and Executive Director SENCABAUGH.

Case included 21 self-reported CE deficiencies, and 7 QREs. All had satisfactorily remediated.

ACTION: So noted

TOPIC VI POLICIES

Amendment to Licensure Policy 13-01: adding Transfer of Ownership

Presented by R. HARRIS and D. SENCABAUGH

DISCUSSION: R. HARRIS and D. SENCABAUGH asked the Board to grant staff action to allow approval of transfer of ownerships in certain cases, involving known entities already having at least one pharmacy licensed with the Board.

ACTION: Motion by R. TINSLEY, seconded by P. GANNON, and approved unanimously to give staff action authority to approve Transfer of Ownership of existing registered pharmacies that have at least one community pharmacy registered with the Board of Pharmacy and meet the additional criteria listed in Licensure Policy 13-0.

TOPIC VII REGULATIONS TIME: 9:44 am

247 CMR 19.00 Proposed New Regulation-Hazardous Drugs

PRESENTED BY: W. FRISCH, M. CHAN

W. FRISCH noted that although it is preferred to compound hazardous and non-hazardous drugs in separate rooms, the USP committee indicated that they can be compounded in the same room with the following stipulations: they must be compounded under separate Containment Primary Engineering Controls (C-PECs) and they must be compounded under negative pressure.

Section 19.05 (6): W.FRISCH indicated that section needs to specify how to deal with a power loss. 19.05(15) should be stricken. 19.05(16) T.FENSKY suggested applying 72 square feet requirement for negative pressure buffer room used for sterile hazardous compounding to all new construction as of a specified date. 19.07 (7) P. GANNON suggested that a picture representing this section would be helpful. 19.07 (18) should remain as is and exceptions will be dealt with on a case-by-case basis. 19.09 (9) needs a guidance document with pictures. 19.09 (15) should read, "Personnel shall cleanse hands immediately after removing gloves."

ACTION: None Taken. Need legal team and advisory committee to review before further action is taken

**TOPIC VIII
FLEX SESSION**

1. Board Meeting Schedule

DISCUSSION: D.SENCABAUGH presented to the Board a revised meeting schedule. Of note was the rescheduling of the October meeting from Tuesday October 4, 2016 to Thursday October 6,2016 as not to conflict with the Jewish holiday.

ACTION: Motion by P.GANNON, seconded by, T.FENSKY, and voted unanimously to approve the new Board meeting schedule.

2. Controlled Substance Advisory

DISCUSSION: D.SENCABAUGH presented the Controlled Substance Advisory and recommended approval explaining the advisory had made its way through multiple channels and stating that it may be edited after if necessary since it is an advisory.

ACTION: Motion by M. GODEK, seconded by, R.TINSLEY, and voted unanimously to approve

3. Update on NABP Annual Meeting

DISCUSSION: T.FENSKY updated the Board on the NABP Annual Meeting that was held in San Diego, CA May 14 – 17. T. FENSKY attended as the voting delegate. Topics of discussion at the meeting were telemedicine, telepharmacy, pharmacy robberies, DSCSA in various states, tech-check-tech, and pharmacist prescriptive authority. Eight Resolutions were put forward at the meeting and Task Forces are being developed based on these Resolutions. Elections occurred for Executive Committee Officers and Members for 2016-2017. Officers are as follows:

- Chairperson – Edward G. McGinley, MBA, RPh, DPh
- President – Hal Wand, MBA, RPh
- President-Elect – Jeanne D. Waggener, RPh
- Treasurer – Susan Ksiazek, RPh

New Executive Committee Members were elected for the following open District Seats:

District 1 – Timothy D. Fensky, RPh, DPh, FACA

District 2 – Caroline D. Juran, RPh, DPh

District 5 – Gary Dewhirst, RPh

Board members and Board staff congratulated Massachusetts Board of Registration in Pharmacy President-Elect Tim Fensky on his election to the NABP Executive Committee.

4. POC Review

DISCUSSION: W.FRISCH presented a statistical analysis of the 2015 inspections. It showed a decrease in Plans of Correction and an increase in the number of inspections performed. He discussed how the self-inspection tool(s) available on the Board website is very helpful to pro-active licensees serving almost as an "open book test". In the future the recently approved Controlled Substance Advisory will be helpful in addressing the growing number of CS record deficiencies. Board members asked that future reports include the number of pharmacies that received a satisfactory compliance inspection as well as include percentages as part of the statistical analysis.

5. Discussion: Advisory Committee to study the role of the Pharmacy Technician

DISCUSSION; D.SENCABAUGH defined tech-check-tech explaining that is was technology checking technician and NOT technician checking technician. He discussed the meeting with MSHP members held on 5/23/16 with members present from Baystate, Tufts and BWH. Information was shared that 14 states allow tech-check-tech and the MSHP members will work to provide the Board with best model language. Board members P.GANNON and W.COX volunteered to present the work of the Advisory Committee to the Board.

ACTION: Motion by A.Stein, seconded by, G.Cavanaugh, and voted unanimously to request that the Advisory Committee evaluate the concept of Technology Check Technician", as it relates to the role of pharmacy technicians within specific practice settings. The advisory Committee will review, evaluate, and approve provision to the Board of Pharmacy, any related recommendations and/or suggested regulatory considerations.

TOPIC IX
FILE REVIEW

I. Open File Review

Case #1

SA-INV-7664

Boulevard Pharmacy, DS2973

TIME: 11:17 am

RECUSAL: M. GODEK recused and was not present for the discussion or vote on this matter.

DISCUSSION: G. MELTON presented and summarized the investigation report that pertained to these matters.

- On May 12th, 2015 leaking HEPA filters were found. Two HEPA filters in the negative buffer room (ISO class 7) failed an aerosol challenge installation leak test.
- Non-actionable results reported. Had 1 cfu/m³ coag-negative *Staphylococcus sp.* isolated from an air sample in a Baker Negative Hood taken on May 26th, 2015 in an ISO class 5 space. In an ISO class 7, had 1 cfu/plate coag-negative *Staphylococcus sp.* isolated from a surface sample on a negative pressure buffer room floor. Had 3 cfu/m³ *Bacillus sp.* isolated from an air sample in the Anteroom in an ISO class 7 space.
- Initially suspended compounding on May 12th, 2015.
- Completed remediation by replacing HEPA filters on May 19th, 2015 and cleaning.
- Follow up testing from June 12 testing indicated no USP <797> actionable results.
- Compounding resumed on June 1st, 2015. No further remediation necessary.

ACTION: Motion by P. GANNON, seconded by C. BASILE, and voted unanimously by those present, to CLOSE SA-INV-7664, no violation.

Case #2

SA-INV-8754

Freedom Fertility Pharmacy, DS89717

TIME: 11:28am

RECUSAL: N/A

DISCUSSION: G. MELTON presented and summarized the investigation report that pertained to these matters.

- Had 1 actionable result on November 3rd, 2015.
- Leuprolide 40mcg/0.2mL (lot#FDK0215JC1) batch sterility testing for extension of BUD contained microbial growth. 2 out of 8 batch samples contained *Paenibacillus campinasensis* and *Propionbacterium acnes* respectively.
- Anticipatory batch was quarantined awaiting sterility test results and destroyed upon notification of actionable result.
- On November 10th, 2015 air, surface, and fingertip testing reported no microbial growth

ACTION: Motion by M. GODEK, seconded by C. BASILE, and voted unanimously by those present, to CLOSE SA-INV-8754, no violation.

Case #3

SA-INV-8781 Johnsons Compounding Center, DS3549 TIME: 11:19 am

RECUSALS: M. GODEK and A. STEIN recused and were not present for the discussion or vote on this matter.

DISCUSSION: G. MELTON presented and summarized the investigation report that pertained to these matters.

- 1 cfu/plate of *Penicillium* (fungal) *sp.* isolated on surface sample in positive buffer room of ISO class 7 space on December 2nd, 2015.
- Compounding was suspended on December 9th, 2015.
- All compounded products prepared on December 9th, 2015 were destroyed. Remedial cleaning was performed.
- Cleanroom BioAnalysis repeated on December 10th, 2015 and indicated no USP <797> actionable results.
- Compounding resumed on December 21st, 2015.

ACTION: Motion by K. CONLEY, seconded by T. FENSKY, and voted unanimously by those present, to CLOSE SA-INV-8781, no violation.

Case #4

SA-INV-7945 Option Care (formerly Critical Care Systems), DS3327 TIME: 11:29 am

RECUSAL: M. GODEK recused and was not present for the discussion or vote on this matter.

DISCUSSION: J. TRAN presented and summarized the investigation report that pertained to these matters.

- Had actionable results including: 1 cfu/m³ *Bacillus* species and 1 cfu/m³ *Pentoea* species isolated from an air sample of the horizontal laminar flow hood in ISO class 5 space. 2 cfu/m³ *Pentoea* species isolated from an air sample in ISO class 7 space. 4 cfu/m³ *Pentoea* species isolated from an air sample in ISO class 7 space. 2 cfu/m³ *Pentoea* species isolated from an air sample in ISO class 8 space. 1 cfu/m³ *Lysinibacillus*, 1 cfu/m³ *Pentoea* and 1 cfu/m³ *Klebsiella* species isolated on surface sample of ISO class 5 space. 4 cfu/m³ *Pentoea* species isolated from a surface sample in ISO class 5 space. 1 cfu/m³ *Pentoea* species isolated from a surface sample in ISO class 5 space. 2 cfu/m³ *Pentoea* species isolated from a surface sample in ISO class 5 space. 1 cfu/m³ *Pentoea* species isolated from a surface sample in ISO class 5 space.
- Not opened to public at the time of environmental monitoring and not compounding pharmaceuticals.
- All products used to clean the hoods were removed. Triple clean products used. All cleaning supplies in the cleanroom were removed and destroyed including all solutions, wipes, mop heads, and gowning supplies.
- Follow up EM sampled on August 7th, 2015. Non-actionable results found. 1 cfu/m³ *Micrococcus* and 1 cfu/m³ *Kytococcus* species isolated from an air sample in ISO class 7 space.
- Cleanroom is used as a back-up facility for Walgreens/Option Care locations.
- Want to decommission clean room and maintain their license

ACTION: Motion by T. FENSKY, seconded by A. STEIN, and voted unanimously by those present, to CLOSE SA-INV-7945, no violation.

Case #5

SA-INV-7895 Baystate Home Infusion, DS3300 TIME: 11:33 am
RECUSAL: N/A

DISCUSSION: J. TRAN presented and summarized the investigation report that pertained to these matters.

- Had one above action level result on July 8th, 2015. 1 cfu/m³ *Burkholderia* (gram negative rods) species isolated on a surface sample from the horizontal laminar flow hood in an ISO class 5 space.
- Had non-actionable results found as well. 1 cfu/m³ Coagulase Negative *Staphylococcus* species isolated from a surface sample in the ante room of an ISO class 8 space. 3 cfu/m³ *Bacillus* species isolated from a surface sample from the clean room door in an ISO class 7 space.
- Implemented routine monthly EC sampling to ensure USP 797 processes and procedures are followed. Outsourced all TPN compounding to provide continuity of care for patients.
- Follow-up EM sampled on July 28th, 2015. Non-actionable results found. 1 cfu/m³ *Bacillus* species isolated on a surface sample of the cleanroom table in an ISO class 7 space. 1 cfu/m³ *Bacillus* species isolated on a surface sample of the clean room table in an ISO class 5 space.

ACTION: Motion by P. GANNON, seconded by G. CAVANAUGH, and voted unanimously by those present, to CLOSE SA-INV-7895, no violation.

Case #6

SA-INV-7493 Pentec Health, DS89913 TIME: 11:34 am
RECUSAL: N/A

DISCUSSION: J. TRAN presented and summarized the investigation report that pertained to these matters.

- On May 20th, 2015 had an above action level result. 1 cfu/m³ Gram Negative Rod
- Growth was isolated from a surface sample in an ISO class 8 space.
- Had non-actionable results as well. Had non-actionable results found as well. 1 cfu/m³ *Coagulase Negative Staphylococcus* isolated from an air sample in an ISO 7 class space. 1 cfu/m³ *Corynebacterium ulcerans* and 1 cfu/m³ *Streptomyces* isolated from an air sample in an ISO 8 class space.
- Compounding suspended on June 5th, 2015.
- Disinfecting and garbing procedures put in place to mitigate movement of organism further into clean room. Remedial cleaning performed. Reviewed proper handwashing and garbing technique to all personnel.
- Follow-up EM sampled on August 6th, 2015. Non-actionable results: 1 cfu/m³ *Pasteurella pneumotropica/ Mannheimia haemolytica* (gram negative coccobacillus) species isolated from a surface sample in the Ante room in an ISO class 7 space.
- Resumed compounding on August 17th, 2015.

ACTION: Motion by P. GANNON, seconded by A. STEIN, and voted unanimously by those present, to CLOSE SA-INV-7493, no violation.

Case #7

SA-INV-8308 Pentec Health, DS89913 TIME: 11:35 am
RECUSAL: N/A

DISCUSSION: J. TRAN presented and summarized the investigation report that pertained to these matters.

- On September 24th, 2015 had an above action level result. 1 cfu/m³ *Cladosporium* (mold) was isolated from an air sample in an ISO class 8 space.
- The BUD reduced from 14 days to 3 days until receipt of repeat EM results. On October 14, 2015, the BUD was changed back to that of <797> standards.
- Full cleaning performed with Lysol on September 29, 2015 and then subsequently Spor-Klenz on October 2, 2015.
- Follow-up EM sampled on October 14, 2015 with no USP <797> actionable results

ACTION: Motion by P. GANNON, seconded by M. GODEK, and voted unanimously by those present, to CLOSE SA-INV-8308, no violation.

Case #8

SA-INV-8780 Pentec Health, DS89913 TIME: 11:37 am
RECUSAL: N/A

DISCUSSION: J. TRAN presented and summarized the investigation report that pertained to these matters.

- On December 16th, 2015 had above action level results. 1 cfu/m³ *Stereum complicatum* (mold) was isolated from an air sample in an ISO class 8 space. *Rothia dentocariosa* (gram positive rods) was isolated from a surface sample in an ISO class 8 designated area.
- Compounding suspended on January 4, 2016.
- Remedial clean of the cleanroom complex performed using SporKlenz. Routine weekly cleaning performed with the use of Lysol IC as per policy.
- Remedial clean using a sporicidal disinfectant on January 4, 2016 with resampling on January 5, 2016. Another Validation Manager completed sampling with non-actionable result: 1 cfu/m³ *Micrococcus luteus* isolated from an air sample in an ISO class 8.
- Follow-up EM on December 30th, 2015. 1 cfu/m³ *Staphylococcus like colony* (Gram + staph) and *Brevibacillus brevis* (Gram + rods) was isolated from an air sample in an ISO class 7 space. 2 cfu/m³ *Penicillium* ([ascomycetous fungi](#)) was isolated from an air sample in an ISO class 8 space. 1 cfu/m³ *Brevibacillus brevis* (Gram + rods) and 1 cfu/m³ *Staphylococcus capitis* (Gram + staph) was isolated from an air sample in an ISO class 8 space.
- All testing indicated within USP action levels.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present, to CLOSE SA-INV-8780, no violation.

Case #9

SA-INV-7946

OmniCare Northern MA, DS89931 TIME: 11:20 am

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote on this matter.

DISCUSSION: J. TRAN presented and summarized the investigation report that pertained to these matters.

- On July 22nd, 2015 had above action level results. 1 cfu/m³ Trichophyton (fungi) species was isolated from a surface sample of horizontal ridge above vent to outside in an ISO class 8 space.
- Had non-actionable results as well. 1 cfu/m³ *Bacillus* species isolated from a surface sample of the midfloor of an ISO 7 class space. 1 cfu/m³ *Staphylococcus* species isolated from a surface sample of the midfloor of an ISO class 7 space. 1 cfu/m³ *Bacillus* species isolated from a surface sample of the outside entry door of an ISO class 8 space. 2 cfu/m³ *Bacillus* species isolated from an air sample in an ISO class 7 space. 1 cfu/m³ *Bacillus* species isolated from a surface sample on top of pass thru in an ISO class 8 space. 16 cfu/m³ *Bacillus* species isolated from a surface sample on top of pass thru in an ISO class 8 space.
- Full monthly cleaning completed on July 28th, 2015 using sporicidal agent. Review standard operating procedures regarding garbing, gloving, and cleaning.
- Follow-up EM on August 5th, 2015. Non-actionable results: 1 cfu/m³ *Staphylococcus* species isolated from air sample in an ISO class 7 space, 2 cfu/m³ *Staphylococcus* species isolated from air sample in an ISO class 8 space, and 1 cfu/m³ *Aspergillus* (fungi) species isolated from air sample in an ISO class 8 space.
- Follow-up EM on October 8th, 2015. Non-actionable results: 2 cfu/m³ *Staphylococcus* species isolated from air sample of an ISO class 8 space. 8 cfu/m³ *Staphylococcus* species isolated from air sample of an ISO class 8 space. 4 cfu/m³ *Staphylococcus* species and 2 cfu/m³ *Bacillus* species isolated from air sample of an ISO class 8 space. 2 cfu/m³ *Micrococcus* species isolated from air sample of an ISO class 7 space. 1 cfu/m³ *Micrococcus* species isolated from air sample of an ISO class 7 space. 1 cfu/m³ *Bacillus* species isolated from air sample of an ISO class 7 space. 2 cfu/m³ *Micrococcus* species and 2 cfu/m³ *Staphylococcus* species isolated from air sample of an ISO class 8 space. 2 cfu/m³ *Micrococcus* species isolated from air sample of an ISO class 8 space. 5 cfu/m³ *Staphylococcus* species isolated from surface sample of floor at entry door in an ISO class 8 space. 1 cfu/m³ *Bacillus* species isolated from surface sample of the top of pass thru in an ISO class 8 space.

ACTION: Motion by P. GANNON, seconded by C. BASILE, and voted unanimously by those present, to CLOSE SA-INV-7946, no violation.

Case #10

SA-INV-8117

OmniCare Northern MA, DS89931 TIME: 11:23 am

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote on this matter.

DISCUSSION: J. TRAN presented and summarized the investigation report that pertained to these matters.

- On August 26th, 2015 had above action level results. 1 cfu/m³ Trichophyton (fungi) species was isolated from a surface sample of the outside entry door in an ISO class 8 space.
- Had non-actionable results as well. 1 cfu/m³ *Bacillus* species isolated from a surface sample of a cart in an ISO 7 class space. 1 cfu/m³ *Staphylococcus* species isolated from a surface sample of pipes below sink in an ISO 8 class space. 2 cfu/m³ *Bacillus* species isolated from an air sample in an ISO class 7 space. 1 cfu/m³ *Micrococcus* species and 4 cfu/m³ *Bacillus* species isolated from a surface sample on top of pass thru in an ISO class 8 space. 1 cfu/m³ *Micrococcus* species isolated from a surface sample outside entry door in an ISO class 8 space. 1 cfu/m³ *Micrococcus* species isolated from a surface sample

on horizontal ridge above vent to outside in an ISO class 8 space. 1 cfu/m³ *Bacillus* species isolated from a surface sample on the floor outside entry floor in an ISO class 8 space. 1 cfu/m³ *Micrococcus* species isolated from an air sample in an ISO class 7 space. 1 cfu/m³ *Micrococcus* species isolated from an air sample in an ISO class 8 space.

- Reduced BUD of sterile compounded products. TPNs given a BUD of 3 days and all other admixtures a BUD of 9 days.
- Cleaning completed on a daily basis. Replaced pre-filters and completed proficiency testing on scrubs with vendor.
- Follow-up EM on September 14th, 2015. Actionable Result: 1 cfu/m³ *Aspergillus* species (fungi) isolated from air sample in an ISO class 8 space. Non-actionable results: 1 cfu/m³ *Staphylococcus* species isolated from air sample in an ISO class 7 space, 2 cfu/m³ *Staphylococcus* species isolated from air sample in an ISO class 8 space, and 1 cfu/m³ *Aspergillus* (fungi) species isolated from air sample in an ISO class 8 space.
- Follow-up EM on October 8th, 2015. Non-actionable results: 1 cfu/m³ *Staphylococcus* species and 1 cfu/m³ *Micrococcus* species isolated from surface sample of outside entry door in an ISO class 8 space. 1 cfu/m³ *Micrococcus* species isolated from air sample of an ISO class 8 space. 1 cfu/m³ *Staphylococcus* species and 1 cfu/m³ *Bacillus* species isolated from air sample of an ISO class 8 space.

ACTION: Motion by P. GANNON, seconded by A. STEIN, and voted unanimously by those present, to CLOSE SA-INV-8117, no violation.

Case #11

SA-INV-8309 Amherst Pharmacy, LLC, DS89775 TIME: 11:40am

RECUSAL: N/A

DISCUSSION: J. TRAN presented and summarized the investigation report that pertained to these matters.

- On August 21st, 2015 pharmacy investigators notes that Amherst Pharmacy has routinely compounded and dispensed Hydrocodone capsules.
- Hydrocodone API inventory logs have discrepancies. Inventories been conducted every 7-19 days. Violation of 247 CMR 9.01 (14).
- No longer compounding the Hydrocodone capsules. Will contact other compounding pharmacies to ensure continuity of care for patient.

ACTION: No vote today; investigation is still ongoing.

Case #12

SA-INV-8621 Coram/CVS Specialty Infusion Services, DS3601 TIME: 11:25 am

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote on this matter.

DISCUSSION: G. MELTON presented and summarized the investigation report that pertained to these matters.

- On November 11th, 2015 had above action level result. 1cfu/plate of *Aspergillus* (fungal) *sp.* in center of compounding room of an ISO class 7 space. Had non-actionable results as well. In ISO class 7 space: 1 cfu/m³ *Micrococcus sp.* in compounding area, near ante door. 1 cfu/m³ *Micrococcus sp.* back center of compounding room, in front of pass thru. 1 cfu/m³ *Micrococcus sp.* in compounding room, shelf of pass thru. 1 cfu/m³ *Micrococcus sp.* in compounding room, in front of pass thru. In ISO class 8 space: 1 cfu/m³ coag-negative *Staphylococcus sp.* and 2 cfu/m³ *Micrococcus sp.* in ante, near prep door. 1 cfu/m³

Bacillus sp. in prep, in front of pass thru, 1 cfu/m³ *Bacillus sp.* and 1 cfu/m³ *Micrococcus sp.* in prep, near change door. 1 cfu/m³ *Micrococcus sp.* in prep, near refrigerator. 1 cfu/m³ *Micrococcus sp.* in prep, near office door.

- Suspended compounding on November 20th, 2015 until remedial cleaning completed then resumed compounding due to miscommunication with Board Staff.
- Ceased compounding entirely on November 21st, 2015 after receiving email clarification from Board Staff.
- Destroyed all compounded products remaining on site. Remedial cleaning was performed. Compounding at a 5 day BUD. Restriction of veterinary compounds.
- Follow-up EM on December 7th, 2015 had actionable results. 1cfu/plate of *Aspergillus (fungal) sp.* on surface sample of compounding room, back center on chair of an ISO class 7 space. 1cfu/plate of *Aspergillus (fungal) sp.* in compounding room, back left corner on wall of an ISO class 7 space. 1 cfu/m³ *Cladosporium (fungal) sp.* isolated in air sample of prep, near office door of ISO class 8 space. Non-actionable results from ISO class 8 air sampling: 1 cfu/m³ coag-negative *Staphylococcus sp.* 1 cfu/m³ *Micrococcus sp.* in ante, near prep door. 1 cfu/m³ *Micrococcus sp.* in prep, in front of pass thru. 1 cfu/m³ coag-negative *Staphylococcus sp.* and 7 cfu/m³ *Micrococcus sp.* in ante, near change door. 2 cfu/m³ coag-negative *Staphylococcus sp.* and 2 cfu/m³ *Micrococcus sp.* in ante, near refrigerator. 2 cfu/m³ *Bacillus sp.*, 2 cfu/m³ coag-negative *Staphylococcus sp.* and 7 cfu/m³ *Micrococcus sp.* in prep, near office door.
- Resumed compounding with restrictions on November 25th, 2015. Ceased compounding on December 15th, 2015 due to notification of EM actionable levels.
- Renovating facility and put a remediation plan in place

ACTION: Motion by T. FENSKY, seconded by C. BASILE, and voted unanimously by those present, to CLOSE SA-INV-8621, no violation

TOPIC X.

M.G.L. c. 65C Session

DISCUSSION: None

ACTION: At 1:00 pm motion by T. FENSKY, seconded by W. COX and voted unanimously to enter into M.G.L. c. 65C Session. E. TAGLIERI; yes,

T. FENSKY; yes, G. CAVANAUGH; yes, C. BASILE; yes, P. GANNON; yes,

S. CORNACCHIO; yes, W. COX; yes, A. RAJA; yes, R. TINSLEY; yes. K. CONLEY; yes, A. STEIN: yes M. GODEK: yes

At 2:55 PM motion by P. GANNON, seconded by T. FENSKY, and voted unanimously to adjourn M.G.L. 65 C.

TOPIC XI

EXECUTIVE SESSION

DISCUSSION: None

ACTION: At 3:00 pm motion by P. GANNON, seconded by W. COX and voted unanimously by roll call to enter into Executive Session. E. TAGLIERI; yes,

T. FENSKY; yes, G. CAVANAUGH; yes, C. BASILE; yes, P. GANNON; yes,

S. CORNACCHIO; yes, W. COX; yes, A. RAJA; yes, R. TINSLEY; yes. K. CONLEY; yes, A. STEIN: yes M. GODEK: yes

At 3:51 pm motion by P. GANNON, seconded by R. TINSLEY, and voted unanimously by roll call to adjourn Executive session. E. TAGLIERI; yes,

T. FENSKY; yes, G. CAVANAUGH; yes, C. BASILE; yes, P. GANNON; yes,
S. CORNACCHIO; yes, W. COX; yes, A. RAJA; yes, R. TINSLEY; yes. K. CONLEY; yes, A. STEIN: yes M.
GODEK: yes

TOPIC XII.

ADJUDICATORY SESSION

DISCUSSION: None

ACTION: At 3:52 pm motion by P. GANNON, seconded by A. STEIN and voted unanimously to enter into
Adjudicatory Session: E. TAGLIERI; yes,

T. FENSKY; yes, G. CAVANAUGH; yes, C. BASILE; yes, P. GANNON; yes,
S. CORNACCHIO; yes, W. COX; yes, A. RAJA; yes, R. TINSLEY; yes. K. CONLEY; yes, A. STEIN: yes,
M.GODEK: yes

At 4:04 pm motion by P. GANNON, seconded by K. CONLEY, and voted unanimously to adjourn
Adjudicatory Session. S. CORNACCHIO had left the meeting prior to this vote.

TOPIC XIII.

ADJOURNMENT OF MEETING

DISCUSSION: NONE

ACTION: At 4.05PM motion by P. GANNON, seconded by R. TINSLEY, and voted unanimously to adjourn
the meeting. T. FENSKY; yes, G. CAVANAUGH; yes, C. BASILE; yes, P. GANNON; yes,; yes, W. COX;
yes, A. RAJA; yes, R. TINSLEY; yes. K. CONLEY; yes, A. STEIN: yes, M.GODEK: yes
S. CORNACCHIO had left the meeting prior to this vote.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

4. Draft Agenda for the June 7, 2016, regularly scheduled meeting of the Board of Registration in Pharmacy.
5. Draft May 3, 2016 Open Session Minutes.
6. Application for New Community Pharmacy Charles River Community Health
7. Application for New Community Pharmacy Southwick Pharma
8. Petition of Waivers Long Term Pharmacy Solutions
9. Report of Applications approved pursuant to licensure policy 13-01
10. Report of Application information pursuant to licensure policy 16-01
11. Report from Probation Monitor 4/27/2016 – 5/26/2016
12. Board Delegated Compliant Review report 3/31/2016
13. Board Delegated Complaint Review Report 4/29/2016
11. Licensure Policy 13-01 with draft amendment for transfer of ownership staff action
12. Draft proposed new regulation 247 CMR 19.00: Hazardous Drugs
13. Revised Board of Pharmacy Meeting Schedule for remainder of 2016
14. Draft Controlled Substance Advisory
15. Deficiencies Observations Report 2014/2015
16. Level 1 Plans of Correction (POC) Report pursuant to Enforcement Policy 13-02
17. Investigation report in the matter of Boulevard Pharmacy, DS2973, SA-INV-7664
18. Investigation report in the matter of Freedom Fertility Pharmacy, DS89717, SA-INV-8754
19. Investigation report in the matter of Johnson’s Compounding Cr. DS3549, SA-INV-8781
20. Investigation report in the matter of Critical Care Systems, DS3327, SA-INV-7945
21. Investigation report in the matter of Baystate Home Infusion, DS3300, SA-INV-7895
22. Investigation report in the matter of Pentec Health, DS89913, SA-INV-7493
23. Investigation report in the matter of Pentec Health, DS89913, SA-INV-8308
24. Investigation report in the matter of Pentec Health, DS89913, SA-INV-8780
25. Investigation report in the matter of Omnicare Northern MA, DS89931, SA-INV-8117
26. Investigation report in the matter of Omnicare Northern MA, DS89931, SA-INV-7946
27. Investigation report in the matter of Amherst Pharmacy, DS89775, SA-INV-8309
28. Investigation report in the matter CVS/CoramSpecialty Infusion, DS3601, SA-INV-8621

Respectfully submitted by:
M. GODEK, R.Ph.
