COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

May 14, 2021

Webex Information

The regular session is open to the public by video or phone.

For video access click on the following link:

https://statema.webex.com/statema/onstage/g.php?
MTID=e16736db72c8fcc6d151134d83ce48560
To access the meeting by phone:

Call in Number: 1-203-607-0564 or toll free 1-866-692-3580

Access Code: 185 184 0789

Attendee: #

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator _, Phone: 617-624-5848 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
8:00	I	CALL TO ORDER		J. Lanza
	II	APPROVAL OF AGENDA		
8:05	Ш	 APPROVAL OF BOARD MINUTES Draft of April 30, 2021 Regular Session Minutes 		

8:10	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 PSUD Report-Policy 17-03 	
8:15	v	 FLEX Pharmacy issues related to Covid-19 and the state of emergency BILH Pilot Project Update 	
8:30	VI	POLICIES • Policy 2020-15: Licensee Scope of Practice • Policy 2020-01: Pharmacist License Reactivation after Expiration beyond One Renewal Cycle	
8:40	VII	FILE REVIEW 1 PHA-2021-0009 Walgreens #2781, DS3468 2 PHA-2021-0014 Springfield Pharmacy, DS9086 3 PHA-2021-0017 Rite Aid #10203, DS2570 4 PHA-2021-0013 CVS #920, DS89649 5 SA-INV-17294 Sherese Pearl, PH24512 6 PHA-2021-0004 Betty V. Duong, PH27303 7 SA-INV-17348 Sahar Abed, PH235814	
9:15	VIII	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, to evaluate the Good Moral Character as required for registration for a pending applicant.	CLOSED SESSION
10:00	IX	M.G.L. c. 112, § 65C SESSION	CLOSED SESSION
10:45	X	ADJOURNMENT	

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting May 14, 2021

Board Members Present

Julie Lanza, CPhT, President
Sebastian Hamilton, Pharm D, MBA, RPh President-Elect
Andrew Stein, Pharm D
Susan Cornacchio, JD, RN
Caryn Belisle, RPh, MBA
Leah Giambarresi, Pharm D, RPh
Katie Thornell, RPh, MBA
Dawn Perry, JD
Dr. Richard Lopez, MD
Jennifer Chin, RPh

Board Members Not Present

Timothy Fensky, RPh Carly Jean-Francois, RN, NP Secretary

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, Assist Executive Director
Heather Engman, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh Quality Assurance Pharmacist
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Richard Harris, Program Analyst
Joanna Chow, Office Support Specialist
Joanne Trifone, RPh, Director of Investigation
Gregory Melton, PharmD, JD, Investigator

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:02 AM

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

Roll call attendance: J. Lanza, yes; S. Hamilton, yes; S. Cornacchio, yes; C. Belisle, yes; A. Stein; K. Thornell, yes; R. Lopez, yes; J. Chin, yes. Join at 8:05 AM D. Perry; L. Giambarresi.

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Topic II. Approval of Agenda TIME 8:03 AM

Agenda 5/14/21

DISCUSSION:

Change to Agenda:

- 1. PHA-2021-0017 Rite Adie #10203 will not be heard.
- 2. Executive Session will be heard on 5/28/21, not today.

ACTION:

Motion by J. Chin, seconded by S. Hamilton and voted unanimously by those present to approve the agenda with noted change by roll call vote.

Topic III Approval of Board Minutes TIME: 8:05 AM

Minutes

1. Draft 4/30/21

Change: no noted changes

Action:

Motion by S. Hamilton seconded C. Belisle and voted unanimously to approve the regular session minutes of 4/30/21 with no noted change by roll call vote. J. Chin and R. Lopez abstain

TOPIC IV Reports

Applications approved pursuant to Licensure Policy 13-01 Time: 8:06 AM

Discussion: R. HARRIS noted applications included in the Board packet were approved pursuant to Licensure Policy 13-01 since the last Board meeting.

So noted.

TOPIC IV REPORTS

Monthly Report from Probation

Discussion: R. HARRIS provided the March 30, 2021 – May 11, 2021 Board of Pharmacy Statistics Report for the Probation monitor, which noted that one (1) licensee satisfactorily completed probation monitoring, one (1) licensee given opportunity to cure and there are currently twenty-three (23) licensees on probation.

Time: 8:07 AM

Time: 8:07 AM

So noted.

TOPIC IV REPORTS

Monthly Report from BDR pursuant to Policy 14-02

Discussion: D. SENCABAUGH noted that there were five (5) Board Delegated Review case heard on April 1, 2021 and five (5) heard on April 15, 2021. Ten (10) staff assignments were CE self-disclosures which were closed with discipline not warranted and remediation complete. The Board Delegated Review

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session was attended by Julie Lanza as the Board President, W. FRISCH Director of Pharmacy Compliance, H. ENGMAN as Board Counsel, and Executive Director D. SENCABAUGH.

So noted.

TOPIC IV REPORTS

Above Action Levels Approved by Staff Action 16-04 Time: 8:08 AM

Discussion: N. ALEID noted that there was two (2) above action level report that has been remediated and closed since the last Board meeting pursuant to Licensure Policy 16-04.

So noted.

TOPIC IV REPORTS

PSUD Report by Staff Action 17-03

Discussion: E. TAGLIERI noted that there were twelve (12) active participants, one (1) admission and two (2) referrals. One (1) participant successfully completed the first year.

Time: 8:08 AM

Time: 8:10 AM

So noted.

TOPIC V Flex

1. Pharmacy Issues Related to Covid-19 and State of Emergency Time: 8:09 AM

Presented by: D. SENCABAUGH

Discussion: The mandate for pharmacies and pharmacy departments to be open 1 hour early in the morning for seniors has been discontinued. However, it is still recommended.

2. BILH Pilot Project Update

Presented by: Emmett Hayes, Luca Cattaneo, David Young

Recusal: J. LANZA, H. ENGMAN

Discussion: This pilot project began in November 2021 and is for a specialty pharmacy and retail pharmacy each with a separate license in the same physical space. There is separation of inventory, staff, computer systems, and call centers. At this 6-month juncture, the pharmacies presented their metrics and requested to discontinue the pilot and continue with this model.

Action: Motion by A. STEIN, seconded by L. GIAMBARRESI, and voted unanimously by roll call by all those present to allow the pharmacies to remain in the pilot for now and defer final action to a later date.

TOPIC VI POLICIES

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1. Policy 2020-15: Licensee Scope of Practice

Presented by M. CHAN

Discussion: A few wording clarifications have been made to the existing policy based on stakeholder feedback. The only new change is to allow 2 certified technicians to perform a perpetual inventory.

Action: Motion by S. HAMILTON, seconded by L. GIAMBARRESI, and voted unanimously by roll call by all those present to approve the updated policy.

2. Policy 2020-01: Pharmacist License Reactivation after Expiration beyond One Renewal Cycle

Time: 8:39 AM

Time: 8:38 AM

Presented by M. CHAN

Discussion: One change was added stating that Board staff will review the NABP Clearinghouse for reported discipline in other jurisdictions as a consideration for license reactivation. A similar statement already exists in the reinstatement policy.

Action: Motion by S. HAMILTON, seconded by J. CHIN, and voted unanimously by roll call by all those present to approve the updated policy.

VII: File Review

Case #1

PHA-2021-0009 Walgreens #2781, DS3468 Time: 08:41 AM

RECUSAL: NONE

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

- On 1/25/2021, a DEA 106 only was submitted inaccurately reporting an unknown loss of #96 amphetamine salts 10mg tablets on 12/29/2020 when the loss was for #93 tablets.
- MOR Tarara reported a prescription was filled on 12/29/2020 with a remaining BOH of 393 tablets.
 On 12/30/2020, MOR Tarara filled a prescription for the medication and only found 3 full bottles on hand and failed to investigate the discrepancy. She stated she "knew that the weekly inventory would be checked that weekend and if there was a discrepancy it would be found".
- On 1/3/2021, Pharmacist Marino reconciled the perpetual inventory and realized 93 tablets were
 not accounted for. After investigating by reviewing all recordkeeping, on 1/4/2021, he notified MOR
 Tarara who viewed security footage and contacted patients to confirm no over-dispensing. MOR
 Tarara submitted an untimely initial notification of a loss of controlled substance to the BORP on
 1/20/2021. The reason for the loss was not determined but the tablets may have been
 inadvertently discarded.

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• MOR Tarara and Pharmacist Marino discussed this incident and the proper reporting of a loss of a controlled substance to prevent future occurrences. MOR Tarara stated after CII prescription is filled, the bottle will immediately be returned to the safe and the prescription will be logged into the CII inventory system. The CII will be back counted to make ensure accurate BOH quantities. All staff reviewed the SOP for filling CII prescriptions to prevent future errors. A copy of Walgreens SOP "Controlled Substance - Inventory" was provided that was signed by the Pharmacy team confirming review.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2021-0009), 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 #2

PHA-2021-0014

Springfield Pharmacy, DS90286

Time: 08:44 AM

RECUSAL: NONE

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

- During a retail compliance inspection (ISP-15396) on 03/02/2021, it was discovered a PT application had been submitted for Waleska Robles who had acquired 850 training hours at the Pharmacy without a PTT license. Ms. Robles was identified as a clerk/cashier during the inspection. A POC was issued.
- A copy of the PCS application notarized on 12/30/2020 showed Ms. Robles passed an exam issued by MOR Wu on 12/21/2020 and MOR Wu stated she had worked 850 hours of supervised experience as a PTT. The application was missing the date of graduation from a high school or GED program.
- MOR Wu indicated on 2/4/21, an email was received from PCS stating an email address for Ms. Robles was missing from the application. MOR Wu stated on 2/20/21 and 3/2/21, responses were sent to PCS but BORP staff was never contacted. As of 4/12/21, Ms. Robles had not been licensed by the BORP. MOR Wu contended, "This happened due to a lack of knowledge and experience with the current regulations set forth; I simply did not know".
- According to the POC, prior to submission of a PT application, future applicants will apply for a PTT license and obtain training hours. The store's policy handbook has been updated to include information on 247 CMR 8.03". An updated copy of the Pharmacy's policy and procedure for "Pharmacy Technician Training" was provided. Ms. Robles is currently working as a clerk.

<u>ACTION</u>: Motion by L. GIAMBARRESI, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2021-0014), 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

PHA-2021-0017

Rite Aid #10203, DS2570

Time: XX:XX AM

DEFERRED

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Case #4

PHA-2021-0013 CVS #920, DS89649 Time: 08:48 AM

<u>RECUSAL</u>: S. CORNACCHIO and L. GIAMBARRESI recused and were not present for the discussion or vote in this matter.

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

- RLCS for an unknown loss of #60 amphetamine salts 10 mg tablets reported as discovered on 12/30/2020 but occurred on or about 12/23/2020. On the afternoon of 12/15/2020, a prescription was received and filled for the medication but when the patient came in to pick it up on 12/23/2020, it could not be found in any of the waiting bins. Pharmacist Ha-Trinh filled the prescription again but did not document it in the perpetual inventory. Video was reviewed on 12/24/2020 and it was determined the patient picked up only one prescription the morning of 12/15/2020 prior to issuance of the prescription in question.
- MOR Kilcoyne stated she was notified of the discrepancy on 12/27/2020 upon returning from vacation. She notified her District Leader and Asset Protection and initiated an investigation including review of all recordkeeping, viewing video footage again, and attempting to contact the patient to determine if he had received the medication twice. The reconciliation of the perpetual inventory on 12/30/2020 showed a discrepancy of -60 tablets and MOR Kilcoyne adjusted the BOH on 12/30/2020. MOR Kilcoyne stated the medication may have been given to another patient in error.
- The incident was discussed with the Pharmacy team to prevent future losses moving forward. MOR Kilcoyne ensured security cameras capture video of pharmacy technicians at the registers, when they perform 14 return to stock prescriptions, and when they put prescriptions into the waiting bins. Additionally, MOR Kilcoyne confirmed security cameras capture video of pharmacists when checking in prescription orders, dispensing medications, and performing the perpetual inventory. A copy was provided of CVS SOP "Filling/Dispensing Prescriptions Stores with Two Step Verification Workflow" that was signed and dated by Pharmacy staff confirming review.

<u>ACTION</u>: Motion by C. BELISLE, seconded by K. THORNELL, and voted unanimously by those present, to refer to the matter (PHA-2021-0013), 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 #5

SA-INV-17294

Sherese Pearl, PH24512

<u>RECUSAL</u>: S. CORNACCHIO and L. GIAMBARRESI recused and were not present for the discussion or vote in this matter.

Time: 08:52 AM

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

BORP received a notice from NABP that Pharmacist Pearl's Pennsylvania pharmacist license was
disciplined by the Pennsylvania State Board of Pharmacy (PA Board). Specifically, Pharmacist Pearl
was manager of record (MOR) at a pharmacy license and located in Pennsylvania which failed three

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- consecutive retail compliance inspections during 2019 and 2020. The failed inspections were mainly due to repeat violations involving expired drugs and expired return to stock drugs. All violations were ultimately remedied, and Pharmacist Pearl's pharmacy "passed" an inspection with "no violations" in July 2020.
- Pharmacist Pearl entered into a consent agreement for discipline against her Pennsylvania pharmacist license with PA Board to resolve the matter which resulted in a reprimand and a \$4,500.00 fine plus administrative costs.
- Pharmacist Pearl indicated that she returned to PA in 2018 and took over as MOR at a PA CVS. She explained that she worked hard to resolve the issues during the inspections. However, she required an extended period of time to resolve issues which involved the pharmacy's prescription software and to hire quality technicians after the death of her lead technician. She emphasized that the death of her lead technician was difficult for staff to overcome. She then indicated that the pharmacy passed inspection in 07-2020 after fully implemented her corrective action plan.

<u>ACTION</u>: Motion by A. STEIN, seconded by K. THORNELL, and voted unanimously by those present, to CLOSE the matter (SA-INV-17294), No discipline Warranted, Remediation Complete.

Case #6

PHA-2021-0004

Betty V. Duong, PH27303

Time: 08:54 AM

<u>RECUSAL</u>: S. CORNACCHIO and L. GIAMBARRESI recused and were 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.

- NABP notified BORP that Pharmacist Duong's Oregon pharmacist license was disciplined the Oregon Board of Pharmacy.
- Confirmation was obtained that Pharmacist Duong entered into a disciplinary consent agreement with the Oregon Board of Pharmacy Oregon for a reprimand and a \$1000.00 fine with \$500.00 stayed pending no further violations for a period of three years by the Oregon Board of Pharmacy.
- Furthermore, details in a consent agreement described that Pharmacist Duong failed to ensure proper storage of refrigerated prescription drugs between 35° F and 46° F when temperatures were under 35° F for approximately 45 minutes with a low reading of 32.5° F. She then failed to take action to mitigate harm to patients in response to the temperature excursion.
- Pharmacist Duong confirmed receipt of the notice of complaint. Pharmacist Duong indicated that she was not planning to renew her MA license or practice in MA. She failed to provide any further response.

<u>ACTION</u>: Motion by K. THORNELL, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2021-0004), 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

SA-INV-17348 Sahar Abed, PH235814

Time: 08:58 AM

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RECUSAL: NONE

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

- In January 2020, the OPP received notification from the National Association of Boards of Pharmacy (NABP) Clearinghouse that pharmacist Sahar Abed was disciplined in another jurisdiction.
- On or about January 30, 2018, pharmacist Abed dispensed doxepin 100 mg capsules to a 73-yearold-patient on a new electronically prescribed prescription written for doxycycline 100 mg capsules.
 The prescription was incorrectly data entered by a pharmacy technician and was incorrectly verified by pharmacist Abed. The prescription vial was labeled 20 doxepin 100 mg capsule with directions to take one capsule by mouth daily with food for 10 days.
- The patient took approximately six doses of doxepin as directed by the label and experienced adverse effects, including disorientation, urinary retention, and exacerbation of a preexisting prostate condition.
- On November 5, 2019, in an agreed Board Order #2019-03327, the Texas State Board of Pharmacy reprimanded Sahar Abed's pharmacist license, ordered an administrative penalty of \$2000, and required an additional six hours of continuing education.
- The six credits in medication error prevention ordered by the Texas Board were completed in 2020.
- In 2019, pharmacist Abed completed 18 continuing education credits consisting of 1 law, 9 live, and 5.5 specific to immunization. Pharmacist Abed remediated by completing 3 continuing education credits in 2021 (including 1 law) and attested that these credits will not count towards the 2021 Massachusetts requirements.
- Pharmacist Abed provided a signed attestation that she has reviewed 247 CMR 15, Continuous Quality Improvement Program, in its entirety.

<u>ACTION</u>: Motion by A. STEIN, seconded by L. GIAMBARRESI, and voted unanimously by those present, to CLOSE the matter (SA-INV-17348), No discipline Warranted, Remediation Complete.

Julie ends public session	Time: 9:00 <u>AM</u>	
Topic VIII:	Executive Session Call to Order:	
Deferred till 5/28/21.		

65C Sessions MGL c. 112 section 65C

Time: 9:00 AM

DISCUSSION: None

Topic IX:

ACTION: President J. Lanza request a motion to enter 65C.

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At 9:00 AM L. Giambarresi, seconded by J. Chin and voted unanimously by all those present to enter 65C by roll call vote.

Topic IX ADJOURMENT OF MEETING TIME: 9:48 AM

ACTION: Motion by S. Hamilton seconded by L. Giambarresi and voted unanimously by those present, to adjourn from General Session by roll call vote.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

- 1. Draft Agenda of the 5/14/21 General Session
- 2. Draft Minutes of the 4/30/21 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. Report on PSUD 17-03
- 8. BILH Pilot Project Presentation
- 9. Policy 2020-15 Licensee Scope of Practice
- 10. Policy 2020-01 Pharmacist License Reactivation after Expiration beyond One Renewal Cycle
- 11. PHA-2021-0009 Walgreens #2781, DS3468
- 12. PHA-2021-0014 Springfield Pharmacy, DS9086
- 13. PHA-2021-0017 Rite Aid #10203, DS2570
- 14. PHA-2021-0013 CVS #920, DS89649
- 15. SA-INV-17294 Sherese Pearl, PH24512
- 16. PHA-2021-0004 Betty V. Duong, PH27303
- 17. SA-INV-17348 Sahar Abed, PH235814

Respectfully Submitted, Carly Jean-Francois, NP, Secretary

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