COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

September 6, 2018 239 Causeway Street ~ Room 417 A&B Boston, Massachusetts 02114

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Beth Rabasco, Phone: 617-624-5291 in advance of the meeting. While the Board will do its best to accommodate you, certain accommodations may require distinctive requests or the hiring of outside contractors and may not be available if requested immediately before the meeting.

Agenda

Time	#	Item	Page	Contact
8:30	I	CALL TO ORDER		M. Godek
	II	APPROVAL OF AGENDAIntroduction of new interns: Tina Gianellis		
	III	 APPROVAL OF BOARD MINUTES Draft of August 2, 2018 Regular Session Minutes 		
8:40	IV	 REPORTS Applications approved pursuant to Licensure Policy 13-01 Monthly report from probation Board Delegated Review pursuant to licensure policy 14-02 Above Action Levels approved by Staff Action 16-04 		
8:45	V	 APPLICATIONS Bright Health Pharmacy-New Community Pharmacy Eterna Pharmacy – New Community Pharmacy Apothecare Pharmacy(DS89820)- Transfer of Ownership Apothecare Pharmacy(DS89820)-Relocation PetNet Solutions(NU15) – Renovation Western Mass Compounding Center (DS89965)- Change of Manager ACC Apothecary(DS3530) – Renovation PharmaHealth Hawthorne(DS3473) – Transfer of Ownership 		

9:30	VI	 FLEX Advisory on Conducting Repairs or Service to Sterile Compounding Facilities or Facilities Engaging in Complex Non-Sterile Compounding Delegate for the NABP District 1&2 meeting Proposed Resolutions for the NABP District meeting Revocation of outdated Board policies 	
10:00	VII	REGULATIONS • 247 CMR 17.00 – Sterile Compounding • 247 CMR 22.00 - Fining	
11:45	VIII	FILE REVIEW 1 PHA-2018-0013 Fenway Pharmacy, DS89656 2 PHA-2018-0014 Fenway Pharmacy, DS3583 3 SA-INV-13333 Kabafusion, DS89700 4 PHA-2018-0016 Smith Drug, DS2198 5 SA-INV-13332 CVS #1132, DS1734 6 PHA-2018-0009 CVS #4471, DS3552 7 PHA-2018-0044 CVS #2071, DS3589 8 PHA-2018-0018 CVS #260, DS2294 9 PHA-2018-0019 CVS #2128, DS2720 10 PHA-2018-0034 CVS #765, DS2910 11 SA-INV-13476 Rite Aid #10119, DS90131 12 PHA-2018-0047 Rite Aid #10116, DS90149 13 PHA-2018-0046 Walgreens #10562, DS3617	

12:30 LUNCH BREAK							
1:30	IX	EXECUTIVE SESSION 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. Specifically, review requests for reinstatement, review request for termination of probation, and to evaluate the Good Moral Character as required for registration for pending applicants.		CLOSED SESSION			
3:00	X	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)					
3:30	XI	M.G.L. c. 112, § 65C SESSION		CLOSED SESSION			
5:00	XII	ADJOURNMENT		CLOSED SESSION			

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION 239 Causeway Street, Fourth Floor ~ Room 417A Boston, Massachusetts, 02114 September 6, 2018

Board Members Present

Board Members Not Present

Andrew Stein, Pharm D, RPh. President Elect Michael Godek, RPh. President

Kim Tanzer, PharmD, RPh. Secretary Dawn Perry, JD

Susan Cornacchio, JD, RN, (arrived 8:48 AM) Leah Giambarresi, Pharm D, RPh

Patrick Gannon, RPh (out of meeting 9:00 AM to 9:30 AM)

Julie Lanza, CPhT
Timothy Fensky, RPh
Ali Raja, MD, MBA, MPH
Carly Jean-Francois, RN, NP (left meeting at 12:30 PM)
Sebastian Hamilton, MBA, Pharm D, RPh
Stephanie Hernandez, Pharm D, BCGP, RPh

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, CPhT, Associate Executive Director
Heather Engman, JD Board Council
William Frisch, RPh Director of Pharmacy Compliance
Joanne Trifone, RPh., Director of Pharmacy Investigations
Kimberly Morton, CPhT, Compliance Officer
Greg Melton, JD, PharmD, BCPS, RPh, Investigator
Julienne Tran, Pharm D, RPh Investigator/Quality Assurance Pharmacist
Christina Mogni, RPh Investigator
Joseph Santoro, RPh Investigator
Ed Taglieri, MSM, NHA, RPh
Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:37 AM

A quorum of the Board was present, established by roll call. President A. Stein chaired the meeting and asked if anyone was recording hearing, no one responded. He explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: A. Stein, yes; K. Tanzer, yes; S. Hernandez, yes; J. Lanza, yes; Patrick Gannon, yes; T. Fensky, yes; A. Raja, yes; S. Hamilton, yes; C. Jean-Francois, yes (S. Cornacchio join meeting 8:48 AM)

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Topic II. Approval of Agenda TIME 8:37 AM

Agenda September 6, 2018

DISCUSSION:

Change to Agenda:

1. ACC Apothecary DS3530 Renovation in applications is deferred

ACTION:

Motion by T. Fensky, seconded by S. Hamilton, and voted unanimously to approve the agenda with noted changes.

Dave introduced the 2 interns, Benjamin Gilman from University of Rhode Island Program and Tina Gianellis from MCP Worcester Pharmacy Program. Andrew asked all students in the audience to stand and introduce themselves.

Topic III Approval of Board Minutes TIME: 8:40 AM

Minutes

Draft, August 2, 2018 Regular Session Minutes

Changes:

Correct: Page 11 of 13 at bottom grammatical correction from" be being" to "be"

Action:

Motion by S. Hamilton, seconded T. Fensky, and voted unanimously to approve the regular session minutes of August 2, 2018 with noted changes.

TOPIC IV REPORTS

Applications approved pursuant to Licensure Policy 13-01 Time: 8:41 AM

<u>Discussion</u>: M.BOTTO noted that during the past month there have been twenty-four (24) changes of manager on record (MOR).

So noted

TOPIC IV REPORTS

Monthly Report from Probation

<u>Discussion</u>: M.BOTTO noted that during the past month two (2) licensees satisfactorily completed

probations.

So noted

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BOP Approved: 10/4/18

Time: 8:41 AM

TOPIC IV REPORTS
Monthly Report from BDCR pursuant to Policy 14-02

<u>Discussion:</u> M.BOTTO noted that during the past month there have been six (6) staff actions for board delegated reviews. The first five were regarding CE deficiencies (SA-INV-13610, SA-INV-13538, SA-INV-13717, SA-INV-13693, and SA-INV-13692), the last one being a consumer grievance (SA-INV-13621.) All staff assignments were closed with discipline not warranted and remediation complete.

So noted

TOPIC IV REPORTS
Above Action Levels Approved by Staff Action 16-04

<u>Discussion:</u> K.MORTON noted that during the past month there were four (4) above action level results pursuant to licensure Policy 16-04, all of which were successfully remediated and closed.

So noted

Topic V: APPLICATIONS Time: 8:42AM

1. Bright Health Pharmacy

New Community Pharmacy

TIME: 8:42 AM

Time: 8:41 AM

Time: 8:41 AM

Recusal: None

<u>Discussion</u>: Bright Health Pharmacy was represented by the sole proprietor and pharmacist, Frederick Alamba, who is applying to manage and operate a new community pharmacy in Brockton, MA. Mr. Alamba feels a need for an independent pharmacy within the community. The pharmacy's hours of operation will be from 8AM – 6PM Monday through Friday, and Saturday from 8AM to 2PM. It will be closed on Sundays. Mr. Alamba desires to do simple and moderate compounding and will edit his application accordingly. The pharmacy is located as a store front, with a church connected to the right. Security measures are currently in progress, and already have cameras. Administration of vaccines will take place.

A.STEIN had asked Mr. Alamba his plans on continuity of care. His response was that he believes his software has the capability for phone forwarding, but he will look into it.

- T. FENSKY had asked Mr. Alamba how many hours he plans to work, with a response of 52 hours per week. T. FENSKY recommended that he hire a part-time pharmacist. Mr. Alamba plans to hire one technician and one technician trainee in the near future.
- P. GANNON inquired about special packaging, delivery service, and what will the security process be for the prescriptions being delivered. Mr. Alamba stated that he will have blister packaging, along with a delivery service with discreet drivers. P.GANNON recommended considering a process of

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signing in and signing out to reduce the risk of possible diversion. P. GANNON recommended looking at the Board's guidance on delivery practices.

<u>Action</u>: Motion by K. TANZER, seconded by S. HAMILTON, and voted by the majority of those present to approve the application to manage and operate a new community pharmacy contingent upon successful inspection. T. FENSKY opposed the motion.

2. Eterna Pharmacy

New Community Pharmacy

TIME: 9:26 AM

Recusal: None

<u>Discussion</u>: Eterna Pharmacy was represented by the MOR, Felix Baez, who is applying to manage and operate a new community pharmacy in New Bedford, MA. He has previous experience as a MOR in Rhode Island and is bilingual in Spanish and English. He believes this will allow him to provide good customer service. He estimated ~40-50% of his patients will be geriatrics. Mr. Baez stated he is currently in the process of interviewing staff, and is looking to hire one pharmacist and three technicians. He is not yet registered with the prescription monitoring program (PMP) in MA, but will do so.

Considering that the pharmacy will be closed on Sundays, P. GANNON inquired about the after-hour process. Mr. Baez stated they will have the ability to respond quickly to any requests after hours; delivery of prescriptions will all be tracked done by "in house" couriers, and that all couriers will be HIPAA certified. The pharmacy is a store front and to the left of it is Seven Hills Behavioral Health Center, with Rite Aid being located to the right.

P. GANNON considered the large Mayan population and asked how will he be able to communicate with them if they were to become his patients. Mr. Baez responded that he will hire a pharmacist or a technician to be able to provide the interpreting service if the need arises.

Immunizations will be administered at the pharmacy, along with the ability to provide specialty packaging. Mr. Baez has looked at a couple of systems regarding specialty packaging. The computer system that will be utilized is "Pioneer Rx" and the wholesaler is not yet determined. Simple and moderate compounding will be performed. The Board was satisfied with his security measures. Mr. Baez stated that he will use a nationally-known security company, cloud based IVRs, cameras in all four corners, including the front and back door.

P.GANNON made a recommendation to review the draft regulations for best practices.

<u>Action</u>: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present, to approve the application to manage and operate a new community pharmacy contingent upon successful inspection.

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3. Apothecare Pharmacy (DS89820)

Transfer of Ownership TIME: 11:24 AM

Recusal: T. FENSKY

<u>Discussion</u>: Apothecare Pharmacy was represented by Geoffrey Peterson, the director of pharmacy; Rudy Dajie, CEO and president; Lori Bassinger, JD, R.Ph; and Katherine Day, post doctorate fellow; who are applying for a transfer of ownership. Apothecare Pharmacy LLC was purchased by Apothecare Pharmacy Acquisition Corporation on July 17, 2018. The legal entity has not changed, and Ms. Bassinger informed the Board there was no change in manager or staff.

<u>Action</u>: Motion by S. HAMILTON, seconded by K. TANZER, and voted unanimously of those present, to approve the application for transfer of ownership contingent upon successful inspection.

4. Apothecare Pharmacy (DS89820)

Relocation TIME: 11:24 AM

Recusal: T. FENSKY

<u>Discussion</u>: Apothecare Pharmacy was represented by Geoffrey Peterson, the director of pharmacy; Rudy Dajie, CEO and president; Lori Bassinger, JD, R.Ph; and Katherine Day, post doctorate fellow; who are applying for a relocation of a community pharmacy. Mr. Peterson stated the reason for relocating was because they feel as if they have outgrown the space. They will go from having 4,000 square feet to 13,000 square feet. Rudy Dajie informed the Board that the proposed date to relocate will occur November to December 2018.

<u>Action</u>: Motion by S. HAMILTON, seconded by K. TANZER, and voted unanimously of those present, to approve the application for relocation contingent upon a successful inspection.

5. PetNet Solutions (NU15)

Renovation

TIME: 8:52 AM

Recusal: S. Cornacchio

<u>Discussion</u>: PetNet Solutions was represented by Paul Mahan, Senior Regulatory Specialist, Nu R.Ph; Craig Sawyer, MOR; and Scott Rusik; who are applying for pharmacy renovations.

Following a detailed overview, provided by J.TRAN, of the above action level findings, Mr. Mahan began to explain their unique model. Mr. Mahan requested a sink and refrigerator waiver. This way, the space will act as a buffer room around the hot cell. Temporary walls will be erected to reduce contaminants and wall returns and HEPA filters will be added. They are trying new technology, a ring halo system with Hydrogen on the return portion of the HVAC system, to reduce viable contaminants.

Mr. Mahan informed the Board that even with all of the renovations, they will not always have optimal conditions, given the regulatory constraints.

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The addition of air scrubbers to help decrease particulates, environmental monitoring within the enclosures, and weekly monitoring of viable contaminants will be required.

Regarding the waiver to remove the refrigerator, Mr. Mahan indicated there are no radiopharmaceuticals required to be refrigerated. H. ENGMAN informed those present that the waiver is not necessary, and recommends withdrawing the waiver request. W. FRISCH stated that PetNet Solutions have been very cooperative.

<u>Action</u>: Motion by T. FENSKY, seconded by K. TANZER, and voted unanimously of those present, to approve the application for renovation conditioned upon the weekly environmental monitoring within the enclosures around the hot cell, placement of air scrubbers outside of the enclosures, withdrawal of the waiver requests, and provision of a detailed project timeline.

6. Western Mass Compounding Center (DS89965) Change of Manage TIME: 9:22 AM

Recusal: none

<u>Discussion</u>: Western Mass Compounding Center was represented by the owner, Bradley Sprecher, requesting a change in manager. Mr. Sprecher is requesting to manage the pharmacy. He stated this compounding pharmacy is non-sterile only. Mr. Sprecher is registered with PMP and is not planning to immunize.

A. STEIN asked Mr. Sprecher if he had any pending matters of an impending administrative hearing concerning the compounding of a FDA commercially available product. Mr. Sprecher responded that they have worked with counsel and the Board.

<u>Action</u>: Motion by S. HERNANDEZ, seconded by C. JEAN-FRANCOIS, and voted unanimously of those present, to approve the application for a change in manager. P. Gannon stepped out of room, thus did not participate or vote.

7. ACC Apothecary (DS3530) Renovation TIME: 9:26AM

This renovation request has been deferred at the pharmacy's request.

8. Pharmahealth Pharmacy Hawthorn DS3473 Transfer of Ownership TIME: 9:36 AM

Recusal: None

<u>Discussion</u>: Pharmahealth Pharmacy Hawthorn was represented by the owner, Sreenivas Athuluri, who is requesting a transfer of ownership. Mr. Athuluri was a pharmacy manager in the past, and

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has been a pharmacist for 12 years. He has been looking to open an independent pharmacy in the area, and has a partner who is a pharmacist in Connecticut. He is planning on delivering and blister packaging medication. Mr. Athuluri has been doing paperwork to establish the pharmacy since August 15, 2018 and is still in the process. The pharmacy will be open Monday through Friday, and he is trying to change the wholesaler. The pharmacy was still operating when he purchased it.

T. FENSKY asked if he was keeping the same pharmacy name. Mr. Athuluri responded stating he is only changing the corporate name and is keeping the same MOR.

A. STEIN inquired about whether or not the control count was done and if he was registered with PMP. Mr. Athuluri answered yes to both.

<u>Action</u>: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously to approve the application for transfer of ownership.

Topic VI. FLEX Time: 9:55 am

1. Advisory on Conducting Repairs or Service to Sterile Compounding Facilities or Facilities Engaging in Non-Sterile Compounding

Presented by: W. FRISCH and M. CHAN

Discussion: M. CHAN discussed the minor changes to the advisory including the addition of a provision that a major repair/renovation application would be needed if a PEC was moved, removed, added, modified and/or replaced.

Action: Motion by T. FENSKY, seconded by K. TANZER, and voted unanimously by those present to approve the changes to the advisory.

2. Delegate for the NABP District 1 & 2 meetings

Presented by: D. SENCABAUGH

Discussion: The discussion centered on the members who would be attending the conference and who expressed interest in being the official delegate from the Board. D. SENCABAUGH nominated L. GIAMBARRESSI who was not present but had previously expressed interest in being the delegate. J. LANZA nominated S. HAMILTON as the alternate delegate in the event that L. GIAMBARRESSI is unable to attend.

Action: Motion by T. FENSKY, seconded by S. HERNANDEZ, and voted unanimously by those present to designate L. GIAMBARRESI as the delegate and S. HAMILTON as the alternate.

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3. Proposed Resolutions for the NABP District meeting

Presented by: D. SENCABAUGH

Discussion: The Board sought out recommendations for proposed resolutions that could be brought to the NABP for further discussion and guidance. D. SENCABAUGH brought up two possible resolutions.

The first one is in regards to FDA Voluntary Recall Announcements for outsourcing facilities and the structuring of consistency with the handling of such recalls. The Board would seek for NABP to study and recommend a process on how to react in this scenario.

The second resolution was regarding suspected/confirmed loss of controlled substances that were "lost in transit". The Board seeks NABP's guidance and recommendations with this issue.

P. GANNON proposed a third resolution to bring to the NABP. With the rapid rise in use of e-prescriptions, P. GANNON mentioned that there should be a way to "e-deprescribe" in which providers could discontinue/inactivate prescriptions which would prevent pharmacies from inadvertently refilling medications that patients no longer need. Due to many pharmacies using an "auto-refill" process, this could help solve the issue of unnecessary medications being filled and utilized by patients. P. GANNON also requests exploration of the possibility to electronically flag prescriptions with a "do not auto-fill" designation.

S. HAMILTON briefly proposed a resolution regarding naloxone but was satisfied with the three previous resolutions and would bring it up at a later time if necessary.

Action: Motion by P. GANNON, seconded by S. HERNANDEZ, and voted unanimously by those present to bring the three proposed resolutions to the NABP meeting

4. Revocation of outdated Board Policies

Presented by: M. CHAN and D. SENCABAUGH

Discussion: M. CHAN presented to the Board a list of outdated policies to be revoked. The policies had either been replaced by regulation, new policies, or no longer represent the standard of practice.

Policies to be revoked:

96-01: Expiration of CII prescriptions

96-02: Electronic Transfer of a prescription where no pharmacist is on duty

96-03: Clean room construction

96-04: Perpetual Inventory

96-05: Twelve Hour Limit

98-01: Policy on Technicians and Refill Authorizations

98-02: Continuing Education Audits and Compliance

98-03: Computerized Compendia

98-05: Automated Dispensing Devices

98-06: Canadian Council on Continuing Pharmaceutical Education (CCCEP)

98-08: Emergency Kits

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98-09: Probationary License Status

99-01: Prescribing Limits for Schedules II and III Controlled Substances

00-01: Disease State Management Requirements/Pharmacist Credentialing

00-04: Guideline for Confidentiality and Compliance Programs

00-05: Board-Approved Continuing Education Programs

00-06: Medication Error/Adverse Drug Event Reporting

01-01: Board Interpretation of USP BUD Requirements

07-01: Issuance of Multiple Prescriptions for Schedule II Controlled Substances

09-01: Policy on Management of Pain

Action: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present to revoke the listed policies.

Topic VII. REGULATIONS

1. 247 CMR 22.00: Fining

Presented by: W. FRISCH, M. CHAN, and H. ENGMAN

Discussion: The Board staff brought the regulation, staff action policy, and fining matrix to the Board for discussion and votes on each specific document

TIME: 10:17 AM

Regulation:

- H. ENGMAN mentioned that the regulation document was the legal framework for the Board's ability to fine licensees. The document included portions regarding assessment, notice, and a right to a hearing regarding the fine. There were parameters for amounts and payments and H. ENGMAN also mentioned that nothing in this document precluded the Board from pursuing additional disciplinary actions
- P. GANNON stated that this was a brand-new concept in the Commonwealth of Massachusetts
 and recommended that being more specific in the staff action policy would be better than being
 specific in the regulations. Keeping the regulation document broader would cause less issues in
 the future

Action: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously to approve the draft regulation and move it to administrative review

Staff Action Policy:

• H. ENGMAN stated that this document would authorize board staff to issue monetary penalty notices if the violation/deficiency was listed on the fining matrix.

Action: Motion by S. HAMILTON, seconded by K. TANZER, and voted unanimously to approved draft staff action policy and move it to administrative review

Fining Matrix:

• P. GANNON mentioned that the wording at the beginning of the matrix regarding "criteria" should be changed to "guideline" so that the Board is not permanently tied to certain fines for certain violations

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- S. CORNACCHIO suggested adding ranges of fines instead of a set amount so that the Board staff
 could agree upon fines for certain circumstances without escalating the matter to the Board.
 The Board members and staff wanted a set amount for each fine that the Board staff assessed
 and would escalate to the Board if necessary
- The Board members suggested that there should be a "grace period" in which the fines could be assessed in real scenarios without the actual monetary penalty. This would allow for the Board to see if the fines are set at the right amount and are penalizing the right violations
- P. GANNON suggested that all second offense violations found on re-inspection should automatically be sent to the Board for further evaluation
- Debate whether fines would reduce the reporting of controlled substance losses was had
- W. FRISCH asked for the Board's guidance in determining fine amounts for each violation on the fining matrix
- A. RAJA suggested striking the violation regarding multiple violations as the wording was confusing and unnecessary. The remaining Board members agreed. The violation was struck from the matrix
- P. GANNON suggested a \$1000 fine for both violations including perpetual and biennial
 inventory of CIIs. A. STEIN mentioned that this could result in unfair fining for "one-time"
 situations in which circumstances prevented the regular pharmacist doing these tasks from
 completing them. D. SENCABAUGH said it should be zero tolerance and any extenuating
 circumstances could be brought to the Board or appealed
- P. GANNON mentioned that this violation was very subjective and specifications would need to be added. There should be photographic evidence that is required and possibly be specific to equipment cleanliness. K. TANZER was uncomfortable with assessing a fine on subjective matters such as this. P. GANNON suggest \$250 as there was too big of a range of possible circumstances that fall under this violation and egregious violations could be brought to the Board. \$250 was also suggested for cleanliness of compounding equipment and the refrigerators and freezers
- P. GANNON also relayed the same thoughts about expired medications. A wide range in terms
 of severity of the violation is possible and suggested a \$250 fine with egregious violations having
 the possibility of being brought to the Board
- S. HAMILTON suggested \$500 for fridge temperature violations due to patient safety issues. This also was suggested for immunization storage violations
- S. HAMILTON suggested \$1000 for BUD violations due to patient safety issues as well as Master Formulation and Compounding Record violations
- \$250 was suggested for the remaining violations on the fining matrix
- The Board suggested removing the provisions for 237 CMR 17.00 and 18.00 fines to reduce confusion
- P. GANNON asked where the staff ratio violation was since it is such a common violation. W.
 FRISCH responded that it was not a clear-cut violation and was removed. P. GANNON suggested adding it back on and base it on the citation that an investigator would give. Everyone agreed and a \$250 fine was suggested
- P. GANNON also asked about technician-in-training violations and a similar discussion was had
- S. HAMILTON brought up fining out-of-state pharmacies that will be licensed in the future and that discussion would be needed

Action: Motion by T. FENSKY, seconded by S. HERNANDEZ, and voted unanimously to approve draft fining matrix and move it to administrative review

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2. 247 CMR 17:00 Sterile Compounding

Presented by: W. FRISCH, M. CHAN, and H. ENGMAN

Discussion:

17.24 (8)

 W. FRISCH mentioned that 17.24 (8) would have daily EM struck from the regulation and that medium/low risk viable air sampling would be quarterly. High risk viable air sampling would be monthly and viable surface sampling would be aligned with USP <797>

TIME: 11:28AM

T. FENSKY agreed that viable surface sampling monthly would be achievable

Action: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously to approve standards for viable air and surface sampling frequencies

17.27

 W. FRISCH mentioned that action levels would be aligned with USP <797>. Remediation responses would be moved to a policy document. High pathogenic organisms would be mentioned in a policy document as well

Action: Motion by P. GANNON, seconded by K. TANZER, and voted unanimously to approve changes

17.28

• W. FRISCH asked to remove language from 17.28 and refer to a policy

Action: Motion by T. FENSKY, seconded by S. HAMILTON, and voted unanimously to approve changes

D. SENCABAUGH suggested the addition of another Board meeting specifically for discussion on 247 CMR 17.00 and/or a sub-committee. A sub-committee was deemed too complicated to create and Board members were receptive to the idea of an additional "night" meeting. P. GANNON also mentioned that a sub-committee would still need to re-hash details with the full Board and would end up being not as efficient. Board members would show their availability and a meeting will try to take place in the next few weeks

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Topic VIII. OPEN FILE REVIEW Time: 12:08 PM

Case #1

PHA-2018-0013 Fenway Pharmacy, DS89656 Time: 12:08 PM

RECUSAL: NONE

<u>DISCUSSION</u>: G. MELTON presented and summarized the investigative report that pertained to these matters.

- •Comingling of duties, staff, drug ordering, drug storage and inventory between the pharmacy and Fenway Health Center clinic was observed during ISP-7168 on 04/24/2017;
- •Despite MOR Mele reporting on 11/28/2017 that the practice was discontinued, on 03/07/2018 during ISP-9303, OPP Pharmacy Investigators determined the practice was ongoing;
- Pharmacy has DS/CS from BORP with a retail pharmacy DEA registration and the clinic has a MCSR for CIIIs and CVIs with a hospital/clinic DEA registration for CIIIs;
- •MOR Mele indicated the medications received for the clinic were placed in the "clinic pharmacy", which is a supply cabinet outside of the pharmacy;
- •03/01/2017-03/08/2018: Pharmacy ordered 263 medications/products from the wholesale distributor including CIIIs, CVIs and OTCs and 2 IUDs from the manufacturer for clinic use;
- •7/12/18 Pharmacist Lao provided a clarification on behalf of MOR Mele who was on leave clarifying process 11/28/17 when assurances were made to BORP to 3/5/18 and provided a response in conflict to MOR Mele's;
- •CA: Clinic staff will have ability to order medications for the clinic which will be delivered to the specified clinic floor. Pharmacy staff will no longer be able to receive clinic medications.

<u>ACTION</u>: Motion by S. HERNANDEZ, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2018-0013) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #2

PHA-2018-0014 Fenway Pharmacy, DS3583 Time: 12:10 PM

RECUSAL: NONE

<u>DISCUSSION</u>: G. MELTON presented and summarized the investigative report that pertained to these matters.

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- •Comingling of duties, staff, drug ordering, drug storage and inventory between the pharmacy and Fenway Health Center clinic was observed during ISP-7167 on 04/24/2017;
- Despite Director of Pharmacy Mele reporting on 11/28/2017 that the practice was discontinued, on 03/07/2018 during ISP-9302, OPP Pharmacy Investigators determined the practice was ongoing;
- •Pharmacy has DS/CS from BORP with a retail pharmacy DEA registration and the clinic has a MCSR for CIIs-CVIs with a hospital/clinic DEA registration for CIIs-CVs;
- •MOR Balram stated he was instructed to order Clinic medications and distribute the drugs to the medical staff;
- •Fenway Medical SEA Profile indicated 95 medications provided to the Clinic from 03/01/2017-04/02/2018 but invoices submitted indicated additional medications were ordered but not included on the Profile;
- •7/12/18 Pharmacist Lao provided a clarification on behalf of MOR Mele who was on leave clarifying process 11/28/17 when assurances were made to BORP to 3/5/18 and provided a response in conflict to MOR Mele's;
- •CA: Clinic staff will have ability to order medications for the clinic which will be delivered to the specified clinic floor. Pharmacy staff will no longer be able to receive clinic medications.

<u>ACTION</u>: Motion by S. HERNANDEZ, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2018-0014) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #3

SA-INV-13333 Kabafusion, DS89700 Time: 12:16 PM

RECUSAL: NONE

<u>DISCUSSION</u>: G. MELTON presented and summarized the investigative report that pertained to these matters.

- •USP 797 inspection ISP-9420 on 3/22/18 OPP Investigators discovered EM conducted 10/11/17 showed 1 cfu of mold in the anteroom air sample and 1 cfu of mold from a surface sample in the buffer room that were not reported as required; deficiency cited for missing documentation of monthly clean; •MOR Fynn did not realize the abnormal results were actionable as he was following Kabafusion's SOP
- at the time which allegedly was based on USP 797;
- •Remediation included a triple clean on 10/11/17, 10/12/17, and 10/13/17 and repeat EM with no actionable results; RCA determined that there were concerns about technician from the testing company with his aseptic technique, hand washing, garbing, and handling of the equipment and samples and he was most likely the cause;
- •All 291 CSPs compounded 10/5/17 3/22/18 were dispensed with no recalls or reported adverse effects;

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- •Cleaning logs provided did not indicate monthly clean was performed 1/2018 or 2/2018, but MOR Fynn asserted it was done but not documented;
- •Monthly EM from 11/30/17 to 5/1/18 showed no above action results;
- •CA: Kabafusion has required all contracted companies entering the clean room to thoroughly clean all equipment with SIPA, inspect all garb prior to entering, use dedicated scrubs or shoes, Notify the pharmacy of any issues with the samples, re-educate all employees on hand hygiene, garbing and proper aseptic technique.

<u>ACTION</u>: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present, to CLOSE (SA-INV-13333) DISCIPLINE NOT WARRANTED, REMEDIATION COMPLETE contingent upon receipt of policy addressing vendors. Additionally, Board Members requested that a copy of the Board Advisory titled "Recommended Pharmacy Response to Above Action Level Environmental Monitoring Results" be included in the closing letter.

Case #4

PHA-2018-0016 Smith Drug, DS2198 Time: 12:24 PM

RECUSAL: NONE

<u>DISCUSSION</u>: G. MELTON presented and summarized the investigative report that pertained to these matters.

- Inspectional deficiencies (ISP-9094) on 3/5/18 for controlled substance recordkeeping, expired drugs, issues with refrigeration documentation, repackaging of drugs dispensed from other pharmacies, lack of labeling on multi-dose packaging, and non-compliant labeling on multi-dose packaging;
- Pharmacy dispenses drugs in vials, Dispill, blister cards, and daily primarily to individual residents and assisted living facilities;
- Pharmacy notified of the complaint on 3/30/18;
- •POC received on 4/17/18 and the response to the complaint received on 5/25/18 did not adequately address non-compliant labeling deficiencies;
- Re-inspection (ISP-10060) on 7/17/18 cited for controlled substance recordkeeping & security, disposing if controlled substances via police Take-Back box, outdated API, and non-compliant labeling (175 of 400 on Dispill);
- •7/18/18 Board staff recommended the Pharmacy discontinue the use of non-compliant labeling & packaging and no longer accept drugs dispensed from other pharmacies for repackaging in multi-dose packaging which MOR Fournier agreed to on 7/19/18;
- POC received 7/20/18-

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- MOR Fournier responded she reviewed the draft regulations for multi-dose packaging and completed 2 CEU on patient safety;
- Effective immediately Smith Drug will only dispense package product dispensed by Smith Drug and from no other source;
- o Smith Drug will comply with labeling requirements for multi-dose packaging;
- o Policy/Procedure developed to cleaning daily planners;
- Use of daily planners is being phased out as soon as possible, with the potential for exceptions requests for a limited number of patients with handicaps that preclude using that system;
- •MOR Fournier stated she intended to convert the majority of the multi-dose packaging to Dispill by 7/28/18;
- •Site Visit (ISP-10130) on 8/20/18: although all labeling was not fully compliant, MOR Fournier estimated 320 of 400 patients had been converted to Dispill labeling with some also converted to Dispill packaging;
- •8/22/18 MOR Fournier indicates she signed a formal agreement to work with a consultant who is aware of the outstanding issues to be addressed for full compliance.

<u>ACTION:</u> Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present, to DISMISS (PHA-2018-0016), NO DISCIPLINE WARRANTED contingent upon another inspection to confirm remediation complete.

Case #5

SA-INV-13332

CVS #1132, DS1734

Time: 12:30 PM

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

<u>DISCUSSION</u>: G. MELTON presented and summarized the investigative report that pertained to these matters.

- •On 1/24/18, timely RLCS of #60 amphetamine salts ER 30 mg capsules at CVS #1132 due to a confirmed dispensing error;
- •CVS Corporate Regulatory Affairs provided the response on behalf of the MOR and pharmacy staff indicating the loss was discovered during cycle counts on 01/12/18;
- •An internal review of perpetual inventory logs, dispensing reports and pharmacy cameras confirmed that a patient was dispensed 60 extra amphetamine ER 30mg capsules;
- •Pharmacist Mandel performed production and verification of the prescription on 1/11/18;
- •MOR Krigest spoke the patient who the patient confirmed receipt of the 60 additional capsules but refused to return them to the Pharmacy;
- •CA: MOR reviewed with pharmacy staff the best practices when filling CII prescriptions including double counting and back-counting with the back-count quantity noted on the hardcopy of the

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prescription; Pharmacist Mandel submitted proof of completion of 2 CEs in medications errors and attested to reviewing 247 CMR 15.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by K. TANZER, and voted unanimously by those present, to CLOSE (SA-INV-13332), NO DISCIPLINE WARRANTED, REMEDIATION COMPLETE

Case #6

PHA-2018-0009 CVS#4471, DS3552 Time: 12:31 PM

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

<u>DISCUSSION</u>: K. MORTON presented and summarized the investigative report that pertained to these matters.

- RLCS-#101 Oxycodone HCL 10mg tablets, on or about December 13, 2017;
- Pharmacy initially submitted no loss notification to OPP for a suspected loss of #99 oxycodone HCL 10mg tablets. OPP requested additional information from the pharmacy;
- Pharmacy response indicated that further investigation by field management after the submission of the no loss letter concluded there was a loss of controlled substances;
- MOR indicated that the investigation did not uncover an explanation for the loss;
- Corrective action included coaching and re-training the pharmacy team;
- CVS Pharmacy #4471 has one prior reported loss;
- A retail compliance inspection was conducted on March 14, 2018 with no deficiencies noted.

<u>ACTION</u>: Motion by P. GANNON, seconded by S. HERNANDEZ, and voted unanimously by those present, to refer the matter (PHA-2018-0009) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #7

PHA-2018-0044 CVS #2071, DS3589 Time: 12:32 PM

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

<u>DISCUSSION</u>: K. MORTON presented and summarized the investigative report that pertained to these matters.

- RLCS- #2,451 tramadol 50mg tablets as a result of an unknown loss;
- •Investigation was conducted, and the pharmacy was unable to determine the cause of the loss. No evidence of diversion or violation of any company policy;

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- The DEA also conducted an investigation at the pharmacy following the loss, they found no further significant discrepancies and closed their investigation;
- CVS #2701 has one prior reported loss;
- A retail compliance inspection was conducted on June 1, 2018 with no deficiencies noted.

ACTION: Motion by P. GANNON, seconded by S. HERNANDEZ, and voted unanimously by those present, to refer the matter (PHA-2018-0044) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for STAYED PROBATION, with special terms to include conducting an exact count CS inventory for all scheduled 3-5 medications within 30 days if haven't already performed, and a monthly exact count of all tramadol containing products for 12 months, staff retraining in the areas of inventory management, prescription production, and waiting bin management within 30 days and increased store visits from the Pharmacy Supervisor or Loss Prevention at least once every 30 days to validate and sign off on the BOH report cover page.

Case #8

PHA-2018-0018 CVS #260, DS2294

Time: 12:34 PM RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote on this matter **DISCUSSION**: J. TRAN presented and summarized the investigative report that pertained to these

matters.

- •RLCS- #30 dextroamphetamine 30mg tablets on or about November 21, 2017;
- MOR Papaioannou indicated that the unknown loss occurred as the result of a system glitch that did not record the pharmacy's dispensing;
- Video surveillance confirmed by MOR that the correct quantity was dispensed. The pharmacy ran a report to verify all the pharmacy's dispensing with that specific national drug code (NDC) number against the electronic prescriptions that would not have been on file, and verification of hard copies to confirm everything was recorded;
- •The suspected loss was due to a two-day national computer outage that did not recognize when a medication was being dispensed. Cameras were reviewed during that time period for the drug in question to review the number of swipes the personnel made to count the medication which revealed no over-dispensing;
- MOR Papaioannou indicated that she has reviewed the best practices when filling Schedule II prescriptions with the pharmacist team; specifically, double counting the medication, back counting the stock bottle and documenting the back-count amount on the hard copy of the prescription to minimize the likelihood of future variances."

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present to DISMISS, (PHA-2018-0018), NO VIOLATION.

Case #9

PHA-2018-0019 CVS #2128, DS2720 Time: 12:36 PM

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

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<u>DISCUSSION</u>: J. TRAN presented and summarized the investigative report that pertained to these matters.

- •RLCS- unknown loss of #60 oxycodone 5mg tablets and #90 Oxycontin 10mg tablets on or about December 29, 2017 as a result of the medication thrown away in the trash or a dispensing error;
- •The loss discovered when the patient came in to pick up the prescriptions, the computer system indicated that the prescriptions were in the waiting bin but could not be located;
- •The investigation included inspection of the entire waiting bin and prescription bags, video footage reviewed but after verification of the prescription bag was out of camera view;
- Former MOR Patel indicated that in response to this event, all schedule II prescriptions have been retained in a separate area close to the pharmacist that is visible on camera.

<u>ACTION</u>: Motion by S. HERNANDEZ, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2018-0019) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #10

PHA-2018-0034 CVS #765, DS2910 Time: 12:37 PM

<u>RECUSAL</u>: S. CORNACCHIO recused and was not present for the discussion or vote on this matter <u>DISCUSSION</u>: J. SANTORO presented and summarized the investigative report that pertained to these matters.

- RLCS, #1688 alprazolam 1 mg tablets identified via corporate controlled substance monitoring on or about February 14, 2018. LP confirmed the loss on April 9, 2018;
- Loss identified via corporate CS monitoring;
- CCTV footage was reviewed for suspicious behavior or deviation from procedures. The dispensing of drug was also reviewed on CCTV footage but did not reveal any evidence of diversion or gross violation of current policy. LP Team was able to rule out active losses but did not uncover an explanation of the loss;
- The pharmacy team was coached to double count all controlled medication prior to dispensing. All base line loss prevention procedures, especially those that prevent drug diversion were also reviewed with staff. Loss prevent policy and procedures included: inventory management, dispensing standards and bag/smock check.

<u>ACTION</u>: Motion by P. GANNON, seconded by S. HERNANDEZ, and voted unanimously by those present, to refer the matter (PHA-2018-0034) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for STAYED PROBATION, with special terms to include conducting an exact count CS inventory for all scheduled 3-5 medications within 30 days if haven't already performed, and a monthly exact count of all benzodiazepine products for 12 months, staff retraining in the areas of inventory management, prescription production, and

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waiting bin management within 30 days and increased store visits from the Pharmacy Supervisor or Loss Prevention at least once every 30 days to validate and sign off on the BOH report cover page.

Case #11

SA-INV-13476 Rite Aid #10119, DS90131 Time: 12:41 PM

RECUSAL: NONE

<u>DISCUSSION</u>: J. TRAN presented and summarized the investigative report that pertained to these matters.

- •RLCS- #500 diazepam 10mg tablets as a result of an unknown loss;
- Pharmacy could not determine if the bottle was received from their warehouse, but it was checked into the inventory;
- MOR Murguz indicated that an investigation could not determine the reason for the loss and no diversion suspected;
- A retail compliance inspection (ISP- 8981) was conducted at Rite Aid #10119 on January 8, 2018 with no deficiencies noted;
- •Three prior reported losses (on old DS).

<u>ACTION</u>: Motion by S. HERNANDEZ, seconded by S. HAMILTON, and voted unanimously by those present, to CLOSE (SA-INV-13476), NO DISCIPLINE WARRANTED.

Case #12

PHA-2018-0047 Rite Aid #10116, DS30149 Time: 12:42 PM

RECUSAL: NONE

<u>DISCUSSION</u>: J. SANTORO presented and summarized the investigative report that pertained to these matters.

- RLCS-unknown loss of #20 Vyvanse 50 mg capsules discovered by a pharmacist during a back on 3/28/2018;
- It is believed that the last patient that had a RX filled on 3/27/2018 received #50 Vyvanse 50mg capsules instead of # 30 capsules. There was a correct perpetual inventory on 3/25/2018;
- The pharmacist left a message on the patient's voicemail but was unable to verify the over-dispense;
- Pharmacist Asaad (floating pharmacist) acknowledged that he worked on the day the prescription was filled but could not understand how he could make that mistake because his practice is to double count all CII medications filled;
- MOR Portnoy indicated that the team will ensure that there is a double count on all CII medications to ensure there is the appropriate quantity dispensed for all medications. Pharmacist Asaad completed 2

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CE credits in the area of preventing medication errors and provided a signed copy of 247 CMR 15 indicating that he read he regulations.

<u>ACTION</u>: Motion by P. GANNON, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2018-0047) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #13

PHA-2018-0046 Walgreens #10562, DS3617 Time: 12:45 PM

RECUSAL: NONE

<u>DISCUSSION</u>: J. SANTORO presented and summarized the investigative report that pertained to these matters.

- RLCS- # 90 Vyvanse 30mg capsules discovered on May 6, 2018 during weekly count
- During the filling process, a CPhT mistakenly threw a stock bottle of #90 Vyvanse 30mg capsules into the trash;
- Incident was seen on camera;
- Investigator Melton and this OPP Investigator reviewed the DVD footage of the CPhT filling a prescription for #30 Vyvanse 30mg capsules and it clearly shows two bottles being thrown in the trash;
- MOR Cannizzo indicated that a change in policy allows only pharmacists to count schedule II scripts.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to DISMISS (PHA-2018-0046), NO DISCIPLINE WARRANTED.

Topic IX: EXECUTIVE SESSION Time: 12:45 PM

Read by A. Stein

DISCUSSION:

ACTION: At 12:45 PM President M. GODEK read the statement on reasons for Executive Session.

12:45 PM to 1:40 PM Lunch Break

Topic IX: Executive Session Call to Order:

By: A. Stein

<u>ACTION</u>: Motion by T. Fensky, seconded by S. Hernandez, and voted unanimously by roll call to call the August 6, 2018 meeting of the Executive Session to order.

Time: 1:40 PM

A. Stein, yes; K. Tanzer, yes; S. Hernandez, yes; J. Lanza, yes; Patrick Gannon, yes; T. Fensky, yes; A. Raja, yes; S. Hamilton, yes; S. Cornacchio, yes.

Topic X: ADJUDICATORY SESSION (MGL 30A § 18) Time: 2:37 PM

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DISCUSSION: None

<u>ACTION</u>: President Elect A. Stein request a motion to enter Adjudicatory Session.

At 2:37 PM, Motion by P. Gannon, seconded by T. Fensky and voted unanimously to enter Adjudicatory Session.

Topic XI: M.G.L. 65 C Time: 2:44 PM

DISCUSSION: None

ACTION: President Elect Andrew Stein request a motion to enter M.G.L 65 c Session.

At 2:44 PM, Motion by T. Fensky, seconded by S. Hernandez and voted unanimously to enter M.G.L.

chapter 65 c Session:

Topic XII: ADJOURMENT OF MEETING Time: 3:25 PM

ACTION: Motion by S. Hamilton seconded by K. T. Fensky, and voted unanimously by those present, to adjourn from General Session.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

- 1. Draft Agenda of the 9/6/18 General Session
- 2. Draft Minutes of the 8/2/18 Meeting
- 3. Report on Applications approved pursuant to Licensure Policy 13-01
- 4. Report on probation
- 5. Report on Board Delegated Complaint Review to licensure policy 14-02
- 6. Report on Above Action Levels approved by Staff Action 16-04
- 7. Bright health Pharmacy- New Community Pharmacy
- 8. Eterna Pharmacy- New Community Pharmacy
- 9. Apothecare Pharmacy (DS89820) Transfer of Ownership and Renovation
- 10. PetNet Solutions (NU15) Renovation
- 11. Western Mass Compounding Center (DS89965) Change of Manager
- 12. ACC Apothecary (DS3530) Renovation
- 13. Pharmhealth Darthmouth, MA Change of Ownership
- 14. Advisory on Conducting Repairs or Service to Sterile Compounding Facilities or Facilities Engaging in Complex Non-Sterile Compounding
- 15. Revocation of outdated Board Policies
- 16. 247 CMR 17.00 Sterile Compounding Grid Public Comments
- 17. 247 CMR 22.00 Fining, Staff Action Policy and Fining Grid
- 18. 247 CMR 22:00 Fines; Draft regulation, draft staff action policy & draft fining matrix
- 19. PHA-2018-0013 Fenway Pharmacy, DS89656
- 20. PHA-2018-0014 Fenway Pharmacy, DS3583

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- 21. SA-INV-13333 Kabafusion, DS89700
- 22. PHA-2018-0016 Smith Drug, DS2198
- 23. SA-INV-13332 CVS #1132, DS1734
- 24. PHA-2018-0009 CVS #4471, DS3552
- 25. PHA-2018-0044 CVS #2071, DS3589
- 26. PHA-2018-0018 CVS #260, DS2294
- 27. PHA-2018-0019 CVS #2128, DS2720
- 28. PHA-2018-0034 CVS #765, DS2910
- 29. SA-INV-13476 Rite Aid #10119, DS90131
- 30. PHA-2018-0047 Rite Aid #10116, DS90149
- 31. PHA-2018-0046 Walgreens #10562, DS3617

Respectfully Submitted, Kim Tanzer, PharmD, RPh Secretary

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