# COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

# MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting June 5, 2025

# **Board Members Present**

**Board Members Not Present** 

Sami Ahmed, PharmD., RPh, BCPS, BCSCP, President
Saad Dinno, RPh, FACP/FACA, President-Elect
Mark Sciaraffa, CPhT, Secretary
Katie Thornell, RPh, MBA
Caryn Belisle, RPh, MBA
John Rocchio, RPh, PharmD
Delilah Barnes, RPh
Rita Morelli, PharmD, BCACP, RPh
Julie Dorgan, RN
Frank Lombardo
Timothy Fensky, RPh
Stephanie Patel, MD, MBA, FFHPM, HMDC

#### **Board Staff Present**

Michael Godek, Executive Director
Monica Botto, Associate Executive Director
Jacqueline Petrillo, PharmD, RPh, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh, Quality Assurance Pharmacist
Richard Harris, Program Analyst
Joanna Chow, Program Analyst
Taylor Lee, Office Support Specialist
Joanne Trifone, RPh, Director of Investigations
Julienne Tran, PharmD, Investigator
Gregory Melton, JD, PharmD, BCPS, Investigator
Keith Johnstone, Compliance Officer
David Sencabaugh
Susan Kim, Pharmacy Intern
Gayatri Ramasubramanian, Pharmacy Intern

**TOPIC I**. Attendance by roll call:

# **CALL TO ORDER 8:02 AM**

A quorum of the Board was present, established by roll call. President Sami Ahmed chaired the meeting and explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: S. Dinno, yes; M. Sciaraffa, yes; D. Barnes, yes; J. Dorgan, yes; C. Belisle, yes; R. Morelli, yes; J. Rocchio, yes; K. Thornell, yes; S. Ahmed, yes. T. Fensky, yes; F. Lombardo; yes; S. Patel; yes.

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Topic II. Approval of Agenda TIME 8:03 AM

Agenda: 06/05/25

DISCUSSION: Deferred: REVIEW OF COMPLIANCE Option Care, DS90107, PHA-2020-0066

Hans Pharmacy

**ACTION:** Motion by J. ROCCHIO, seconded by C. BELISLE and voted unanimously by those present to

approve the agenda with the noted change by roll call vote.

Topic III Approval of Board Minutes TIME: 8:04 AM

**Minutes** 

1. Draft 05/01/2025

Change: None

Action: Motion by K. THORNELL seconded M. SCIARAFFA and voted to approve the regular session

minutes of 5/1/25 with the noted changes by roll call vote. S. Patel abstained.

Topic IV. REPORTS

Applications approved pursuant to Licensure Policy 13-01

PRESENTED BY: R. HARRIS

<u>DISCUSSION:</u> R. Harris reported a total of 71 Resident Change Pharmacist Manager of Record applications, 3 Non-Resident Change Pharmacist in Charge applications, and 9 facility closures that have been closed via Staff Action since the last Board meeting.

TIME: 8:05 AM

**TIME: 8:05 AM** 

So noted.

Topic IV. REPORTS

Monthly Report from Probation

PRESENTED BY: R. HARRIS

<u>DISCUSSION:</u> R. Harris reported 1 licensee that was given the opportunity to cure and 5 successful completions of probation monitoring since the last report. Currently, there are a total of 39 active cases

So noted.

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Topic IV. REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

PRESENTED BY: R. HARRIS

<u>DISCUSSION</u>: R. Harris indicated 11 CE deficiencies that have been reported, all closed with discipline not warranted with remediation completed. 6 Controlled Substances losses were reported and each issued a reprimand. Waivers have been approved for 3 pharmacies since the last report.

**TIME: 8:06 AM** 

TIME: 8:06 AM

**TIME: 8:10 AM** 

So noted.

TOPIC V FLEX

NABP Annual Meeting update

Presented by: S. Dinno

**Discussion:** Included activities at the meeting were installation of new president Bradley Hamilton and approval of this Board's resolution regarding medications lost in transit. Next year's meeting will be held in Boston.

So noted.

Board Member update

Presented by: M. Godek

Discussion: New Board member Stephanie Patel was welcomed as the physician representative.

Action:

TOPIC VI REGULATIONS

247 CMR 22.00: Monetary Penalties TIME: 8:11 AM

Presented by: M. CHAN

**Discussion:** Since edits were last brought before the Board in 2024, the legal team has suggested a few wording changes.

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**Action**: Motion by T. FENSKY, seconded by M. SCIARAFFA, and voted by the majority of those present, to forward the document for administrative review and approval to hold a public hearing. J. ROCCHIO voted against the action.

Topic VII. APPLICATION

1. Vital Care of Cambridge Sterile Compounding, Renovation TIME: 8:19 AM

REPRESENTED BY: Dave Adams, Brook Rezendes

RECUSAL: Fensky

**DISCUSSION:** See Board packet

#### Questions:

- Can you summarize your background [Brooke Rezendes] as a MOR/PIC?
  - After graduating I started working with a sterile compounding pharmacy, and also for a specialty pharmacy where I ran two positive pressure rooms and one negative pressure room, and a staff of 20 people, so I am very well versed.
- Are you currently open and operating in the retail space?
  - No we are not, as we are still working to develop vendor relationships
- What types of products will you be compounding?
  - Category II, Sterile-to-sterile compounding. We have the capabilities to do anti infectives, antivirals, perinatal nutrition, nootropic agents, and pain management, however we do not plan to engage in compounding pain medications unless required.
- Is the intent for you all to provide onsite infusions?
  - Yes, once we can change over the licensure and have the renovation complete, we plan to have our current licensed dispensing space remove its current licensure and will petition DPH to have this space for an ambulatory infusion clinic.
- Once the renovation is complete, will you be evaluating what staff are going to be working in the sterile area to deal with the demand that will happen?
  - We won't begin sterile compounding without adequate staff. Our parent company has staff who have been trained who will come to train us as well.

<u>ACTION:</u> D. Barnes made a motion to approve the renovation application upon successful inspection; Seconded by C. Belisle and voted unanimously by roll call of those present to approve the motion.

D. Barnes made a motion to approve the sterile compounding application upon successful inspection; Seconded by J. Dorgan and voted unanimously by roll call of those present to approve the motion

Topic VII. APPLICATION

2. Seven Cells Non-Resident Sterile Compounding TIME: 8:34 AM

REPRESENTED BY: Venus Hensley (PIC)

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#### RECUSAL:

**DISCUSSION: See Board Packet** 

#### Questions:

- Can you describe the nature of your business?
  - Our goal is to be a wellness pharmacy that supports the physicians/providers in our area, as that is big here in Florida. We are looking to provide supplements, vitamins, and other weight loss meds that we have pulled back on offering.
- Are you still compounding GLP-1 Medication?
  - o At a patient specific basis requested by their physician
- If a provider requests a commercially available drug are you compounding it?
  - No we are not
- Could you clarify your previous statement regarding the GLP-1 compounding?
  - We had a clinic that wanted to try microdosing with Semaglutide and adding a vitamin to it, however we have exhausted our supply and are pivoting elsewhere.
- Are all your medication compounding pursuant to a prescription?
  - Yes, we do not do batch compounding
- Have you had people certified in complete in-house environmental monitoring?
  - Our original plan was to do in-house testing, but we are now instead using a third party testing facility who will come monthly.
- Are you doing Category 3?
  - o No we are doing category 2 and doing the monthly testing to keep standards high.
- I saw that in the previous inspection that your media fills were not up to the compounding processes, has this been resolved?
  - Yes, at that time we were not compounding
- There were some issues regarding the differential pressure, has that been resolved? Are they align with USP 800
  - Yes that has since been fixed and rectified.
- There were also some issues regarding the calibration of thermometers and some equipment such as the autoclave. Has that been validated since?
  - Yes, this has all be rectified. At the time we were not compounding and we have since had everything certified.
- With regard to BUD assignments, can you please explain how you assign BUD and if it is in alignment with standards?
  - We are using table 13 of the USP to assign BUDs for category two
- My understanding is that you do further dilutions from the multiple use vials, what kind of BUDs are being assigned to the final vials?
  - That practice is no longer being done
- Are you in alignment with the number of articles used for sterility testing?
  - o Yes we are.
- What kind of products do you plan to ship to Massachusetts?
  - We are leaving that up to the providers, previously we shipped a handful of GLPs

<u>ACTION:</u> T. Fensky made a motion to approve the non-resident sterile compounding license; Seconded by M. Sciaraffa

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and voted by roll call of those present to approve the motion. See below for vote

S. Dinno abstain, M. Sciaraffa ay, D. Barnes abstain, C. Belisle Ay, J. Dorgan Ay, T. Fensky Ay, F. Lombardo ay, R. Morelli ay, Dr. Patel Ay, J. Rocchio Ay, S. Ahmed Ay

## 3. Health Care Family Pharmacy LLC

**New Retail Pharmacy** 

**TIME: 8:50 AM** 

REPRESENTED BY: Sam, Sotheara, Ron Lanton

**RECUSAL:** 

**DISCUSSION:** See board packet

#### Questions

- Can you give me background about your history?
  - I've been working at this pharmacy for 8 years
- Sam, will you be staying on as the MOR?
  - I am currently the MOR, but after the transfer of ownership Sotheara will be taking over as the MOR and I will be working part time
- Will you be working the minimum number of hours required of an MOR during this transition, Sam?
  - Yes, this will be a gradual transition so I will be working those hours and over the course of the next year or so, will be dropping my hours gradually as Sotheara takes over.

<u>ACTION:</u> S. Dinno made a motion to approve the new retail pharmacy application; Seconded by J. Rocchio and voted unanimously by roll call of those present to approve the application.

## 4. CarePartners Pharmacy, LLC

**New Retail Pharmacy** 

**TIME: 9:00 AM** 

REPRESENTED BY: Matthew Moy, PIC of the CarePartners Pharmacy

# **RECUSAL:**

DISCUSSION: Applied for retail pharmacy license

Specialty/community pharmacy

Provides medications for patients with chronic and complex conditions

Dispenses injectables and oral tablets

Prescriptions are delivered to patients

No waivers requested

**Tim.F**: Are you doing just specialty medications or all medications and mailing them out? A: Primarily doing IBIG. In the process of doing waivers once pharmacy is in operation in the future.

**Tim.F**: Why not do it all at once?

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A: Was under the impression that if you do waivers, it might delay application process. Wants to get licensed first and tackle waivers later.

**Rick.H**: When do you hope to open?

A: Have to apply to different licenses and have to finalize some systems in the pharmacy so hopes to get things finished after a month after inspection.

**Mike.G**: Will you be applying for a waiver once you get a license and prior to opening? A: Yes

**Jakie.P**: There is no board meeting in July so you would have to wait until August. It doesn't make sense to request waivers later. Potentially might not pass inspection so those waivers should be presented with the application. If your license is approved without waivers, your pharmacy needs to meet all requirements of the regulations.

Pharmacy confirms that it is following all policies and regulations without waivers.

**Caryn B**: Do you plan on becoming URAC?

A: Yes, currently working on ACHC and eventually will be URAC accredited. System in Chicago is already URAC accredited.

**Saad.D**: What is the cooperate structure of the pharmacy? CEO, President, COO is in Chicago and Matt Moy is the PIC of the pharmacy in MA.

<u>ACTION:</u> Motion by Caryn, seconded by Julie, voted unanimously by those present to approve the application for retail pharmacy upon successful inspection of the pharmacy.

TIME: 9:11 AM

# Boston Children's Health Solutions Rx, LLC Renovation, Complex Non-Sterile Compounding License

**REPRESENTED BY: Jo Stewart, Pharmacy Manager** 

**RECUSAL:** 

#### DISCUSSION:

Renovation application Complex nonsterile compounding application No waivers requested

**Tim. F**: Give me an idea of the products you'll be compounding

A: CVS in the hospital will be closing. Will be taking on the compounds the CVS pharmacy used to work on which are all nonhazardous, non-sterile compounds around 10-15 that are not commercially available.

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**Tim.F**: Give me an idea regarding the pharmacists that are working and the training process A: All pharmacists are going through noncompound training and software has compounding records (using epic software).

Pharmacy confirmed that hood is certified.

Caryn B back on at 9:15 AM

**John.R**: Addition to the compounding will be providing any other medications? A: Yes, the pharmacy is also a full retail pharmacy by 7/19

**Will.F:** Was the space that is taken over previously a licensed space?

A: Yes, it was previously a pharmacy that had a office, sink, and table and they just added a table

Saad.D: Only 795 compounds but no 800?

A: Yes, as of now, only 795

<u>ACTION:</u> Motion by Delilah, seconded by Caryn, voted unanimously by those present to approve the renovation upon successful inspection of the pharmacy.

Motion by Delilah, seconded by Caryn, voted unanimously by those present to approve complex nonsterile license upon successful inspection of the pharmacy.

6. Hann's Pharmacy

**New Non-Resident Retail Pharmacy** 

TIME:

**New Sterile Compounding** 

#### **DEFERRED**

VIII. WAIVERS

1. Baystate Franklin Medical Center -Institutional Sterile ISNE21022

**TIME: 9:31 AM** 

PRESENTED BY: R. HARRIS

**RECUSAL:** NONE

<u>DISCUSSION:</u> A petition for waiver was submitted for 247 CMR 9.234 regarding the 30-hour requirement for the Manager of Record. Andrew Szkiladz is the current MOR who currently works full-time and floats between 3 sites as needed.

The prerequisite documentation for Baystate Franklin Medical Center was not provided in the Board packet at the time of the meeting, thus prompting a vote to be deferred to a later date.

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<u>ACTION:</u> A motion was made by T. Fenski, seconded by K. Thornell, voted unanimously by those present to defer a vote to a future date when all documentation is provided to Board members to review.

**TIME: 9:31 AM** 

TIME: 9:31 AM

TIME: 9:45 AM

#### 2. Baystate Noble Hospital – IS21024

REPRESENTED BY: R. HARRIS

**RECUSAL:** None

<u>DISCUSSION:</u> A petition for waiver was submitted for 247 CMR 9.234 regarding the 30-hour requirement for the Manager of Record. Andrew Szkiladz is the current MOR who currently works full-time and floats between 3 sites as needed.

<u>ACTION:</u> A motion was made by T. Fenski, seconded by J. Dorgan, voted unanimously by those present to approve the waiver request for 247 CMR 9.234.

#### 3. Baystate Wing Hospital ISNE21025

REPRESENTED BY: R. HARRIS

**RECUSAL:** None

<u>DISCUSSION</u>: A petition for waiver was submitted for 247 CMR 9.234 regarding the 30-hour requirement for the Manager of Record.

<u>ACTION:</u> A motion was made by T. Fenski, seconded by F. Lombardo, voted unanimously by those present to approve the waiver request for 247 CMR 9.234.

# 4. Boston Children's Hospital ISNE20941

REPRESENTED BY: R. HARRIS

**RECUSAL: None** 

<u>DISCUSSION</u>: A petition for waiver was submitted for 247 CMR 9.234 regarding the 30-hour requirement for the Manager of Record. Shannon Manzi is the current MOR and Director of Safety and Quality for the Department of Pharmacy. Shannon currently works between two sites, dedicating 40-hours a week to the Longwood location. The submitted waiver is regarding the Waltham site (ISNE21035).

The prerequisite documentation for Boston Children's Hospital was not provided in the Board packet or the posted agenda at the time of the meeting, thus prompting a vote to be deferred to a later date.

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<u>ACTION:</u> A motion was made by T. Fenski, seconded by R. Morelli, voted unanimously by those present to defer a vote to a future date when all documentation is provided to Board members to review.

TIME: 9:52 AM

#### 5. Dana Farber Cancer Institute Foxborough ISNE20996

REPRESENTED BY: R. HARRIS

RECUSAL: C. BELISLE

<u>DISCUSSION:</u> A petition for waiver was submitted for 247 CMR 9.234 regarding the 30-hour requirement for the Manager of Record. David Roderick is the current MOR and the Pharmacy Infusion Manager for the Foxborough and Milford sites of which hours are split based on operational needs. An assigned pharmacist at each site oversees sterile compounding operations and report to David.

The prerequisite documentation for the Dana Farber Milford location was not provided in the Board packet or the posted agenda at the time of the meeting, thus prompting a vote to be deferred to a later date.

<u>ACTION:</u> A motion was made by D. Barnes, seconded by M. Sciaraffa, voted unanimously by those present to defer a vote for the Milford location to a future date when all documentation is provided to Board members to review.

An additional motion was made by D. Barnes, seconded by J. Dorgan, voted unanimously by those present to approve the waiver request of Dana Farber Cancer Institute Foxborough for 247 CMR 9.234 upon a successful inspection.

#### 6. Dana Farber Cancer Institute at St. Elizabeth's Medical Center ISNE21002 TIME: 10:01 AM

**REPRESENTED BY: R. HARRIS** 

RECUSAL: C. BELISLE

<u>DISCUSSION</u>: A petition for waiver was submitted for 247 CMR 9.234 regarding the 30-hour requirement for the Manager of Record. Vahid Rohani is the current MOR overseeing the Weymouth and Brighton campuses.

<u>ACTION:</u> A motion was made by R. Morelli, seconded by T. Fenski, voted unanimously by those present to approve the waiver request for 247 CMR 9.234 upon a successful inspection.

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# 7. UMass-Hahnemann Campus ISNE21038

**REPRESENTED BY: R. HARRIS** 

**RECUSAL:** None

<u>DISCUSSION:</u> A petition for waiver was submitted for 247 CMR 9.234 regarding the 30-hour requirement for the Manager of Record. Angel Amaral is the current MOR and Director of Pharmacy Operations for Hahnemann and Memorial campuses.

TIME: 10:06 AM

<u>ACTION:</u> A motion was made by D. Barnes, seconded by M. Sciaraffa, voted unanimously by those present to approve the waiver request for 247 CMR 9.234 upon a successful inspection.

# 8. UMass Medical Center Memorial Campus-8th floor ISNE21008 TIME: 10:06 AM

**REPRESENTED BY: R. HARRIS** 

**RECUSAL: None** 

<u>DISCUSSION</u>: A petition for waiver was submitted for 247 CMR 9.234 regarding the 30-hour requirement for the Manager of Record. Angel Amaral is the current MOR and Director of Pharmacy Operations for Hahnemann and Memorial campuses.

<u>ACTION:</u> The incorrect documentation for the Memorial campus was provided in the Board packet at the time of the meeting, thus prompting a vote to be deferred to a later date.

#### TOPIC IX: REQUEST TO CLOSE PROBATION MATTER DUE TO PHARMACY CLOSURE TIME: 10:10 AM

Walgreens 1847, DS1359, PHA-2023-0109

Presented by: K. Fishman

Recusals: None

Discussion: Case PHA-2023-0109 - Probation & Closure

- Probation Agreement: Walgreens 1847 entered into a one-year probation agreement in February 2025 due to an unknown loss of controlled substances.
- Closure: The pharmacy ceased operations on or about April 28, 2025.
- Board Consideration: Because staff action policy does not permit closure by administrative means, the matter is brought to the Board for formal action.
- Recommendation: Terminate the probation agreement and close the case, as the pharmacy is no longer operational and cannot fulfill the terms of the agreement.

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**Action:** Motion by T. FENSKY, seconded by K. THORNELL, and voted unanimously by roll call to terminate the probation agreement and close the matter for Walgreens 1847 (DS1359; PHA-2023-0109), in accordance with staff recommendation.

TOPIC X: REVIEW OF COMPLIANCE TIME:

• Option Care, DS90107, PHA-2020-0066

**Moved to Closed Session** 

TOPIC XI: REVIEW OF COMPLIANCE TIME: 10:13 AM

• CVS 946, DS3442; PHA-2023-0120

Presented by:

Recusals: Rocchio

**Discussion:** Case PHA-2023-0120 – Probation Review & Compliance

- Probation Agreement: CVS 946 entered into a one-year stayed probation agreement on April 29, 2024, following an unknown loss of controlled substances.
- Violation: During an inspection on March 26, 2025, improper storage of Pfizer COVID-19 vaccines was documented. A box of expired vaccine doses was found in the pharmacy's refrigerator, and the error was attributed to a failure to discard unused doses after their recommended use date. The incident was classified as a vaccine administration error.
- Corrective Actions: The pharmacy promptly notified the affected patient's guardian and offered re-vaccination. A compliance plan was implemented to prevent future occurrences.
- Board Review: Upon review, the Board determined the pharmacy violated the terms of the agreement regarding regulatory compliance. However, given the responsive actions and implementation of the compliance plan, the Board found substantial compliance overall.
- Recommendation: To find the licensee in violation but take no further action, and to terminate the probation agreement for substantial compliance.

**Action:** Motion by T. FENSKY, seconded by R. MORELLI, and voted unanimously by roll call to find CVS 946 (DS3442; PHA-2023-0120) in violation but take no further action.

Motion by T. FENSKY, seconded by D. BARNES, and voted unanimously by roll call to terminate the probation agreement for substantial compliance, in accordance with staff recommendation.

TOPIC XII: FILE REVIEW

Case #1/CASE-2024-2783

PHA-2025-0008 Kayla McCracken, PTT102325 Time: 11:04 AM

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

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

- On 09/04/2024, Investigator Seed discovered during an RCI that Pharmacist El Nabbout permitted PTT McCracken to perform drug utilization review and provide counseling on a new prescription by providing PTT McCracken with her pharmacist credentials.
- In summary, PTT McCracken admitted that she routinely performed DUR and counselled patient when Pharmacist El Nabbout was the pharmacist-on-duty at CVS 498. PTT McCracken described that Pharmacist El Nabbout provided her pharmacist credentials to her to override DURs "which Pharmacist El Nabbout felt were easy such as pregnancy warning when the person was not pregnant."
- PTT McCracken further described that she was new to dealing with floater pharmacists and new to the
  pharmacy at the time of the incident. PTT McCracken conveyed that Pharmacist El Nabbout routinely
  provided her credentials to multiple pharmacy technicians and she expected that those technicians
  would process DURs "if it was something not important."
- PTT McCracken expressed that she was still in training at the time and did not comprehend the degree which processing DURs and counseling patients undermined patient safety until later as she progressed in her training towards obtaining a pharmacy technician licensure.
- PTT McCracken then pledged, "I will not do it again we've had a lot of floaters come in and go since then our normal pharmacist is back to work now and ever since then I have not used anybody else's credentials and I will not use anybody else's credentials I also do not allow anybody on my register under my credentials for any reason and I apologize profusely for doing it."

<u>ACTION</u>: Motion by T. FENSKY, seconded by M. SCIARAFFA, and voted unanimously by those present, to DISMISS the matter (PHA-2025-0008), No Discipline Warranted.

Case #2/CASE-2025-0032

PHA-2025-0010 Galaxy Pharmacy, DS90255 Time: 10:29 AM

**RECUSAL**: NONE

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

- Galaxy entered into a settlement agreement effective 11/19/2024 with AGO to pay over \$270,000.00 in restitution to the Commonwealth to resolve allegations involving the submission of false claims to MassHealth for automatically refilling prescriptions for MassHealth members without an explicit request from the member or caregiver for each filling event and the failure to notify BORP about the agreement within seven days in violation of 247 CMR 6.15(2).
- Galaxy argued that BORP regulations did not define "...non-routine notices, correspondence..." In addition, disciplinary action as defined in BORP Regulations did not include settlement agreements. Galaxy argued that there was no violation. Galaxy further argued that the settlement agreement expressly acknowledged that the pharmacy made no admission or denial of wrongdoing and "no party shall issue a public statement to the contrary."

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Galaxy next explained that the pharmacy was in all practicality prohibited by the settlement
agreement from arguing the merits of AGO's allegations cited in the complaint opened by BORP.
Nonetheless, Galaxy respectfully requested that the matter be dismissed because no violation
occurred and any pursuit of discipline by BORP using the covered conduct was already resolved as part
of the settlement agreement with no admission of wrongdoing.

<u>ACTION</u>: Motion by J. ROCCHIO, seconded by J. DORGAN, and voted unanimously by those present, to DISMISS the matter (PHA-2025-0010), No Violation.

Case #3/CASE-2025-0027

PHA-2025-0009 Center Pharmacy, DS2730 Time: 10:31 AM

**RECUSAL: NONE** 

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

- Center Pharmacy entered in a settlement agreement with AGO on 12/10/2024 to pay over \$230,000.00 in restitution to the Commonwealth to resolve allegations that the pharmacy submitted false claims for ProFola prescriptions to MassHealth. In addition, Center Pharmacy was required to contract with an independent compliance monitor at the pharmacy's expense and upon approval by AGO to review and establish P&P & training, monitor ongoing compliance, and submit reports to AGO annually for three years.
- According to the agreement, Center Pharmacy contacted physicians directly to request prescriptions for ProFola for MassHealth members at a reimbursement rate of approximately \$1,600.00/prescription. However, members did not make requests nor were they consulted about the requests for the ProFola prescriptions. Furthermore, many members were not previously prescribed a MVI or used an OTC MVI costing \$11.00/bottle. In addition, Center Pharmacy did not inform the physicians contacted by the pharmacy that the affected MassHealth members did not make requests nor were they consulted about the requests for the ProFola prescriptions. Instead, Center Pharmacy justified the requests for ProFola prescriptions "based on the general assertion that long term care facility residents are " 'malnourished,' " despite never meeting many of the MassHealth members or possessing relevant information about each MassHealth members' nutritional health."
- Center Pharmacy argued that the new regulations for reporting discipline did not include settlement agreements in definitions. In addition, any standards of pharmacy practice violations were already resolved fully and with finality according to the settlement agreement. Therefore, Center respectfully requested that BORP dismiss the complaint.

<u>ACTION</u>: Motion by D. BARNES, seconded by M. SCIARAFFA, and voted unanimously by those present, to DISMISS the matter (PHA-2025-0009), No Violation.

Case #4/CASE-2025-0217

PHA-2025-0016 Fagron Sterile Services, NO00033 Time: 10:34 AM

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

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

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- On 01/13/2025, Fagron reported to BORP that the facility was issued a Warning Letter by FDA on 12/19/2024. Fagron VP McEniry asserted that Fagron received the aforementioned Warning Letter "fourteen business days ago." However, FDA also referenced an FDA inspection between 06/18/2024 and 06/28/2024 which resulted in the issuance of an FDA Form 483 on 06/28/2024. Fagron did not notify BORP about the inspection and FDA Form 483 within 14 days.
- The Warning Letter listed examples of violations of FDCA Section 503B, adulterated drugs, violations of CGMP, marketing of unapproved drugs, and misbranded drugs observed during the inspection.
- Furthermore, FDA deemed parts of Fagron's corrective action plan deficient. FDA also declared that documentation to support parts of corrective action was lacking. Thus, FDA was not able to evaluate corrective action implemented for those parts. In turn, FDA requested additional documentation to facilitate evaluation. Of note, a Warning Letter Close-Out Letter had not yet been issued by FDA as of 04/17/2025.
- VP McEniry responded on behalf of the facility. He inquired whether he was sending notifications to
  the correct email address. Investigator Melton confirmed that VP McEniry submitted the Warning
  Letter notification to the correct email address. Investigator Melton then clarified that Fagron failed
  to notify BORP within 14 days about the 06/2024 FDA inspection and FDA Form 483 from 06/28/2024.
  Fagron failed to provide a response for their failure to properly report the FDA inspection and
  resulting 483.
- Investigator Melton provided a copy of 247 CMR 21.00 to VP McEniry and emphasized 247 CMR 21.09: Notifications in communications with VP McEniry.

Time: 10:39 AM

<u>ACTION</u>: Motion by T. FENSKY, seconded by J. DORGAN, and voted unanimously by those present (except for S. PATEL and K. THORNELL who abstained), to refer the matter (PHA-2025-0016), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #5/CASE-2025-0503

PHA-2025-0028

Walgreens #10638, DS3585

**RECUSAL: NONE** 

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

- On 02/23/2025, WAG 10638 submitted an amended final report of loss 100 amphetamine mixed-salts 10mg tablets which occurred on 01/07/2025 "while filling medication for several [amphetamine mixed-salts 10mg tablets] prescriptions, a full bottle was accidentally tossed in the trash can along with 2 other empty bottles."
- WAG 10638 later clarified that the loss was, in fact, 70 tablets. Former MOR Hitchcock acknowledged
  that she was responsible for the inadvertent discard. WAG 10638 also provided video which captured
  the inadvertent discard. Lastly, WAG APM also confirmed the loss was caused by the inadvertent
  discard.
- Former MOR Hitchcock described that corrective action to mitigate recurrence of a similar incident included "maintaining a clean and clutter free environment" and "reinforce proper handling of controlled substances."

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<u>ACTION</u>: Motion by B. BARNES, seconded by M. SCIARAFFA, and voted unanimously by those present, to refer the matter (PHA-2025-0028), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #6/CASE-2025-0501

PHA-2025-0030 Partners of MA, DS3419 Time: 10:42 AM

**RECUSAL: NONE** 

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

- BORP opened a complaint against Partners after the pharmacy failed to submit an annual sterile compounding report. However, upon further review, Partners did not violate the requirement due to timing of renewal of its pharmacy license and promulgation of new regulations by BORP.
- CA: MOR Vogel submitted a July through December sterile compounding report for 2024 to BORP as
  requested in the notice of complaint. MOR Vogel then described that Partners "instituted a process to
  ensure this requirement is met every six months. Sterile Compounding Reporting has been added as a
  task in Simplifi 797 two weeks before each due date with daily reminders leading up to August 15th
  and February 15th. This task will show as due for all users involved in sterile compounding, including
  myself, the Director, and the IV department." Partners closed for business on 03/31/2025.

<u>ACTION</u>: Motion by C. BELISLE, seconded by M. SCIARAFFA, and voted unanimously by those present, to DISMISS the matter (PHA-2025-0030),No Violation.

Case #7/CASE-2025-0502

PHA-2025-0031 Sullivan's Healthcare, Inc., DS3335 Time: 10:44 AM

RECUSAL: T. FENSKY and S. PATEL recused and were not present for the vote or discussion in this matter.

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

- BORP opened a complaint against SHC after the pharmacy failed to submit an annual sterile compounding report. However, upon further review, SHC did not violate the requirement due to timing of renewal of its pharmacy license and promulgation of new regulations by BORP.
- CA: MOR Methratta indicated that "moving forward the reporting will be submitted to the Board annually at the time of license renewal per the updated regulation" as corrective action to mitigate recurrence of a similar incident." In addition, MOR Methratta submitted sterile and non-sterile compounding reports for the "July through December" 2024 period as requested in the notice of complaint

<u>ACTION</u>: Motion by R. MORELLI, seconded by M. SCIARAFFA, and voted unanimously by those present, to DISMISS the matter (PHA-2025-0031), No Violation.

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Case #8/CASE-2025-0668

PHA-2025-0039 PerformSpecialty, NDS31588 Time: 10:46 AM

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**RECUSAL: NONE** 

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

- BORP was notified on 03/03/2025 by NABP that PerformSpecialty was fined \$500 by ME BOP in 2021 for failing to timely report discipline by KS BOP in 2019. The KS BOP discipline was a \$2160.00 fine for failure to timely report a change in PIC. Upon review, PerformSpecialty failed to disclose the ME BOP and KS BOP in the pharmacy's application for licensure as a non-resident retail pharmacy submitted on 02/05/2025 and approved on 02/20/2025.
- PerformSpecialty admitted to inadvertently failing to upload one of two documents with descriptions of discipline history when the application was submitted. Therefore, the pharmacy only notified BORP about an approximately \$9,863.55 payment to FL Medicaid for overpayments received in 2019.
- Perform Specialty then provided the missing document which contained the pharmacy's discipline history. PerformSpecialty was fined \$1K by the HI BOP for failure to timely report discipline by KS BOP, admonished by CA BOP for delay in therapy, fined \$1,500.00 by AL BOP for failure to report discipline by KS BOP and HI BOP in renewal application, admonished by CO BOP for failing to timely report CA BOP discipline, and fined \$2000.00 and reprimanded by ME BOP in a second incident for failing to report discipline by HI BOP in renewal application and failure to timely report discipline by HI BOP in addition to the discipline by AHCA, ME BOP, and KS BOP already noted.
- Perform Specialty submitted the missing document with the summary of discipline history.

<u>ACTION</u>: Motion by F. LOMBARDO, seconded by R. MORELLI, and voted unanimously by those present, to REFER the matter (PHA-2025-0039), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

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Case #9/CASE-2024-3584

PHA-2024-0238 Winn Pharmacy, DS90341 Time: 10:50 AM

**RECUSAL**: NONE

<u>DISCUSSION</u>: K. JOHNSTONE presented and summarized the investigative report that pertained to this matter.

- On 10/29/2024, during a retail compliance inspection, the Pharmacy was cited for failure to conduct a perpetual inventory every 10 days. A repeat deficiency.
- On 11/21/2024, Investigator Lathum telephoned the Pharmacy and although no pharmacist was on duty the Pharmacy's phone was answered.
- On 11/26/2024, a follow-up site visit was conducted, and it was observed that the perpetual inventory was still not being conducted every 10 days.
- On 12/17/2024, a POC was received from MOR Quach who stated that the Pharmacy will only be open when a pharmacist is on duty. She is the Pharmacy's only employee.
- On 01/17/2025, MOR Quach responded to the complaint. She stated that the perpetual inventory was current and will be conducted every Saturday morning. She stated that on 11/21/2024, she closed the Pharmacy due to a personal emergency. She asked her son to retrieve a personnel item within the Pharmacy and he answered the phone.

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- MOR Quach attested that she is the only one with access to the Pharmacy, access is limited to authorized personnel, and that she is always on the premises when the Pharmacy is open. She attested that Pharmacy will comply with all BORP regulations. The perpetual inventory will be conducted every 7 days.
- A Retail Compliance Inspection conducted on 04/22/2025 was deemed satisfactory.

<u>ACTION</u>: Motion by M. SCIARAFFA, seconded by D. BARNES, and voted unanimously by those present, to REFER the matter (PHA-2024-0238), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

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Case #10/CASE-2024-3741

PHA-2025-0001 Avita Pharmacy, DS90320 Time: 10:53 AM

**RECUSAL: NONE** 

<u>DISCUSSION</u>: K. JOHNSTONE presented and summarized the investigative report that pertained to this matter.

- During a retail compliance inspection conducted on 12/13/2024 at Avita Pharmacy, Investigator Van Allen observed that the Pharmacy completed a renovation/expansion without submittal of an application and subsequent BORP approval.
- On 12/17/2024, a plan-of correction was received. MOR Masse stated that a renovation application was submitted to the BORP.
- BORP records indicate that a renovation application was submitted on 12/17/2024 indicating that the renovation took place between 07/16/2024 and 11/22/2024 resulting in an increase in the pharmacy licensed space from 470 sq.ft. to 671 sq.ft.
- On 01/13/2025, MOR Masse responded that the renovation consisted of creating a doorway between 2 spaces, upgrading and addition of work counters and undercounter cabinets, upgrading and relocating the pharmacy refrigerator, and relocation of the IT cabinet.
- MOR Masse stated that a building permit was not required as the renovations did not involve any structural modifications, did not alter the building's use or occupancy classification, and did not involve regulated equipment. The work was limited to interior non-structural, non-load bearing walls and cabinetry. There were no major electrical alterations, nor any alterations to plumbing or HVAC systems.
- Going forward Avita Pharmacy will ensure that any renovation or modification will obtain BORP approval prior to commencement.

<u>ACTION</u>: Motion by R. MORELLI, seconded by M. SCIARAFFA, and voted unanimously by those present, to REFER the matter (PHA-2025-0001), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND

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Case #11/CASE-2024-3747

PHA-2024-0245 Walgreens #13805, DS89711 Time: 10:55 AM

**RECUSAL**: NONE

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DISCUSSION: J. TRAN presented and summarized the investigative report that pertained to this matter.

- An unknown loss of 15 controlled substances in Schedules II-V discovered on 11/15/2024 during a CS inventory completed during the permanent closure of the Pharmacy.
- No video footage was available to review as it had been "removed and wiped clean" when the Pharmacy closed.
- Staff were interviewed and an investigation conducted with no conclusive reason for the loss.
- The Pharmacy closed permanently on 11/14/2024.

<u>ACTION</u>: Motion by T. FENSKY, seconded by M. SCIARAFFA, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0245), Business Closed.

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Case #12/CASE-2024-3579

PHA-2024-0232 FarmaKeio Outsourcing, NO00056 Time: 10:57 AM

**RECUSAL: NONE** 

DISCUSSION: J. TRAN presented and summarized the investigative report that pertained to this matter.

- BORP was notified by the licensee on 10/31/2024 that they entered into a settlement agreement with the Ohio Board of Pharmacy on 10/01/2024, which is greater than 14 days as required.
- VP Graves indicated that they regret submitting the settlement agreement late by 16 days and noted that this was their first disciplinary matter.
- VP Graves indicated that FarmaKeio ensures the Board that any required notices will be timely. FarmaKeio is learning from this matter and is improving its reporting systems to ensure compliance with all applicable federal and state pharmacy laws and regulations.

<u>ACTION</u>: Motion by T. FENSKY, seconded by F. LOMABRDO, and voted unanimously by those present, to refer the matter (PHA-2024-0232), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

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Case #13/CASE-2024-3575

PHA-2024-0239 CVS #114, DS2821 Time: 10:59 AM

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

DISCUSSION: J. TRAN presented and summarized the investigative report that pertained to this matter.

- On 10/24/2024, CVS #114 experienced an unknown loss of #95 methylphenidate 20mg tablets.
- Former MOR Norphel indicated that Current MOR Pham discovered the loss on 10/19/2024 while conducting a back-count during the filling of a new prescription. He checked with the distributor who did not report any shipment discrepancy, checked all the shelves, and multiple pharmacists searched the safe to see if Pharmacist Pham may have placed it in a different area.
- Video footage was inconclusive.
- MOR Norphel indicated that as corrective action the Schedule II prescriptions are double counted and the back counted with a sticker placed on top of the bottle or the side of the bottle. They have

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reorganized the safe, and cycle counts will be done daily. Also, when receiving the C2 order, both on duty pharmacists will verify that the correct amount has been received.

ACTION: Motion by M. SCIARAFFA, seconded by D. BARNES, and voted unanimously by those present, to CONSOLIDATE the matter (PHA-2024-0239) with PHA-2025-0019. A second motion was made by R. MORELLI, seconded by J. DORGAN, and voted unanimously by those present, to refer the consolidated matters to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

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Case #14/CASE-2025-0209

PHA-2025-0019 CVS #114, DS2821 Time: 11:00 AM

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

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

- During a retail compliance inspection conducted on 01/17/2025, the Investigator found that the licensee had experienced a break-in while the pharmacy was closed which was not reported to BORP.
- Former MOR Norphel related that on 08/08/2024, video footage showed a customer opening a locked pharmacy door and grabbing a prescription. The alarm sounded when the male customer entered the pharmacy space for about 3 minutes before leaving.
- Video reviewed by this investigator showed the individual sliding a cane through a gap between the security grate and the half door releasing the inside handle and gaining access to the Pharmacy.
- On 08/09/2024, the male patient came back to the Pharmacy to pay for the prescription he admitted to taking the night before. The police responded and did not press charges. It was discovered that the patient took his own prescription for #30 atomoxetine 40mg capsules.
- The MOR indicated that they had work completed to properly close off and tightly secure the pharmacy door to minimize any future risk.

<u>ACTION</u>: Motion by M. SCIARAFFA, seconded by D. BARNES, and voted unanimously by those present, to CONSOLIDATE the matter (PHA-2025-0019) with PHA-2024-0239. A second motion was made by R. MORELLI, seconded by J. DORGAN, and voted unanimously by those present, to refer the consolidated matters to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #15/CASE-2025-0306

PHA-2025-0020 CVS/Specialty or CarelonRx Specialty Pharmacy, DS3416 Time: N/A

# **DEFERRED**

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Topic XIII: Executive Session Call to Order: TIME: 11:10 AM

By: President S. Ahmed reads the executive session language and requests a motion to enter executive session.

**Action:** Motion by J. DORGAN, seconded by M. SCIARAFFA, voted unanimously by roll call to enter executive session #1.

Topic XIV: Adjudicatory Session TIME: 02:12 PM

**DISCUSSION: None** 

ACTION: President S. Ahmed request a motion to enter Adjudicatory Session.

At 2:12 PM J. ROCCHIO seconded by R. MORELLI and voted unanimously by all those present to enter the Adjudicatory Session by roll call vote.

Lunch 01:40 PM - 02:10 PM

Topic XV: 65C Sessions MGL c. 112 section 65C TIME: 02:23 PM

**DISCUSSION: None** 

ACTION: President S. Ahmed request a motion to enter M.G.L 65 c Session.

At 02:23 PM M. SCIARAFFA seconded by S. DINNO and voted unanimously by all those present to enter M.G.L. chapter 65 C Session by roll call vote. J. Dorgan was not present for the vote.

Topic XVI: ADJOURMENT OF MEETING TIME: 03:07 PM

ACTION: Motion by M. SCIARAFFA seconded by S. DINNO and voted unanimously by those present, to adjourn the meeting by roll call vote.

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#### EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

- 1. June 5, 2025, Agenda
- 2. May 1, 2025, Board Minutes
- 3. Licensure Policy 13-01 Report
- 4. **Monthly Probation Report**
- 5. BDR Licensure Report pursuant Policy 14-02
- 6. 247 CMR 22.00: Monetary Penalties
- 7. Vital Care of Cambridge-Sterile Compounding, Renovation
- 8. Seven Cells, Non-Resident Sterile Compounding
- 9. Care Family Pharmacy LLC – New Retail Pharmacy
- 10. CarePartners Pharmacy, LLC-New Retail Pharmacy
- 11. Boston Children's Health Solutions Rx, LLC- Renovation, Complex Non-Sterile Compounding License
- 12. Baystate Noble Hospital – IS21024
- 13. Baystate Wing Hospital ISNE21025
- 14. Dana Farber Cancer Institute Foxborough ISNE20996
- 15. Dana Farber Cancer Institute at St. Elizabeth's Medical Center ISNE21002
- 16. UMass-Hahnemann Campus ISNE21038
- 17. Walgreens 1847, DS1359, PHA-2023-0109
- 18. CVS 946, DS3442; PHA-2023-0120
- 19. CASE-2024-2783 PHA-2025-0008 Kayla McCracken, PTT102325
- 20. CASE-2025-0032 PHA-2025-0010 Galaxy Pharmacy, DS90255
- 21. CASE-2025-0027 PHA-2025-0009 Center Pharmacy, DS2730
- 22. CASE-2025-0217 PHA-2025-0016 Fagron Sterile Services, NO00033
- 23. CASE-2025-0503 PHA-2025-0028 Walgreens #10638, DS3585
- 24. PHA-2025-0030 Partners of MA, DS3419 CASE-2025-0501
- 25. CASE-2025-0502 PHA-2025-0031 Sullivan's Healthcare, Inc., DS3335
- 26. CASE-2025-0668 PHA-2025-0039 PerformSpecialty, NDS31588
- 27. CASE-2024-3584 PHA-2024-0238 Winn Pharmacy, DS90341
- 28. CASE-2024-3741 PHA-2025-0001 Avita Pharmacy, DS90320
- 29. PHA-2024-0245 Walgreens #13805, DS89711 CASE-2024-3747
- 30. CASE-2024-3579 PHA-2024-0232 FarmaKeio Outsourcing, NO00056
- 31. PHA-2024-0239 CVS #114, DS2821 CASE-2024-3575
- 32. CASE-2025-0209 PHA-2025-0019 CVS #114, DS2821
- 33. CASE-2025-0306 PHA-2025-0020 CVS/Specialty or CarelonRx Specialty Pharmacy, DS3416

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