

COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy

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

April 16, 2021

Webex Information

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

For video access click on the following link:

<://statema.webex.com/statema/onstage/g.php?MTID=>

For phone access

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

Access Code: 185 524 0307

Attendee: #

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Yulanda Kiner, 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	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">Draft of April 2, 2021 Regular Session Minutes		
8:10	IV	REPORTS <ul style="list-style-type: none">Research Drug Study Report2020 Plan of Correction Statistics2020 Inspectional Summary		

8:20	V	FLEX <ul style="list-style-type: none"> Pharmacy issues related to Covid-19 and the state of emergency Discussion on the Pharmacy Advisory Committee May meeting 																	
8:30	VI	APPLICATIONS <ul style="list-style-type: none"> Nantucket Cottage Pharmacy-New Community Pharmacy 																	
8:45	VII	POLICIES <ul style="list-style-type: none"> Policy 2021-03: License Reinstatement Following Surrender, Suspension, or Revocation Policy 2018-06: Retail Pharmacy Participation in Research Drug Studies Policy 16-04: Staff Action to Handle Above Action Level Results (and associated reporting form) 																	
9:00	VIII	FILE REVIEW <table border="1"> <tr> <td>1</td> <td>SA-INV-17281</td> <td>Marjorie Hunt, PH237165</td> </tr> <tr> <td>2</td> <td>PHA-2021-0005</td> <td>Walgreens #4403, DS2805</td> </tr> <tr> <td>3</td> <td>PHA-2021-0007</td> <td>Hardik S. Patel, PH234865</td> </tr> <tr> <td>4</td> <td>PHA-2020-0065</td> <td>CVS #619, DS89660</td> </tr> <tr> <td>5</td> <td>SA-INV-17258</td> <td>CVS #16827, DS89923</td> </tr> </table>	1	SA-INV-17281	Marjorie Hunt, PH237165	2	PHA-2021-0005	Walgreens #4403, DS2805	3	PHA-2021-0007	Hardik S. Patel, PH234865	4	PHA-2020-0065	CVS #619, DS89660	5	SA-INV-17258	CVS #16827, DS89923		
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4	PHA-2020-0065	CVS #619, DS89660																	
5	SA-INV-17258	CVS #16827, DS89923																	
9:20	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, to evaluate the Good Moral Character as required for registration for a pending applicant.		CLOSED SESSION															
9:40	X	M.G.L. c. 112, § 65C SESSION		CLOSED SESSION															
10:00	XI	ADJOURNMENT																	

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

MINUTES OF THE GENERAL SESSION

Via Remote WebEx Meeting

April 16, 2021

Board Members Present

Julie Lanza, CPhT, President
Sebastian Hamilton, Pharm D, MBA, RPh President-Elect
Dr. Richard Lopez, MD
Andrew Stein, Pharm D
Susan Cornacchio, JD, RN (leaves meeting 10:21 AM)
Timothy Fensky, RPh
Jennifer Chin, RPh
Caryn Belisle, RPh, MBA
Leah Giambarresi, Pharm D, RPh (Leaves meeting 10:21 AM)
Carly Jean-Francois, RN, NP Secretary
Katie Thornell, RPh, MBA
Dawn Perry, JD (Leaves meeting 8:57 AM)

Board Members Not Present

Board Staff Present

David Sencabaugh, RPh, 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
Cheryl Lathum, PharmD RPh, Investigator
Gregory Melton, PharmD, JD, Investigator

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:11 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; Dr. Lopez, yes; S. Hamilton, yes; S. Cornacchio, yes; T. Fensky, yes; C. Belisle, yes; A. Stein; K. Thornell, yes; J. Chin, yes, D. Perry, yes; C. Jean-Francois, yes, L. Giambarresi, yes.

Topic II.

Approval of Agenda

TIME 8:12 AM

Agenda 4/16/21

DISCUSSION:

Change to Agenda:

Defer File Review #5 SA-INV-17258 CVS #16827

ACTION:

Motion by L. Giambarresi, seconded by C. Belisle and voted unanimously by those present to approve the agenda with noted change by roll call vote.

Topic III

Approval of Board Minutes

TIME: 8:13 AM

Minutes

1. Draft 4/2/21

Change: no noted changes

Action:

Motion by L. Giambarresi seconded C. Belisle and voted unanimously to approve the regular session minutes of 4/2/21 with no noted change by roll call vote.

TOPIC IV

Reports

Research Drug Study Report by Staff Action Policy 18-02

Time: 8:14 AM

Discussion: W. FRISCH noted there are two (2) new studies approved, two (2) studies concluded and twelve (12) active Research Drug Studies since the last report.

So noted.

TOPIC IV

REPORTS

2020 Investigation and Plan of Correction Statistics

Time: 8:15 AM

Discussion: N. ALEID noted there were 877 retail inspections completed in 2020, which was a decreased from 1,062 inspections from 2019. This is a significant decline in retail compliance inspections which was related to the COVID-19 restrictions in 2020. These 877 retail inspections resulted in 124 Plan of Corrections issued. Of the 124 Plan of Corrections issued, 116 were approved, 8 results in reinspection and 2 were referred to triage. Controlled substance records were the most cited category in 2020, refrigeration was and equipment facility, and drug storage were in position. New to the top 5 in 2020 were display and non-sterile compounding which included simple and moderate citations. When you look at chain pharmacy only inspections, Plan of Correction citations are notable different that those of the combined inspections; with refrigeration being the top cited and controlled substance records and

display being fifth. None chain citations, top 5 citations, were more varied in that Manager of Record and immunizations elevated to the top 5.

So noted.

TOPIC V

FLEX

1. Pharmacy Issues Related to Covid-19 and State of Emergency

Time: 8:17 AM

Presented by: D. SENCABAUGH

Nothing to report.

2. Discussion of the Pharmacy Advisory Committee May Meeting

Time: 8:17 AM

Presented by: E. TAGLIERI

Discussion: The request is for a Board member to bring forward two requests for Pharmacy Advisory Committee input. The topics are smoke visualization studies and pharmacy point-of-care testing/scope of practice.

Action:

Motion by S. HAMILTON, seconded by L. GIAMBARRESI, and voted unanimously by roll call by all those present to request input on the topics of smoke visualization studies and pharmacy point-of-care testing/scope of practice from the Pharmacy Advisory Committee.

Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by roll call by all those present to have T. FENSKY and L. GIAMBARRESI take the documents to the meeting.

TOPIC VI

Applications

1. Nantucket Cottage Pharmacy

TIME: 8:22 AM

REPRESENTED BY: Karen Ryle, MOR; David Small, Direction of Pharmacy Operations at Nantucket Cottage Hospital

RECUSAL: T. FENSKY, C. JEAN-FRANCOIS, C. BELISLE, L. GIAMBARRESI

DISCUSSION: W. FRISCH has reviewed the application and the waiver for balance. They are planning to compound. Nantucket Cottage Pharmacy is a standalone building across the street from Nantucket Cottage Hospital. Nantucket Cottage Hospital is an affiliate of MGH Brigham and has purchased the pharmacy. MOR Karen Ryle is currently Director of Outpatient Pharmacy at MGH. The pharmacy is in mid island. They are purchasing prescription files from Island Pharmacy. The pharmacy will service patients from Island Pharmacy, Nantucket Cottage Hospital, and the community. This will also serve

Health Safety Net patients. Security at the pharmacy includes fifteen cameras outside and inside along with panic buttons. They do plan to immunize, and staff will be trained and certified.

ACTION: Motion by S. HAMILTON seconded by A. STEIN, voted unanimously by those present to approve the application pending a successful inspection and waiver for 247 CMR 6.01 (5)(1)(4)

TOPIC VII

Policies

1. Policy 2021-03: License Reinstatement Following Surrender, Suspension, or Revocation

Time: 8:35 AM

Presented by M. CHAN

Discussion: This is a complete update and revision of the 10-year-old policy. It has been streamlined for ease of use and has eliminated outdated requirements. It supersedes policy 2011-02.

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

2. Policy 2018-06: Retail Pharmacy Participation in Research Drug Studies

Time: 8:36 AM

Presented by M. CHAN

Discussion: The policy was updated to remove the requirement for a copy of the MCSR application and to have the pharmacy provide a description of the nature of the drug study.

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

3. Staff Action Policy 16-04: Staff Action to Handle Above Action Level Results

Time: 8:38 AM

Presented by M. CHAN

Discussion: The sterile compounding Above Action Level (AAL) notification procedure has been amended to streamline it and make it more self-directed. Pharmacies will still submit the details of the AAL but also attest that they will remediate in accordance with Board policy.

The requirement for routine follow-up notification upon remediation has been eliminated.

Each above action level will be reviewed and assessed by Board staff for safety issues.

Investigators will follow-up on certain notifications including:

- AALs of concern (e.g. high CFU count, multiple locations, etc.);
- repeat AAL; and
- a random selection of 10% of files.

The policy would allow staff to close the file if the pharmacy has attested to successfully remediate and was compliant with reporting requirements; or in the case of Investigator follow-up, demonstrated successful remediation.

The reporting form has also been updated to reflect this change.

Action: Motion by T. FENSKY, seconded by C. BELISLE, and voted unanimously by roll call by all those present to approve the updated policy.

Topic VIII

File Review

Case #1

SA-INV-17281

Marjorie Hunt, PH237165

Time: 08:41 AM

RECUSAL: NONE

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

- Repeat self-reported CE deficiency on 12/7/2020 of 0.5 CEs for 2019 but in 2019, she oversaw complex non-sterile compounding resulting in a deficiency of 3.5 CEs. All the other states she is licensed in require only 15 CEs yearly with no specific CE requirements for compounding. In 2018, the Pharmacist Hunt had self-reported CE deficiencies for 2016 and 2017 which were remediated in 2018 according to SA-INV-14227.
- Pharmacist Hunt completed 24.5 CEs in 2020 remediating her deficiency of 0.5 CEs for 2019. As of 2/18/2021, she completed 3 CEs in complex non-sterile compounding for remediation.

ACTION: Motion by L. GIAMBARRESI, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to CLOSE the matter (SA-INV-17281), No Discipline Warranted, Remediation Complete.

Case #2

PHA-2021-0005

Walgreens #4403, DS2805

Time: 08:43 AM

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

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

- Untimely, unknown RLCS reported as occurring on 12/2/2020 for losses of #60 oxycodone 15mg tablets discovered on 11/12/2020 but not documented until 11/14/2020 and #78 amphetamine salts 15mg tablets discovered on 11/21/2020 but not documented until 11/23/2020. Both losses were identified during CII counts. All CII recordkeeping was reviewed, the Pharmacy was searched, and staff was interviewed. Four patients who had received oxycodone 15mg between 11/8/2020 and 11/12/2020 were contacted and all denied an over-dispensing. Only 1 prescription for amphetamine salts 15mg tablets was filled between 11/14/2020 and 11/21/2020 and Current MOR Rezendes had documented the back count on the hard copy. Security footage was reviewed but was inconclusive. Diversion was not suspected. The oxycodone may have been an over-dispensing and the amphetamine salts may have been inadvertently discarded.

- When Current MOR Rezendes assumed the position as MOR on 11/15/2020, there were numerous discrepancies in the perpetual inventory that were unresolved by Former MOR Accime who had been terminated. There was no staff pharmacist working at the time and floater pharmacists were not back counting relying on CPhTs to count CII. Occasionally when CII counts were occurring, the safe had been left open for short periods, particularly with oxycodone.
- Current MOR Rezendes reviewed the regulations and the requirements to avoid a future occurrence of untimely reporting. Current MOR Rezendes stated, "CII medications under the previous MOR were double counted, but not back counted, and certified technicians and pharmacists could count them for dispensing". Current MOR Rezendes asked all staff pharmacists and floater pharmacists to personally count CII. As of 11/14/2020, CII must be double counted and back counted. The quantity remaining must be compared to the perpetual inventory to confirm the correct balance on hand. Current MOR Rezendes or the staff pharmacist will inform new floater pharmacists the Pharmacy's policy for handling CII.

ACTION: Motion by L. GIAMBARRESI, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2021-0005), 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-2021-0007

Hardik S. Patel, PH234865

Time: 08:47 AM

RECUSAL: NONE

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

- BOP was notified through NABP's clearinghouse in January 2021 that the Virginia BOP ordered a mandatory suspension of Pharmacist Patel's Virginia pharmacist license because he was convicted on 18 felony counts including "17 counts of distribution of a Schedule I or II controlled substance and 1 count of money laundering" in Virginia.
- Pharmacist Patel was served notice of this complaint and provided a copy of BOP's Pharmacy Substance Use Disorder (PSUD) Program's information pamphlet at Rappahannock Regional Jail in Stafford, VA because he was no longer represented by an attorney. Pharmacist Patel did not respond to the complaint as of the date of this report.

ACTION: Motion by L. GIAMBARRESI, seconded by T. FENSKY, and voted unanimously by those present, to REFER the matter (PHA-2021-0007), 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 VOLUNTARY SURRENDER.

Case #4

PHA-2020-0065

CVS #619, DS89660

Time: 08:47 AM

RECUSAL: S. CORNACCHIO and L. GIAMBARRESI had exited the meeting and were not present for the discussion or vote in this matter.

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

- Inspectional deficiencies were observed at CVS #619 during a retail compliance inspection on 9/16/2020. The violations included failures to submit a timely change in MOR application, maintain copies of DEA Form 222 and return records for Schedule II controlled substances, and return records for Schedule III-V controlled substances, and failure to maintain copies of CPR and immunization certification.
- Of note, CVS #619 did not violate requirements for reconciliation of C-II's every 10 days because reconciliation requirements were extended to every 30 days by COVID emergency regulations.
- MOR indicated that he was unaware that the change of MOR application was not submitted. MOR indicated that previous DEA 222's were triplicates, so he kept a copy, but the new form was not a triplicate, so he didn't keep a copy. MOR provided a copy of his immunization and CPR certification.
- With respect to corrective action MOR Mathews wrote, "Once we were notified that the licensing team and Board of Pharmacy did not receive the initial change in MOR application, the application was resubmitted... I have reviewed policy and procedures with all staff pharmacists regarding performing an inventory on all CII product every 10 days, will continue to monitor that all CII products are being inventoried every 10 days until removed from the pharmacy... Going forward, we now make a photocopy of the completed 222 form and retain this copy for our pharmacy records... All staff have been retrained on the expectation to have the proper immunization documentation easily accessible in the Regulatory Box."
- Follow up inspection on 04/14/2021 resulted in a plan of correction for repeat deficiencies.

ACTION: Motion by T. FENSKY, seconded by A. STEIN, and voted unanimously by those present, to open a companion complaint to the matter (PHA-2020-0065), on MOR Matthews (PH24657) and hold off voting on PHA-2020-0065 until it can be considered alongside the PHA on MOR Matthews.

Julie Reads Executive Session Language

Time: 8:57 AM

Topic IX:

Executive Session Call to Order:

Time: 8:57 AM

By: J. Lanza

ACTION: Motion by, S. Hamilton, seconded by C. Belisle, all voted affirmatively by those present to enter executive session.

Roll call attendance: J. Lanza, yes; Dr. Lopez, yes; S. Hamilton, yes; S. Cornacchio, yes; T. Fensky, yes; C. Belisle, yes; A. Stein; K. Thornell, yes; J. Chin, yes, D. Perry, yes; C. Jean-Francois, yes, L. Giambarresi, yes.

D. Perry leaves meeting at 8:57 AM

Topic X:

65C Sessions MGL c. 112 section 65C

Time: 9:44 AM

DISCUSSION: None

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

At 9:44 AM L. Giambarresi, seconded by K. Thornell and voted unanimously by all those present to enter 65C by roll call vote.

S. Cornacchio leaves meeting at 10:21 AM

L. Giambarresi leaves meeting at 10:21 AM

Topic XI

ADJOURNMENT OF MEETING

TIME: 10:27 AM

ACTION: Motion by S. Hamilton seconded by K. Thornell 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 4/16/21 General Session
2. Draft Minutes of the 4/2/21 Meeting
3. Report on Research Drug Study
4. Report 2020 Summary Investigations and Plans of Correction
5. Application: Nantucket Cottage Pharmacy New Community Pharmacy
6. Policy 2021-03: License Reinstatement Following Surrender, Suspension, or Revocation
7. Policy 2018-06: Retail Pharmacy Participation in Research Drug Studies
8. Policy 16-04: Staff Action to Handle Above Action Level Results (and associated reporting form)
9. SA-INV-17281 Marjorie Hunt, PH237165
10. PHA-2021-0005 Walgreens #4403, DS2805
11. PHA-2021-0007 Hardik S. Patel, PH234865
12. PHA-2020-0065 CVS #619, DS89660

Respectfully Submitted,
Carly Jean-Francois, NP, Secretary