

**COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy**

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

August 21, 2020

Webex Information

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

Access Code: 161 762 3790

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
8:00	I	CALL TO ORDER
	II	APPROVAL OF AGENDA
8:05	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">• Draft of August 14, 2020 Regular Session Minutes
8:10	IV	APPLICATIONS <ul style="list-style-type: none">• Shivani Patel: PH234024 - Reactivation application• Walgreens 1847 (DS1359) – Change of Manager• Acnos Pharmacy – Wholesale Distributor
8:40	V	FLEX <ul style="list-style-type: none">• Pharmacy issues related to Covid-19 and the state of emergency• Notice of Retirement of Carmen Catizone, NABP• Vote on resolutions, delegates and alternate for District I and II meetings

General Session Agenda

August 21, 2020

8:55	VI	FILE REVIEW	
		1	PHA-2020-0021 Walgreens #6739, DS1896
		2	PHA-2020-0047 Walgreens #3020, DS2492
		3	PHA-2020-0046 CVS #1870, DS90040
9:15	VII	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 hold a sanction hearing and an investigative conference and also to evaluate the Good Moral Character as required for registration for a pending applicant.	
9:45	VIII	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)	
10:00	IX	M.G.L. c. 112, § 65C SESSION	
10:30	X	ADJOURNMENT	

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

MINUTES OF THE GENERAL SESSION

Meeting held via WEBEX remotely

Boston, Massachusetts, 02114

August 21, 2020

Board Members Present

Kim Tanzer, PharmD, RPh. President
Julie Lanza, CPhT, President Elect (leaves 10:15 AM)
Sebastian Hamilton, Pharm D, RPh
Leah Giambarresi, Pharm D, RPh, Secretary (Leaves 10:10 AM)
Dr. Richard Lopez, MD
Andrew Stein, Pharm D
Katie Thornell, RPh
Susan Cornacchio JD, RN
Patrick Gannon, RPh (Leaves 10:00 AM)
Carly Jean-Francois, RN, NP

Board Members Not Present

Stephanie Hernandez, Pharm D, BCGP, RPh
Timothy Fensky, RPh
Dawn Perry, JD

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, Assistant Executive Director
Heather Engman, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Joanne Trifone, RPh, Director of Investigator
Gregory Melton, Pharm D, JD, RPh Investigator
Christina Mogni, RPh Investigator
Leo McKenna, PharmD, RPh Investigator
Julienne Tran, PharmD, RPh Investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Joanna Chow, Office Support Specialist

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:03 AM

A quorum of the Board was present, established by roll call. President K. Tanzer chaired the meeting. She explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: K. TANZER: yes, J. LANZA: yes, L. GIAMBARRESI: yes, A. STEIN: yes, S. HAMILTON: yes, C. Jean-Francois: yes, S. CORNACCHIO: yes, R. LOPEZ: yes, K. THORNELL: yes. P. Gannon joins meeting at 8:05 AM.

Topic II.

Approval of Agenda

TIME 8:03 AM

Agenda August 21, 2020

DISCUSSION:

Change to Agenda:

1. Defer Applications: Acnos and Walgreens 1847
2. Defer Adjudicatory Session

ACTION:

Motion by L. Giambarresi, seconded by J. Lanza and voted unanimously by those present by roll call vote to approve the agenda with noted changes.

Topic III

Approval of Board Minutes

TIME: 8:05 AM

Minutes

1. Draft 8/14/20 General Session Minutes

No noted Changes.

Action:

Motion by S. Hamilton, seconded by L. Giambarresi and voted unanimously by roll call vote to approve the regular session minutes of 8/14/20 with no noted changes.

TOPIC IV

Applications

1. Shivani Patel PH234024 Reactivation application

TIME 8:16 AM

Represented by: Shivani Patel

Recusal: none

Discussion: Shivani Patel previously held a pharmacist license but let it lapse after becoming a practicing dentist. She has petitioned the board for reinstatement of her pharmacist license. Ms. Patel joined by phone and was asked by K. TANZER to walk the board through the circumstances on why she was looking to reactivate her pharmacist license.

Ms. PATEL responded by describing that she graduated in from pharmacy school and got licensed in 2012, and then started dental school in the fall. She worked per diem during the months before starting and periodically through dental school to keep up with pharmacy but eventually let her license lapse. She stated that the COVID emergency has given her some new perspectives, and she considers herself a front-line worker in the medical field. The COVID emergency also made her reflect on her time spent in pharmacy.

Ms. PATEL answered questions from the board members on why she let her license lapse, if she was open to sitting for the NAPLEX, how she has kept up her pharmacy knowledge base, what practice settings she plans on working in, and how she would plan to balance her dental practice with her

pharmacy practice. Ms. PATEL also answered questions about continuing education since the years her pharmacy license lapsed. Ms. PATEL stated that she has continued to complete pharmacy CEs since her licensed lapsed. This was confirmed by M. BOTTO based on submissions by Ms. PATEL

Action: Motion by L. GIAMBARESSI, seconded by A. STEIN and voted unanimously by roll call by those present by roll call vote to reinstate Shivani PATEL’s license with the stipulation that she retake the MPJE.

2. Walgreens 1847 DS1359 Change of Manager

DEFERRED

3. Acnos Pharmacy Wholesale Distributor

DEFERRED

V: Flex:

Time: 8:06-8:10 AM

Time: 8:33 AM

1 a. Pharmacy issues related to Covid-19 and the state of emergency

Presented by: Dave Sencabaugh

Recusal: none

Discussion: The state has announced the requirement for all school aged children learning through a hybrid model or fully remote, with some exceptions, to get a flu shot this year. This will likely increase the number of people that will be looking for flu shots at pharmacies. Our current policy for pharmacists administering immunizations is only for people aged 9 and up. There have been inquiries because the HHS federally announced that pharmacists could immunize children 3 years old and up.

DPH is aware and has already begun the discussion to get guidance out to all concerned parties. D. SENCABAUGH read the following statement out loud. “We share the interest in expanding access to flu and other vaccines during the emergency, and the DPH is working very quickly to interpret and implemented newly released federal guidance”.

L. GIAMBARESSI asked if the gap between 3 to 9 years of age is covered or do the standing orders need to be updated to reflect administering immunizations to 3 to 9-year-olds.

D. SENCABAUGH answered that those are the things that are being looked at in terms of the guidance. It’s clear that pharmacists are going to be able to do it, but the question is... what we will need in terms of reporting to physicians because it is for all immunizations so the whole plan for a patient needs to be reported appropriately.

L. GIAMBARESSI responded that they are all required to report to MIIS anyways, and the physicians should be able to access that, are pharmacists able to administer with just the HHS emergency or if their standing orders need to get updated for that age range?

H. ENGMAN answered that that is something we will consider carefully and make sure is in any guidance that comes out.

L. GIAMBARESSI recommended that we not have the pharmacies have to update the standing order since it would cause a delay because most large companies would have to go through their legal department and have the whole standing order redone and get it signed off on. It would probably cause some additional time.

S. CORNACCHIO asked if there was any discussion about expanding the scope of practice for technicians to administer vaccines to accommodate the influx of patients.

D. SENCABAUGH answered that there have been discussions and stated that he has recommended that, especially early on because there is going to be training required. The likelihood, if allowed, would be certified technicians but this is all part of everything that's being looked at very closely, and we relay any information as soon as we get it.

P. GANNON asked if pharmacist immunization training addresses pediatric patients as well or will this require retraining for everybody.

L. GIAMBARESSI responded that the training covers both and there is a lot information for pediatrics that can be easily accessed.

R. LOPEZ stated that in primary care practice, medical assistants can administer vaccines in Massachusetts, so it wouldn't be a big leap for Massachusetts to approve for certified techs.

J. LANZA stated that there are some states where technicians are immunizing currently.

L. GIAMBARESSI stated that it is allowed in Rhode Island and asked S. CORNACCHIO if she has seen anything with the techs immunizing and how is it going.

S. CORNACCHIO responded by stating that she hasn't heard anything negative, only positives in terms of expanding access.

J. LANZA stated that there are a handful of states that let technicians immunize and there is data out there that tells you how many they have immunized and if there is any adverse effect. Idaho is a big one, the Indian Reservations in New Mexico and Alaska are big ones. So, you can get all that data and really good training resources for training programs that have been set up.

L. GIAMBARESSI stated that she sees this as being huge because a lot of people are going to get flu shots that never have, and pharmacies are going to be overwhelmed, so it is something we should explore.

1 b. Pharmacy issues related to Covid-19 and the state of emergency

Presented by: Dave Sencabaugh

Recusal: none

Discussion: During the COVID-19 emergency, there is an order that allows pharmacists and technicians who have out of state licenses to work in Massachusetts using their current and in good standing out of state licenses. This order was never intended to put these pharmacists in a position of authority, and we did have a situation in which someone proposed a change of manager for a pharmacy with a pharmacist who is not licensed in Massachusetts.

It is completely up to the board to make that decision if they want to agree or approve someone to be in that position. This was caused by a sudden departure which has been fixed, but if someone suddenly leaves a pharmacy or leaves employment, the board needs to know as soon as possible the name, in at least an email, of the person who at that moment becomes responsible for the pharmacy, even if that person doesn't want or plan to be the MOR of the future. Somebody needs to oversee the pharmacy at all times. The draft 247 CMR 9 gives a 5-day period for the sudden departure of somebody.

As it stands now, if somebody was on a long term leave of absence, they have a hundred days before they must change the manager, but if you know in the thirty days that that person is not coming back

for a while, then you have to name an interim MOR who is still employed. That was the whole idea of the grace period. The two issues here are:

1. We need to know who is responsible for that pharmacy ASAP if somebody leaves suddenly.
2. In our opinion, it would not be somebody who does not hold a Massachusetts license, because that person has never taken the MPJE. That was never the intent of the order that allowed us, through the NABP Passport Program or Board Staff Approval for someone to work on their out of state license as a MOR.

2. Notice of Retirement of Carmen Catizone, NABP

Presented by: David Sencabaugh

Recusal: none

Discussion: President Carmen Catizone of NABP is retiring this year after over 30 years, and in recognition of all of the efforts that Carmen has given, David Sencabaugh took the liberty of writing a message from the Mass Board of Pharmacy, and is looking for board approval and authorization for him to deliver that message at the District I and II meeting on behalf of The Board which will be held virtually on September . The message is:

“The Massachusetts Board of Registration of Pharmacy wishes to express its thanks and congratulations to Carmen Catizone of the National Association of Boards of Pharmacy. Congratulations Carmen on your retirement after over 30 years as Executive Director of NABP and heartfelt thanks for the tireless support you have given our board of pharmacy as well as the many other members of NABP through both good and challenging times. To say that your efforts have been essential in guiding pharmacy into this century would simply be a huge understatement. In the most carefully thought out and well executed manner imaginable, you assembled an amazing team at NABP and connected them to the key pharmacy and legal players whose feet are on the ground in the states. You have always demonstrated an uncanny ability to use meetings, correspondence, and fantastic training opportunities to determine the best use of NABP resources available in the name of improved patient care and public safety. Considering the wholesale changes to the practice of pharmacy that have occurred during your tenure including once unimaginable advances in technology, as well as the many changes to the various players, both individuals and stakeholders, one cannot help but be both amazed and appreciative of your impressive book of work. All of this with a steady, calm, and professional demeanor second to none. The product you now turn over to Mr. Carter is in great shape and your legacy will be forever intact. Thank you from all us in Massachusetts, board members and staff alike. We will miss you.”

Action: Motion by L. GIAMBARESSI, seconded by S. HAMILTON, and voted unanimously by roll call by those present to authorize David Sencabaugh to deliver this message on behalf of The Board at the next NABP District 1 & 2 meeting.

Comments during roll call: A. STEIN- “Well written”, S. CORNACCHIO- “Great Letter”

3. Vote on resolutions, delegate, and alternate delegate for District I and II meetings NABP

Presented by: Dave Sencabaugh and William Frisch

Recusal: none

Discussion: NABP's District I and II meeting is being held virtually on September , 2020. This is the meeting where resolutions are asked for voting on to bring forward, which will then be voted by both District 1 and District 2 members. Ideas of resolutions to be brought forward include:

1. NABP undertaking a study to look at pharmacist to staff ratios and comparing them to quality related events that have occurred for a committee to look at.
2. Recommend NABP putting together a committee to put together a model and a plan to be prepared for the next pandemic or resurgence of this pandemic to be more proactive and wouldn't have to think everything through again.
3. Aside from COVID-19 testing, pharmacies have expressed interest in conducting testing such as rapid strep, hemoglobin A1c, lithium and many others. Recognizing that states are in different places on the spectrum of such pharmacy-based testing, could NABP take up the issue in order to develop some guidance and standardized language for the states possible through the NABP model act.

Questions/Discussion:

L. GIAMBARESSI – All testing is essentially monitored by CLIA, and CLIA has their own requirements depending on what type of test it is, so if they are meeting requirements, weather they have a CLIA waiver or CLIA certificate, shouldn't the pharmacy be able to do the testing as long as they meet those requirements.

Answer- W. FRISCH – It is more of a pharmacy or pharmacist scope of practice issue. Historically there are pharmacies that participate in the health promotion screening, which is a limited menu of tests, so there are considerations about scope of practice, and drawing blood, etc. All that stuff is controlled by the Clinical Laboratory Program. In as much as it occurs in a pharmacy, we don't know what the scope of practice issues are relative to some of the tests, so it would be good to look at.

C. FRANCOIS- Where are the tests reported to?

Answer- W. FRISCH – I think that part of the questions that we have. How are they getting reported, and where are they getting reported? For COVID testing, there is a pathway to the Department of Public Health, but as far as some of the other tests, we just don't know how that is going to work or what a pharmacist does with those results in relation to the patient and relaying that to the prescriber. From our standpoint there are a lot of unanswered questions.

C. FRANCOIS- So, as they increase the scope of practice, do they have to change staffing ratios or no?

Answer-W. FRISCH- That could be part of the discussion

K. TANZER- When pharmacist became immunizers, it didn't change the staffing, but that is one of the things we are concerned about. If we do expand the scope of practice that is going to be a company decision on how they are going to manage that staffing so that pharmacists have time to do that type of work.

D. SENCABAUGH- That's the whole idea behind the NABP, they have money and resources that they put towards these issues, and then the issues that resonate across

the country are the ones that get voted in. If approved at the annual meeting, then NABP assigns a task force or a committee to study these issues.

S. CORNACCHIO- I think a comprehensive review by a task force that has the time to take a deep dive into this would be helpful, rather than a bunch of ad hoc programs that are going to get sprinkled around because this is where the profession is going.

L. GIAMBARESSI- I don't want to handcuff pharmacists on these tasks. If they are approved by CLIA to be done by a minimally trained person, pharmacists would qualify based on the CLIA guidelines to administer a lot of these tests. Are we going to put more stringent requirements on pharmacist for giving these tests than what's currently being done for tests across the testing industry?

D. SENCABAUGH- I would suggest not. What this is for is for NABP to put out model language that we would have to use as we needed.

K. TANZER- The model language is a guideline or a template that you can adjust accordingly to what you are willing to support.

Action: Motion by P. GANNON, seconded by A. STEIN and voted unanimously by roll call by those present for the 3 draft resolutions to go forward for further development.

Action: Motion by K. TANZER, seconded by A. STEIN and voted unanimously by roll call by those present to name S. HAMILTON as the Delegate, and L. GIAMBARESSI as the alternate delegate for the District 1 and 2 NABP meeting held on September 8, 2020.

VI: File Review:

Case #1

PHA-2020-0021

Walgreens #6739, DS1896

Time: 08:59 AM

RECUSAL: NONE

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

- During February 2020, Walgreens 6739 reported an unknown loss of multiple controlled substances (alprazolam 0.5mg #22, amphetamine mixed salts 30mg #35, hydrocodone-apap 5-325mg #18, lorazepam 1mg #4, and oxycodone 5mg #9) discovered during a random audit by DEA. Walgreens #6739 conducted an internal investigation but was unable to determine the reason for the loss. DEA completed its audit without further action against the pharmacy.
- CA: MOR Winroth described that pharmacy staff was provided training and several measures were implemented as part of corrective action including "the proper filing of controlled substance invoices," a review of the location of all records required to manage Schedule II-V controlled substances to ensure proper documentation was readily retrievable, the reorganization and cleaning of the filing system, review of controlled substance loss reporting, and disposal procedures for controlled substances.

ACTION: Motion by S. HAMILTON, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2020-0021), 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 #2

PHA-2020-0047

Walgreens #3020, DS2492

Time: 09:02 AM

RECUSAL: NONE

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

- On 6/9/2020, the Pharmacy submitted an untimely, incomplete final report which included only the DEA 106 with the Appendix I information for an unknown loss of #91 hydrocodone/acetaminophen 10/325 mg tablets discovered on 02/22/2020 during the reconciliation of the perpetual inventory. No initial report was emailed to the BORP. Interim MOR Lartey indicated the loss may be due to an invoice not posted, an unconfirmed over-dispensing, or a theft but the investigation was inconclusive.
- The RLCS form which stated the investigation concluded 2/22/2020 was provided by MOR Flanagan (Martini) who was on a leave of absence at the time of the incident. MOR Flanagan (Martini) theorized that a bottle may have been inadvertently discarded causing the loss. MOR Flanagan (Martini) indicated only one prescription had been dispensed between 2/16/2020 and 2/23/2020 and the patient denied an over-dispensing.
- Copies were provided of the perpetual inventory and the CII sheets used to perform the perpetual inventory. A review of the documents determined there were two discrepancies of #42 tablets on 2/16/2020 and #49 tablets on 2/22/2020 that were carried over in the perpetual inventory until 02/26/20.
- CA: Certified pharmacy technicians are not allowed to count CII medications for the next 6 months while pharmacy staff are ensuring to follow the proper SOPs at all pharmacy stations. MOR Flanagan (Martini) reviewed the procedure for filling and receiving CIIs with all pharmacy team members. Interim MOR Lartke has made sure that only she handles CIIs when filling or receiving orders. Interim MOR Lartke stated, "Additionally, the pharmacy manager and health care supervisor reviewed controlled substance loss reporting requirements with me to ensure timely reporting in the future". Copies were provided of Walgreens SOP "WAG.SOP.RX-009 Traditional Filling – Tablets and Capsules" and Walgreens Policy "Controlled Substances – Inventory" that were signed and dated by all pharmacy staff confirming review.

ACTION: Motion by L. GIAMBARRESI, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2020-0047), 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 #3

PHA-2020-0046

CVS #1870, DS90040

Time: 09:06 AM

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

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

- Untimely RLCS received on 6/10/2020 for an unknown loss of #150 oxycodone 5mg tablets allegedly discovered on 4/27/2020 when a patient came in to pick up the prescription and it could not be found in the waiting bin. MOR Hemm stated that security footage was reviewed, and evidence of diversion was inconclusive.
- In a contradictory statement, Floater Pharmacist Frietas indicated the loss was discovered on 4/14/2020 while he was on duty. He stated he searched all areas of the pharmacy including the entire safe and the waiting bin. Pharmacist Frietas alerted the District Leader who engaged the drug loss and loss prevention teams. The investigation included a review of the perpetual inventory and the receipt and dispensing of CII. It was determined that the prescription had not been previously picked up, so a label was re-printed and the prescription was dispensed to the patient on 4/15/2020. The cause of the loss was unknown.
- CA: MOR Hemm indicated that filled CII prescriptions are kept at the pharmacist station until pick up. The pharmacist ensures all prescription bags are stapled and filed neatly to prevent the bags from getting stuck to each other. All CVS policies and procedures related to the handling of CII medications were reviewed with the pharmacy staff to minimize opportunities for potential diversion.

ACTION Motion by S. HAMILTON, seconded by L. GIAMBARRESI, and voted unanimously by those present, to refer the matter (PHA-2020-0046), 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.

Kim Tanzer announces at 9:09 AM the general session will be ending, and the Board will be going into Executive Session and reads the reason for entering Executive Session as required. The Board will not cover any other general session items today.

Topic VII: Executive Session Call to Order: Time: 9:10 AM
By: K. Tanzer

ACTION: Motion by S. Hamilton seconded by L. Giambarresi and voted unanimously by roll call to call the 8/21/20 meeting of the Executive Session to order.

Roll call attendance: K. TANZER: yes, J. LANZA: yes, L. GIAMBARRESI: yes, A. STEIN: yes, S. HAMILTON: yes, C. Jean-Francois: yes, S. CORNACCHIO: yes, R. LOPEZ: yes, K. THORNELL: yes, P. Gannon: yes

K. Thornell Leaves meeting at 10:00 AM
P Gannon leaves meeting at 10:00 AM
L. Giambarresi leaves meeting at 10:10 AM

Topic IX:

M.G.L. 65 C #1

Time: 10:07 AM

DISCUSSION: None

ACTION: President K. Tanzer request a motion to enter M.G.L 65 c Session.

At 10:07 AM L. Giambarresi, seconded by S. Hamilton and voted unanimously by all those present to enter M.G.L. chapter 65 c Session:

Topic XI:

ADJOURNMENT OF MEETING

TIME: 10:30 AM

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

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 8/21/20 General Session
2. Draft Minutes of the 8/14/20 Meeting
3. Applications: Shivani Patel PH234024 Reactivation application
4. PHA-2020-0021 Walgreens #6739 DS1896
5. PHA-2020-0047 Walgreens #3020 DS2492
6. PHA-2020-0046 CVS #1870 DS90040

Respectfully Submitted,
Leah Giambarresi, PharmD, RPh, Secretary