

COMMONWEALTH OF MASSACHUSETTS  
Board of Registration in Pharmacy

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

August 20, 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=](https://statema.webex.com/statema/onstage/g.php?MTID=)

**To access the meeting by phone:**

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

Access Code: 161 347 7053

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		
	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none"><li>Draft of August 6, 2021 Regular Session Minutes</li></ul>		

8:05	IV	<b>FLEX</b> <ul style="list-style-type: none"> <li>Pharmacy issues related to Covid-19 and the state of emergency</li> <li>NABP District 1 &amp; 2 Meeting, September 7-10, 2021, Annapolis, MD</li> <li>September Board Meeting</li> </ul>										
8:10	V	<b>APPLICATIONS</b> <ul style="list-style-type: none"> <li>Sebela Pharmacy RxDirect – New Community Pharmacy</li> <li>Fairhaven Pharmacy Inc - New Community Pharmacy</li> </ul>										
8:40	VI	<b>POLICIES</b> <ul style="list-style-type: none"> <li>Joint Policy 2020-12: Vaccine Administration by Qualified Pharmacy Technicians</li> <li>Policy 2020-15: Licensee Scope of Practice</li> </ul>										
8:50	VII	<b>FILE REVIEW</b> <table border="1"> <tr> <td>1</td> <td>CAS-2020-0777</td> <td>PHA-2020-0065</td> <td>CVS #619, DS89660</td> </tr> <tr> <td>2</td> <td></td> <td>PHA-2021-0028</td> <td>Todd Mathews, PH34657</td> </tr> </table>	1	CAS-2020-0777	PHA-2020-0065	CVS #619, DS89660	2		PHA-2021-0028	Todd Mathews, PH34657		
1	CAS-2020-0777	PHA-2020-0065	CVS #619, DS89660									
2		PHA-2021-0028	Todd Mathews, PH34657									
9:00	VIII	<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								
9:30	IX	<b>M.G.L. c. 112, § 65C SESSION</b>		CLOSED SESSION								
10:30	X	<b>ADJOURNMENT</b>										

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

**MINUTES OF THE GENERAL SESSION**

**Via Remote WebEx Meeting**

**August 20, 2021**

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**Board Members Present**

Sebastian Hamilton, Pharm D, MBA, RPh President-Elect  
Andrew Stein, Pharm D  
Caryn Belisle, RPh, MBA  
Leah Giambarresi, Pharm D, RPh  
Katie Thornell, RPh, MBA  
Jennifer Chin, RPh  
Dr. Richard Lopez, MD  
Dawn Perry, JD  
Timothy Fensky, RPh (leaves at 9:00 AM)

**Board Members Not Present**

Julie Lanza, CPhT, President  
Carly Jean-Francois, RN, NP Secretary  
Susan Cornacchio, JD, RN

**Board Staff Present**

David Sencabaugh, RPh, Executive Director  
Monica Botto, CPhT, Assistant 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  
Nancy Aleid, Compliance Officer  
Gregory Melton, PharmD, JD, Investigator  
Christina Mogni, RPh, Investigator  
Julienne Tran, PharmD, Investigator  
Paul Seed, RPh, Investigator

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

**CALL TO ORDER 8:03 AM**

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

Roll call attendance: S. Hamilton, yes; C. Belisle, yes; L. Giambarresi, yes; J. Chin, yes;  
T. Fensky, yes; D. Perry, yes. K. Thornell, yes. A. Stein and R. Lopez arrive at meeting at 8:05 AM.

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**Topic II.**

**Approval of Agenda**

**TIME 8:04 AM**

**Agenda 8/20/21**

**DISCUSSION:**

**ACTION:**

Motion by C. Belisle, seconded by L. Giambarresi and voted unanimously by those present to approve the agenda with no noted change by roll call vote.

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**Topic III**

**Approval of Board Minutes**

**TIME: 8:05 AM**

Minutes

1. Draft 8/6/21

Change: no noted changes

Action:

Motion by L. Giambarresi seconded C. Belisle and voted unanimously to approve the regular session minutes of 8/6/21 with no noted change by roll call vote. D. Perry abstains.

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**TOPIC IV**

**Flex**

**1. September Board Meeting**

**Time: 8:06 AM**

**Presented by** D. SENCABAUGH

No meeting will be held on September . The next Board meeting will be September .

**So noted.**

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

**Time: 8:06 AM**

**Presented by** D. SENCABAUGH

There has been recent news about COVID-19 “booster” shots. Please stay apprised of the CDC recommendations. The Board will send out information as it becomes available.

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Draft Minutes General Session: 8/20/21

BOP Approved: 9/17/21

So noted.

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**3. NABP District 1 & 2 Meeting, September 7-10, 2021, Annapolis, MD**

**Time: 8:08 AM**

**Presented by** D. SENCABAUGH; W. FRISCH; M. CHAN

S. HAMILTON will be attending the meeting and was nominated to be the Board's delegate.

**Action:** Motion by L. GIAMBARRESI, seconded by C. BELISLE, and voted unanimously by roll call by all those present to have S. HAMILTON represent the Board and present resolutions at the NABP meeting.

A resolution was proposed by W. FRISCH to explore what the scope of being recognized as Health Care Provider means.

**Action:** Motion by C. BELISLE, seconded by J. CHIN, and voted unanimously by roll call by all those present to forward the resolution.

A resolution was proposed by M. CHAN to explore e-prescribing and deprescribing issues.

**Action:** Motion by L. GIAMBARRESI, seconded by K. THORNELL, and voted unanimously by roll call by all those present to forward the resolution.

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**TOPIC V**

**Applications**

**1. Sebela Pharmacy RxDirect**

**New Community Pharmacy**

**TIME: 8:25 AM**

REPRESENTED BY: Lisa Harpel – MOR; Rob Raleigh - Board Manager; Dean Bartello - Consultant Pharmacist

RECUSAL:

DISCUSSION: Sebela's business model is limited to providing specialized service in the area of colonoscopy/bowel prep. The applicant has included several waivers to reflect the specific scope of practice. Their primary focus is to provide continuity of care at the pharmacy level. The medication dispensed will be a fixed price, FDA approved product. It is a tablet formulation that is more tolerable to consume and efficacious. They will not be billing insurance. The responsibility is on the provider with the patient to discuss the price and insurance coverage of alternative medications. The Physician office will have Sebela Pharmacy's information to inform patients of their choices. Sebela can transfer the prescription to other pharmacies if requested by patient.

The location of the business is in its own enclosed space. Part of the facility is shared with Braintree Laboratories. Braintree Laboratories is also the manufacturer they will be working with. Sebela is a parent company. Sebela has a Pilot program with a specific manufacturer but will not be limited to any

particular type of product. They are open to other companies who would like to contract with them and provide a cost-effective price.

The Board brought up DUR concerns. Sebela's solution is patients will sign up through a Web portal link where they will register and enter current medications and disease states. The patient's profile will upload to their pharmacy software system. It will be up to the patient to disclose all information. The pharmacy will bring attention to specific medication known to have drug interactions with colonoscopy medication.

ACTION: Motion by L. GIAMBARRESI, seconded by A. STEIN, voted unanimously by those present to defer the application for a New Community Pharmacy until the next Board meeting.

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**T. Fensky leaves meeting at 9:00 AM**

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**TOPIC VI**

**Policies**

**1. Joint Policy 2020-12: Vaccine Administration by Qualified Pharmacy Technicians**

**Time: 9:00 AM**

**Presented by** M. CHAN

**Discussion:** As mentioned at the August Board meeting, the PREP Act was amended to allow qualified technicians to administer flu shots to adults. Edits were made to the Board's policy to make it clear that these technicians can now administer flu shots to all individuals aged 3 years and older.

There were no changes or allowances for other ACIP vaccines.

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

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**2. Policy 2020-15: Licensee Scope of Practice**

**Time: 9:01 AM**

**Presented by** M. CHAN

**Discussion:** After receiving stakeholder feedback, some edits have been made for clarity.

The statement regarding diagnosing conditions was removed. Even though pharmacists and interns may not diagnose, there may be some confusion with this terminology. For instance, it could be inferred that counseling patients to manage minor conditions with OTC preparations may be considered diagnosing.

Similarly, the word "interpret" was removed from Health Promotion Screening since this term is also not very precise and could be construed to mean that a pharmacist could not counsel based on the results of these tests.

Additionally, it has been confirmed that orders are not necessary for Health Promotion Screening tests, so that was also removed.

In the immunization section, language was clarified to note that pharmacists and interns may administer medications to manage adverse reactions to vaccines.

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

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**TOPIC VII**

**File Review**

Case #1 CAS-2020-0777/PHA-2020-0065

CVS #619, DS89660

Time: 9:10 AM

RECUSAL: none

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 09/16/2020 and 04/14/2021. The violations observed on 09/16/2020 included failures to submit a timely change in MOR application, maintain copies of DEA Form 222 and return records for CII, and return records for CIII-V, and failure to maintain copies of CPR and immunization certification.
- The violations observed on 04/14/2021 included failure to reconcile CII perpetual inventory for over 60 days for amphetamine and oxycodone (Note – reconciliation required every 30 days per COVID emergency regs), failure to maintain accurate CII perpetual inventory including variances of +5, +15, and -69 on amphetamines and oxycodone and continued to reconcile CII drugs which were reverse distributed two weeks prior to the inspection, and failed to enter CII shipment until next business day. In addition, compounding logs were not completed including 9 prescriptions dispensed in the previous three months before the inspection.
- MOR explained that COVID was the root cause of the deficiencies at his pharmacy. MOR indicated that he was unaware that the change of MOR application was not submitted. The application was submitted after the MOR became aware during the inspection. MOR also 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. He indicated that going forward he would make copies of the new DEA 222 forms for the pharmacy's records.
- In addition, MOR provided a copy of his immunization and CPR certification, and he indicated that he retrained staff that proper immunization documentation must be kept on record at the pharmacy. MOR further described that he reviewed P&Ps with all staff. pharmacists after the inspection on 09/16/2020 regarding requirements for CII reconciliation and he would monitor compliance.
- On 8/2/2021, CVS 3619 was inspected again. Controlled substance recordkeeping was compliant. However, a POC was issued for issues with ratios and compounding records (repeat). In addition, CVS #619 had a new MOR.

ACTION: Motion by A. STEIN, seconded by C. Belisle, and voted unanimously by those present, to refer the matter (PHA-2020-0065), 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 probation for 1-year terms to include MOR self-inspection monthly, reconciliation of CSII perpetual inventory 1x/month with district leader.

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Case #2/CAS-2020-0489

PHA-2021-0028

Todd Matthews, PH34657

Time: 9:19 AM

RECUSAL: none

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 09/16/2020 and 04/14/2021. The violations observed on 09/16/2020 included failures to submit a timely change in MOR application, maintain copies of DEA Form 222 and return records for CII, and return records for CIII-V, and failure to maintain copies of CPR and immunization certification.
- The violations observed on 04/14/2021 included failure to reconcile CII perpetual inventory for over 60 days for amphetamine and oxycodone (Note – reconciliation required every 30 days per COVID emergency regs), failure to maintain accurate CII perpetual inventory including variances of +5, +15, and -69 on amphetamines and oxycodone and continued to reconcile CII drugs which were reverse distributed two weeks prior to the inspection, and failed to enter CII shipment until next business day. In addition, compounding logs were not completed including 9 prescriptions dispensed in the previous three months before the inspection.
- MOR explained that COVID was the root cause of the deficiencies at his pharmacy. MOR indicated that he was unaware that the change of MOR application was not submitted. The application was submitted after the MOR became aware during the inspection. MOR also 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. He indicated that going forward he would make copies of the new DEA 222 forms for the pharmacy's records.
- In addition, MOR provided a copy of his immunization and CPR certification, and he indicated that he retrained staff that proper immunization documentation must be kept on record at the pharmacy. MOR further described that he reviewed P&Ps with all staff pharmacists after the inspection on 09/16/2020 regarding requirements for CII reconciliation and he would monitor compliance.
- On 8/2/2021, CVS 3619 was inspected again. Controlled substance recordkeeping was compliant. However, a POC was issued for issues with ratios and compounding records (repeat). In addition, CVS #619 had a new MOR.

ACTION: Motion by A. STEIN, seconded by D. Perry, and voted unanimously by those present, to refer the matter (PHA-2021-0028), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for probation for 1 year and cannot act as a MOR for 1 year.

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**Topic VII:** **Executive Session Call to Order:** **Time: 9:26 AM**  
By: S. Hamilton

ACTION: Motion by, L. Giambarresi, seconded by A. Stein, all voted affirmatively by those present to enter executive session.

Roll call attendance: S. Hamilton, yes; C. Belisle, yes; L. Giambarresi, yes; J. Chin, yes; D. Perry, yes. K. Thornell, yes; A. Stein; R. Lopez yes.

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**Topic VIII:** **65C Sessions MGL c. 112 section 65C** **Time: 9:50 AM**

DISCUSSION: None

ACTION: President-Elect S. Hamilton request a motion to enter 65C.

At 9:50 AM L. Giambarresi, seconded by D. Perry and voted unanimously by all those present to enter 65C by roll call vote.

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**Topic IX** **ADJOURNMENT OF MEETING** **TIME: 10:35 AM**

ACTION: Motion by A. Stein seconded by C. Belisle and voted unanimously by those present, to adjourn from General Session by roll call vote.

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EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 8/20/21 General Session
2. Draft Minutes of the 8/6/21 Meeting
3. Application: Sebela Pharmacy RXDirect-New Community Pharmacy
4. Joint Policy 2020-12: Vaccine Administration by Qualified Pharmacy Technicians
5. Policy 2020-15: Licensee Scope of Practice
6. CAS-2020-0777 PHA-2020-0065 CVS #619, DS89660
7. CAS-2020-0777 PHA-2021-0028 Todd Mathews, PH34657

Respectfully Submitted,  
Carly Jean-Francois, NP, Secretary