# COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

## **February 5, 2021**

#### **Webex Information**

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

Access Code: 178 321 6261

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	Ш	<ul> <li>APPROVAL OF BOARD MINUTES</li> <li>Draft of January 22, 2021 Regular Session Minutes</li> </ul>		
8:10	IV	<ul> <li>REPORTS</li> <li>Applications approved pursuant to Licensure Policy 13-01</li> <li>Monthly report from probation</li> <li>Board Delegated Review pursuant to Licensure Policy 14-02</li> <li>Above Action Levels approved by Staff Action 16-04</li> <li>PSUD Report-Policy 17-03</li> </ul>		
8:15	V	APPLICATIONS  • Pharmacy Amanecer – New Community Pharmacy - Update		

8:20	VI	<ul> <li>FLEX</li> <li>Pharmacy issues related to Covid-19 and the state of emergency</li> <li>Pharmacy Advisory Committee: consideration and appointment of 2 candidates</li> <li>BILH Pharmacy Direct and BIDMC Specialty pharmacies report on pilot project</li> <li>Pro Care Pharmacy – update on CPhT pilot project</li> </ul>		
9:00	VII	POLICIES  • Revision of Staff Action Policy 14-02: Board Delegated Review		
9:05	VIII	FILE REVIEW         1       PHA-2020-0069       Injured Workers Pharmacy, DS89727         2       PHA-2020-0081       Community, A Walgreens #16486, DS90062         3       PHA-2020-0087       Rite Aid #10084, DS2780         4       PHA-2020-0055       Rite Aid #10198, DS2386         5       PHA-2020-0072       CVS #685, DS2646         6       PHA-2020-0077       Omnicare of Central MA, DS89868		
9:45	IX	<b>EXECUTIVE SESSION</b> 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	
10:15	X	M.G.L. c. 112, § 65C SESSION	CLOSED SESSION	
10:45	XI	ADJOURNMENT		

## COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

# MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting February 5, 2021

#### **Board Members Present**

Julie Lanza, CPhT, President
Sebastian Hamilton, Pharm D, RPh President-elect
Carly Jean-Francois, RN, NP Secretary
Leah Giambarresi, Pharm D, RPh
Dr. Richard Lopez, MD
Susan Cornacchio, JD, RN (Leaves meeting 9:30 AM)
Timothy Fensky, RPh
Andrew Stein, PharmD
Dawn Perry, JD (arrives meeting 8:30 AM)
Caryn Belisle, PharmD, RPh
Jennifer Chin, RPh (arrives meeting 8:21 AM)
Katie Thornell, PharmD, RPh

### **Board Members Not Present**

Kim Tanzer, PharmD, RPh

#### **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
Richard Harris, Program Analyst
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Joanna Chow, Office Support Specialist
Joanne Trifone, RPh, Director of Investigator
Julienne Tran, PharmD RPh, Investigator
Gregory Melton, PharmD, JD, Investigator
Christina Mogni, RPh, Investigator

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

#### **CALL TO ORDER 8:03 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; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; T. Fensky, yes; C. Belisle, yes; A. Stein; K. Thornell, yes. J. Chin arrives 8:21 AM; D. Perry arrives 8:30 AM.

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Topic II. Approval of Agenda TIME 8:05 AM

#### Agenda 2/5/21

#### **DISCUSSION:**

Change to Agenda:

1. defer Flex: Pharmacy Advisory Committee

2. defer Flex: BILP Pilot Project

#### **ACTION:**

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

Topic III Approval of Board Minutes TIME: 8:06AM

Minutes

1. Draft 1/22/21

No noted Changes.

#### Action:

Motion by S. Hamilton, seconded L. Giambarresi, and voted unanimously to approve the regular session minutes of 1/22/21 with no changes by roll call vote.

#### Topic IV Reports

1. Applications approved pursuant to Licensure Policy 13-01 Time: 8:11:23am Presented by: Edmund Taglieri

#### Discussion:

E. TAGLEIRI inquired whether BORP had any questions or comments about information provided in the report titled, "Applications Approved Pursuant to Licensure Policy 13-01" in the Board Packet for February 02-05-2021. BORP did not have any inquiries.

So noted.

#### TOPIC IV REPORTS

2. Monthly Report from BDCR pursuant to Policy 14-02 Time: 8:11:56am Presented by: David Sencabaugh

#### Discussion:

D. SENCABAUGH reported a total of nine cases were resolved pursuant to Policy 14-02 in the preceding month. SENCABAUGH then specified that eight cases involving self-disclosed CE deficiencies were closed discipline not warranted – remediation complete during BDCR on January 21, 2021 and one case involving deficiencies was closed discipline not warranted – remediation complete during BDCR on February 4, 2021.

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#### So noted.

#### **TOPIC IV REPORTS**

Above Action Levels Approved by Staff Action 16-04 Time: 8:13:17am

Presented by: Nancy Aleid

#### Discussion:

N. ALEID reported that two licensees successfully remediated above action levels pursuant to Policy 16-04.

#### So noted.

#### **TOPIC IV REPORTS**

4. PSUD report by Staff Action 17-03 Presented by: Edmund Taglieri

#### Discussion:

E. TAGLEIRI reported that PSUD had 12 active participants. He then reported that "all went well" at PSUD's quarterly meeting held in January. He stated, "All the current participants are doing well considering COVID and holding their own during a difficult time, so I have all good reports for PSUD, right now."

Time: 8:13:43am

So noted.

#### **TOPIC V** Applications:

1. Pharmacy Amanecer New Community Pharmacy/Update TIME: 08:14:11am

Represented by: Not Applicable

Recusal: None

#### Discussion:

J. LANZA explained to BORP that W. FRISCH wished to provide an update on the status of AMANECER's application presented in BORP's monthly meeting two weeks ago (1-22-2021). LANZA reminded BORP that AMANECER's application was approved during the meeting two weeks ago with conditions.

W. FRISCH then explained to BORP that the application was approved contingent upon submission of AMANECER's articles of incorporation. He reported that AMANECER submitted its articles of incorporation and its articles were satisfactory. Thus, AMANECER met conditions required for opening pending a successful new pharmacy inspection.

Next, J. LANZA inquired whether BORP had any questions for FRISCH. BORP had not questions. J. LANZA then inquired whether an additional vote was required to approve AMANECER's applications. H. ENGMAN responded that BORP already approved the application with conditions in the previous monthly meeting and FRISCH's discussion was an update for BORP. Thus, no vote was required.

Action: None - Post-Approval Status Update Only

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то	PIC VI	Flex:				
1.	Pharmacy Issues Related to Covid-19 and State of Emergency		Time: 8:10 AM			
No	othing to report.					
2.	Pharmacy Advisory Committee: co	nsideration and appointment of 2 candidates	s Time: 8:10 AM			
De	ferred.					
3.	BILH Pharmacy Direct and BIDMC	Specialty pharmacies' report on pilot project	Time: 8:10 AM			
Deferred.						
4.	ProCare Pharmacy Update on CPh	T Pilot Project Time	Time: 8:12 AM			

Presented by: ProCare staff: Donna Gorka (MOR); Rajiv Dhadwal (chief compliance officer)

**Discussion:** This pilot project was to evaluate the feasibility and safety of certified pharmacy technicians working in a remote setting. ProCare staff presented data that showed a lower percentage rate of errors for the remote entry technicians as compared to the technicians working onsite. The request was made for the Board to update the Shared Services policy to allow the practice after the COVID emergency period ends.

**Action:** Motion by L. GIAMBARRESI, seconded by C. JEAN-FRANCOIS, and voted unanimously by roll call by all those present to end the pilot and allow ProCare to continue the practice under the COVID-19 emergency orders.

TOPIC VII Policies:

1. Staff Action Policy 14-02: Board Delegated Review (BDR) Time: 8:27 AM

Presented by M. CHAN

**Discussion:** This policy was revised with some technical edits as well as an edit regarding technician trainee (PTT) licenses. PTT licenses are not renewable, but the staff has been granted the authority to extend the licenses for up to 1 year. However, some licensees have requested an additional year which this policy would allow to be handled through the BDR group. This group contains at least 1 Board member and certain staff members.

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

Time: 8:39 AM

#### 2. Advisory: Lean Concepts

Presented by M. CHAN

**Discussion:** Although the specialty licensure regulations are not yet in effect, there is a statutory requirement is to attest that employees have been trained in lean concepts before the annual renewal of a specialty license. The specialty licenses include sterile, institutional sterile, and complex non-sterile compounding pharmacies. This document is a reminder of that requirement and suggests different ways to meet it. It also encourages the use of lean concepts in <u>all</u> pharmacy settings. This advisory supersedes policy 2016-03 titled "An Introduction and Guide to the Practice and Implementation of Lean Concepts in a Pharmacy Setting".

The status of the draft of 247 CMR 6.00 licensing regulations is that they have made advances in the past few weeks and are in the final stages of approval. Although the pandemic has delayed things, Board staff is hopeful they will be promulgated soon.

**Action:** Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by roll call by all those present to approve the advisory with an amendment to state that the attestation of employee training in lean concepts will be an annual requirement for specialty pharmacies.

#### TOPIC VIII FILE REVIEW

Case #1

PHA-2020-0069 Injured Workers Pharmacy, DS89727 Time: 08:30 AM

<u>RECUSAL</u>: L. GIAMBARRESI and W. FRISCH recuse and were not present for the discussion or vote in this matter.

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

- Unknown loss of #60 Ambien 10mg tablets
- On August 19, 2020, a prescription for #60 Ambien 10mg was filled and verified by a pharmacist but did
  not ship. The pharmacy staff proceeded to search for the completed prescription but was unable to
  locate it.
- MOR Welch indicated that there were a few possible scenarios for the reason for the loss including: the
  prescription was shipped but the tracking number was not assigned to the package within the system
  due to a software error, the prescription was inadvertently discarded, or the prescription was shipped

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- to the incorrect patient because the shipper may have accidentally put the completed medication in someone else's package without scanning it.
- MOR Welch noted that patients whose prescriptions were filled within the time frame were contacted and those patients did not report receiving this order.
- MOR Welch reported that as part of their internal investigation, Pharmacist McNulty reviewed the inventory, double counted the stock on hand, and did a full search of the entire pharmacy.
- Relevant video footage from the facility's 29 security cameras was reviewed with no diversions in process noticed.
- Corrective actions included a new pharmacy workflow which requires the pharmacist verifying a CIII-CV prescription to double count the medication and place it in a sealed bag prior to shipping. Additionally, the pharmacy has ordered the installation of a new set of cameras to capture the point of shipping, due to be operational by 12/11/2020.

<u>ACTION</u>: Motion by A. STEIN, seconded by T. FENSKY, and voted unanimously by those present, to DISMISS the matter (PHA-2020-0069), No Discipline Warranted.

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Case #2

PHA-2020-0081 Community, A Walgreens #16486, DS90062 Time: 08:36 AM

**RECUSAL: NONE** 

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

- RLCS submitted on 11/11/2020 for a loss of #32 Oxycontin 10mg tablets first discovered on 1/6/2020 during the reconciliation of the perpetual inventory. The loss was first reported to the BORP on 1/15/2020 then retracted on 1/23/2020 after determining the 32 Oxycontin 10mg tablets were expired and allegedly sent to Inmar with an expired return but the drug had not been added to the request for return when the claim was created on 12/12/2019. When the return was packaged on 12/27/2019, MOR McCabe indicates she put the brown and green copies of the DEA 222 form in the box which she confirmed during review of security footage.
- On 1/6/2020, Inmar confirmed receipt of the return but the processing was suspended due to a move to another location. On 3/6/2020, Inmar reported that the return was processed on 3/2/2020 but there were no copies of the DEA 222 forms or Oxycontin 10mg tablets included. On 4/7/2020, the Pharmacy was informed a ATF222 form would not be generated by Inmar for an overage of 32 Oxycontin 10mg as they denied receiving the Oxycontin. The reported loss was escalated to Walgreens Asset Protection, Compliance Investigations, Pharmacy Inventory Reverse Distribution and Pharmaceutical Integrity for further investigation. Guidance was not provided until 10/1/2020 when the DM was notified to file a DEA 106 which was not communicated to MOR McCabe until 11/4/2020.
- Going forward two pharmacists will witness CII returns to prevent future losses of this nature by ensuring all medications are listed on the claim are accounted for. Each CII will be checked individually and counted prior to placing in the bag.

<u>ACTION</u>: Motion by L. GIAMBARRESI, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2020-0081), 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 #3

PHA-2020-0087 Rite Aid #10084, DS2780 Time: 08:40 AM

**RECUSAL: NONE** 

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

- Timely, inaccurate RLCS received on 11/19/2020 reporting unknown losses of #53 oxycodone/acetaminophen 10/325 mg tablets and #1 amphetamine salts ER 20 mg capsule on 11/3/2020. MOR Fullem's statement in Appendix 1 indicated the loss date was 11/1/2020 but the discrepancies were discovered on 10/31/2020 during the reconciliation of the perpetual inventory.
- The internal investigation included nightly counts for 2 weeks with 3 drug reconciliations, searching the safe and will call bins as well as reviewing computer data and hard copy prescriptions. Patients who had been dispensed prescriptions since the previous reconciliation on 10/24/2020 were contacted and none confirmed an over-dispense. There are no security cameras in the Pharmacy. MOR Fullem speculated that the discrepancy of the #1 amphetamine salts ER 20 mg capsule was dispensed as a counting error. Regarding the loss of #53 oxycodone/acetaminophen 10/325 mg tablets, MOR Fullem theorized it was possible that there were two open stock bottles and one of them was inadvertently discarded.
- Procedures for accurate handling, dispensing, and accountability were reviewed with staff. MOR Fullem indicated only the pharmacist will double count CIIs, initial on the prescription label, and back count then document each back count into the prescription notes of Nexgen. A weekly control count will continue to be conducted to ensure accuracy of controlled substance inventory.

<u>ACTION</u>: Motion by L. GIAMBARRESI, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2020-0087), 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 #4

PHA-2020-0055 Rite Aid #10198, DS2386 Time: 08:43 AM

**RECUSAL: NONE** 

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

- During August 2020, Rite Aid properly reported an unknown loss of 110 tramadol 50mg tablets discovered on June 30, 2020. Rite Aid indicated that the unknown loss was discovered during covert counts as part of an audit by its asset protection team. The audit uncovered a loss of 110 tramadol 50mg tablets between May 1, 2019 and June 30, 2020 which represented approximately 0.3% of the total number of tramadol 50mg tablets dispensed during the same period. Rite Aid reported that no further losses were uncovered since June 30, 2020 and diversion was not suspected.
- Rite Aid indicated that corrective action was implemented as follows. Rite Aid explained, "Reviewed procedures for the accurate handling, dispensing and accountability of controlled drugs with the associates. Store will continue to follow policy and procedures in regard to Controlled Substances

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- handling and storage. Only the pharmacist will double count Clls; initial on the prescription label; and back count. A weekly control count will continue to be conducted to ensure the highest level of accuracy of controlled substance inventory in accordance with MA regulations."
- In addition, Rite Aid reported that a staff pharmacist "was issued [a] verbal warning for not reporting shortages." Investigator Melton clarified that the pharmacist in question completed monthly counts as required by Rite Aid policy and documented the tramadol discrepancy in the pharmacy's electronic inventory. However, he did not complete an additional step to directly notify his district manager by email because he wrongly assumed the district manager received electronic copies of the monthly inventory.

ACTION: Motion by L. GIAMBARRESI, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to refer the matter (PHA-2020-0055), 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 STAYED PROBATION for a period of one year, with special terms to include conducting an exact count CS inventory for all scheduled 3-5 medications within 30 days, 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 said terms.

Case #5

PHA-2020-0072 CVS #685, DS2646 Time: 08:46 AM

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 9-28-2020, CVS #685 reported an unknown loss of 400 diazepam 10mg tablets discovered on 6-30-20. Investigator Melton also determined that CVS #685 submitted their initial (~17 days late) and final (~66 days late) reports of loss in an untimely manner.
- MOR Cassista acknowledged that the report was submitted in an untimely manner. She explained
  that CVS corporate transferred her to CVS #685 in 06-2020 and she was on leave at the time the loss
  was discovered. She indicated that staff at CVS #685 did not report the loss to her until several days
  after she returned from leave. This delay caused her to submit the report of loss late to corporate.
   MOR Cassista emphasized that she stressed the importance of timely reporting of issues such as losses
  of controlled substances and quality related events to her.
- CVS #685 indicated that Loss Prevention P & P's were reviewed with the pharmacy staff to "prevent future losses" including "diligent inventory amendment and dispensing standards." Investigator Melton confirmed with MOR Cassista that the corrective action was implemented.
- In addition, CVS #685 entered into a consent agreement (PHA-2019-0058) for a non-disciplinary stayed probation for one year with conditions for enhanced monitoring of benzodiazepines effective November 18, 2019 and ending November 18, 2020. However, CVS #685 had not petitioned to end their stayed probation at the date of this report. CVS #685 had not reported a loss since 2013 until the report in May 2019 according to BORP records.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2020-0072), to Probation as evidence of a violation of probation agreement and

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issue a Notice of Violation and modify the underlying agreement from a Stayed Probation to a disciplinary PROBATION and extend the agreement period for an additional year.

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Case #6

PHA-2020-0077 Omnicare of Central MA, DS89868 Time: 08:55 AM

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.

- Omnicare reported a theft of 300mL clobazam 2.5mg/mL suspension which occurred on 09-10-2020 but was not discovered until 09-18-2020. Omnicare indicated that it used a third-party courier to deliver prescriptions to patient-resident in various LTCF, ALF, and group homes in Massachusetts. In this case, a driver was sent to retrieve 300mL clobazam suspension which the facility requested to return because they wished for the drug to be dispensed in pre-filled oral dose syringes.
- Omnicare sent a driver to the facility and he picked up the clobazam. However, he did not return to Omnicare with the clobazam. The missing clobazam went undetected for approximately 8 days. At that time, Omnicare, the courier service, and police interviewed the driver. The driver did not make an admission.
- Omnicare and the courier service agreed that the driver would not deliver for Omnicare any longer. In addition, a new delivery log specifically for returns was created to ensure the chain of custody loop for returns was closed for returns.
- In addition, Omnicare earned a satisfactory inspection on 01-13-2021. During the inspection,
  Omnicare indicated that it was planning to hire its own delivery drivers to enhance oversight of
  deliveries.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by L. GIAMBARRESI, and voted unanimously by those present, to DISMISS the matter (PHA-2020-0077), No Discipline Warranted, Remediation Complete.

Topic IX: Executive Session Call to Order: Time: 9:00 AM

By: J. Lanza

<u>ACTION</u>: Motion by, L. GIAMBARRESI, seconded by C. JEAN-FRANCOIS, all voted affirmatively by those present to enter executive session with no changes.

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

Topic X: 65C Sessions MGL c. 112 section 65C Time: 9:23 AM

**DISCUSSION: None** 

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

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At 9:37 AM S. Hamilton, seconded by L. Giambarresi and voted unanimously by all those present to enter 65C by roll call vote.

- S. Cornacchio leaves the meeting at 9:30 AM
- D. Perry Leaves the meeting at 10:15 AM prior to adjournment vote.

#### Topic XI ADJOURMENT OF MEETING TIME: 10:15 AM

ACTION: Motion by L. Giambarresi seconded by S. Hamilton 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 2/5/21 General Session
- 2. Draft Minutes of the 1/22/21 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. Applications: Pharmacy Amanecer New Community Pharmacy
- 9. Pro Care Pilot Project presentation
- 10. Staff Action Policy 14-02 Board Delegated Review
- 11. PHA-2020-0069 Injured Workers Pharmacy, DS89727
- 12. PHA-2020-0081 Community, A Walgreens #16486, DS90062
- 13. PHA-2020-0087 Rite Aid #10084, DS2780
- 14. PHA-2020-0055 Rite Aid #10198, DS2386
- 15. PHA-2020-0072 CVS #685, DS2646
- 16. PHA-2020-0077 Omnicare of Central MA, DS89868

Respectfully Submitted, Carly Jean-Francois, NP, Secretary