

# COMMONWEALTH OF MASSACHUSETTS

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

December 15, 2014  
239 Causeway Street ~ Room 417 A&B  
Boston, Massachusetts 02114

### Agenda

Time	#	Item	Exhibits	Contact
8:30	I	<b>CALL TO ORDER</b>		
8:35	II	<b>APPROVAL OF AGENDA</b>		
8:40	VI	<b>FLEX SESSION</b> 1.Introduction of New Board Members 2.Introduction of Pharmacy Interns 3.Introduction of the New Acting Dean of Northeastern School of Pharmacy: David P Zgarrick, PhD, FAPhA 4.Nominations of Board Officers 5.Announcement of Board Officers election at next meeting 6.Board Meeting dates for 2015 7.Scheduling of future Board meetings		D. Sencabaugh
9:00	III	<b>APPLICATIONS</b> 1. Johnson and Johnson Health Care Systems – Wholesale Distributor 2. Partners Pharmacy of MA, LLC – Renovation/Expansion 3. Central Street Pharmacy – New Community Pharmacy 4. Cure-Aid Pharmacy, Inc. – New Community Pharmacy		
10:00	IV	<b>APPROVAL OF BOARD MINUTES</b>  Draft October 9, 2104 Regular Session Minutes		
10:05	V	<b>REPORTS</b> Applications approved pursuant to Licensure Policy 13-01	Reports	R. Harris
10:10	VII	<b>REGULATIONS:</b> 1. Proposed amendments to 247 CMR 6.00: Licensure of Pharmacies. Proposed amendments pertain to licensure of Massachusetts and non-resident pharmacies, sterile compounding pharmacies, and complex non-sterile compounding pharmacies.		H. Engman D. Sencabaugh D. Dunn

12:00		<b>LUNCH BREAK</b>	
1:00	<b>VIII.</b>	<b>REGULATIONS:</b> 1. Proposed amendments to 247 CMR 6.00 pursuant to Chapter 159 of the Acts of 2014. Continued	
2:00	<b>IX.</b>	<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.  1. Specifically, the Board will discuss and evaluate the <u>Good Moral Character</u> as required for registration for pending applicants, petitions for termination of probation, and petitions reinstatement.	CLOSED SESSION
3:15	<b>X</b>	<b>ADJUDICATORY SESSION</b>	CLOSED SESSION
3:45	<b>XI</b>	<b>M.G.L. c. 112, 65C SESSION</b>	CLOSED SESSION
5:00	<b>XII.</b>	<b>ADJOURNMENT</b>	

COMMONWEALTH OF MASSACHUSETTS  
BOARD OF REGISTRATION IN PHARMACY

**MINUTES OF THE MONTHLY MEETING**  
239 Causeway Street, Fourth Floor ~ Room 417A  
Boston, Massachusetts 02114

Monday, December 15, 2014

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**Board Members Present**

Patrick Gannon, RPh, MS, Acting -  
Chairperson  
Edmund Taglieri, RPh, MSM, NHA,  
Acting-Secretary  
Richard Tinsley, MBA, MEd  
Garrett Cavanaugh, R.Ph. (arrived at 9:12 am)  
Michael Godek, R.Ph.  
Catherine Basile, PharmD, R.Ph  
Karen Conley, RN  
William Cox, CPhT.

**Board Members Not Present**

**Board Staff Present**

David Sencabaugh, RPh, Executive Director  
James Lavery, JD, Division Director, DHPL  
Heather Engman JD, MPH, Board Counsel  
David M. Dunn Jr. RPh. Associate Executive Director  
Kelly Ann Barnes, JD, RPh, Dir. Quality Assurance  
Richard Harris, Program Analyst  
William Frisch, Jr., RPh, Director of Compliance  
Christina Mogni, RPh, Investigative Consultant  
Monica Vasquez, Compliance Officer  
Colleen Collins, R.Ph. Contract Investigator

**Board Staff Not Present**

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**TOPIC:**

**I. CALL TO ORDER**

**DISCUSSION:** A quorum of the Board was present. Acting-Chair, P. GANNON opened the meeting and asked if anyone in the audience was recording the meeting; no one indicated that they were recording the meeting. He indicated that the Board was recording the meeting.

**ACTION:** At 8:31 a.m. P. GANNON, called the December 15, 2014, meeting of the Board of Registration in Pharmacy to order. Quorum was established by a Roll Call vote: GANNON; yes, TAGLIERI; yes, TINSLEY; yes, CONLEY; yes, COX; yes, BASILE; yes, GODEK; yes. G. CAVANAUGH was not present for the roll call vote to begin the meeting.

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**TOPIC:**

**II. APPROVAL OF AGENDA**

**DISCUSSION:** Associate Executive Director D.DUNN, asked that the October 9, 2015, Regular Session Minutes be deferred to a future meeting.

ACTION: Motion by E. TAGLIERI, seconded by C.BASILE, and voted unanimously to approve the agenda with the noted changes. G. CAVANUAGH was not present for the discussion of this matter and did not participate in the vote.

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TOPIC:

**III. FLEX SESSION**

**8:33AM-8:50AM**

G. CAVANAUGH was not present at the start of the discussion.

J.LAVERY, Director of Health Professions Licensure, acknowledged and thanked the new Board of Registration in Pharmacy members.

1. Introduction of New Board Members:

Executive Director, D. SENCABAUGH, welcomed the new Board members and thanked them for their flexibility and ability to have the December 15, 2015 meeting. Executive Director D. SENCABAUGH, noted the changes in the Board of Pharmacy composition due c.159 of the Acts of 2014. Executive Director SENCABAUGH noted that Board member W.COX, is the first pharmacy technician ever to serve on the Board of Registration in Pharmacy.

2. Introduction of Legal Intern:

Board Counsel, H. ENGMAN, introduced Legal Intern Ms. Thejasree Kayem from Northeastern University.

3. Introduction of the Acting Dean of Northeastern University School of Pharmacy:

Executive Director, D. SENCABAUGH, introduced David P. Zgarrick PhD. FAPhA., the new Acting Dean of the Northeastern University School of Pharmacy. Acting Dean Zgarrick thanked the Board for the opportunity to attend the meeting. Acting-Dean Zgarrick provided a brief resume of his experience.

4. Nomination of Board Officers:

Executive Director D. SENCABAUGH, informed the new members, that the new Board members would need to nominate new officers to preside over Board meeting for 2015. Executive Director D. SENCABAUGH informed Board members that they would need to nominate the following officers:

- a. President
- b. President-Elect
- c. Secretary

Executive Director D. Sencabaugh, informed the Board of the previous Board of Pharmacy's vote of P. GANNON as President –elect for 2014, and it has been past practice that the President –elect serve as Board President in the year following year.

ACTIONS:

**ACTION 1:** Nomination for President to the Board of Registration in Pharmacy: Motion by E.TAGLIERI, seconded by R.TINSLEY to nominate P.GANNON to serve as President of the Board of Registration in Pharmacy for 2015. G. CAVANAUGH was not present for this matter.

**ACTION 2:** Nomination for President-elect to the Board of Registration in Pharmacy: Motion by P.GANNON seconded by M.GODEK to nominate E.TAGLIERI to serve as President-elect of the Board of Registration in for Pharmacy for 2015. G. CAVANAUGH

was not present for this matter.

**ACTION 3:** Nomination for Secretary to the Board of Registration in Pharmacy: **MOTION** by E.TAGLIERI and seconded by P.GANNON to nominate R.TINSLEY to serve as Secretary of the Board of Registration in Pharmacy. G. CAVANAUGH was not present for this matter.

5. Announcement of Board of Registration in Pharmacy election of Officers  
Executive Director D. SENCABAUGH, announced that the election of Board Officers by Roll Call vote will take place at the next schedule meeting on January 6, 2015.
6. Board Meeting Dates for 2015:  
Executive Director D. SENCABAUGH informed members of the meeting schedule. Board members were made aware that regularly scheduled meeting take place on the first Tuesday of each month. Board members were provided with a list of the meeting dates for 2015 which will be posted on the Board's website.
7. Scheduling of Future Meetings:  
Executive Director D. SENCABAUGH, reviewed with Board members the need for additional meeting in addition to the regularly scheduled monthly meeting. Executive Director D. SENCABAUGH asked the members if they wanted to change the scheduled January 6, 2015, to an evening meeting from 5:30PM to 9:00PM to consider changes to 247 CMR Section 6. Executive Director D. SENCABAUGH proposed alternate dates in January for a full day Board meeting later in January due to the short time frame between the December 15<sup>th</sup> and January 6<sup>th</sup> meeting dates. Board members agreed to hold a full day meeting as planned on January 6, 2015. Executive Director D. SENCABAUGH informed Board members that Board Staff would send out a survey for additional meeting dates for members to consider.

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**TOPIC:**

**III. APPLICATIONS**

**Application for a New Wholesale Distributor**

**8:50 AM**

1. **Johnson & Johnson Health Care System**, 50 Scotland Blvd., Bridgewater, MA  
G. CAVANAUGH, arrived at 9:13AM and was not present at the beginning of the discussion.

**DISCUSSION:** Arthur Raymond, Distribution Manager and Kenshaw, Director of Distribution Services for Johnson & Johnson Health Care Services presented the Application for Licensure as a Wholesale Distributor. Johnson & Johnson Health Care Systems is a third party logistics, share services provider for multiple Johnson & Johnson umbrella companies. Johnson & Johnson assembles medical device kits( approximately 1,500 kits / month) for delivery to end users (hospitals and surgery centers). Johnson & Johnson s based in Bridgewater, MA, and is seeking licensure as a wholesaler in Massachusetts so it can apply for licensure in other jurisdictions in order to achieve additional licensure Johnson and Johnson is seeking licensure in its' home state. The kits contain a vial of xylocaine, which is a federal legend drug product. It was noted by Director of Pharmacy Quality Assurance K. BARNES that the photo provided by Johnson & Johnson with their application depicted the xylocaine "Rx only", and the act of repacking into the kits required a pharmacist and would be a violation of 247 CMR.

ACTION: It was recommended that the best course of action is to defer the matter. Board staff to work with the Drug Control Program for their inspection of the Johnson & Johnson facility. Board staff to notify Johnson and Johnson on next steps. G. CAVANAUGH was not present for the discussion of this matter

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TOPIC:

### III APPLICATIONS

#### Application for a Renovation / Expansion

9:33 AM

#### 2. Partners Pharmacy of MA, LLC, 181 Cedar Hill St., Marlborough, MA DS3419

RECUSAL: E. TAGLIERI recused himself and was not present during the discussion or vote for this matter.

DISCUSSION: E. Johnson, Manager of Record, and P Downey President and Chief of Operations for Partners Pharmacy presented this application for renovation of the pharmacy clean room. Currently Partners Pharmacy had temporarily suspended all sterile compounding activity. Partners Pharmacy contracted with Travis Clear Air to construct a new clean room. Partners Pharmacy desired to add sterile compounding to the services they provide to their long-term care patients.

ACTION: Motion by R. Tinsley, seconded by, C BASILE, and voted unanimously to approve the Partners Pharmacy of MA LLC., Application for the Renovation / Expansion of a Community Pharmacy, pending a successful inspection. (NOTE: G. Cavanaugh arrived at 9:12 and was present for this discussion and vote.)

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TOPIC:

### III. APPLICATIONS

#### Application for a New Community Pharmacy:

#### 3. Central Street Pharmacy, Inc., 50 Central Street, Georgetown, MA. 9:39AM

RECUSAL: M. GODEK recused himself and was not present during the discussion or vote for this matter.

DISCUSSION: Kristen Frias, Manager of Record, and Steven MacNeill President and Owner presented this Application for a New Community Pharmacy. Central Street Pharmacy would be the second location for President / Owner MacNeill, owner and MOR of Winchester Drug. MOR Frias indicated she had previous experience as an MOR. MOR Frias indicated that Central Street Pharmacy would be a traditional community pharmacy service oriented offering immunization and utilizing the prescription monitoring program (PMP). Board members had questions regarding the application.

1. Lack of certified blue prints. Owner MacNeill indicated that he would obtain and provide.
2. Application indicated YES on question 12.  
“(a) Have any of the applicant(s) and / or manager in charge had: 1) any convictions related to the distribution of drugs (including samples); 2) any felony convictions; 3) any suspension(s) or revocation(s) or revocation(s) or other sanction(s) by federal, state, or local governmental agency of any license or registration currently or previously held by the applicant or license for the manufacture, distribution or dispensing of any drugs, including controlled substances? Owner MacNeill indicated that this was an error. Owner MacNeill indicated would submit a new application.

3. Application for MA Controlled Substance Registration did not indicate that Central Street would carry Schedule II and Schedule III controlled substances. Owner MacNeill indicated that this was an oversight and would amend the application.

The Board was concerned with the limited weekend hours and the security of controlled substances. These concerns were satisfactorily addressed by the Central Street Pharmacy representatives.

ACTION:

Motion by E.TAGLIERI seconded by R.TINSLEY and voted unanimously to approve Central Street Pharmacy's Application for a New Community Pharmacy pending receipt of one (1) set of certified blue prints for the new community pharmacy, one (1) amended Application to Manage and Operate a New Community Pharmacy addressing question twelve (12), one (1) amended Controlled Substance Application indicating Schedule II and Schedule III, and a successful inspection.

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TOPIC:

**III. APPLICATIONS**

**Application to Manage and Operate a New Community Pharmacy 9:14AM**

**G. CAVANAUGH arrives at 9:13AM**

4. **Cure-Aid Pharmacy, Inc.**, 203 Essex Street, Lawrence MA,  
DISCUSSION: Proposed MOR Aleksey Grolchotou and Attorney Paul Garbarini present the Application to Manage and Operate a New Community Pharmacy. Attorney Garbarini indicated that Cure-Aid Pharmacy would be servicing and underserved community of Lawrence. The Application contained a waiver of compounding 247 CMR. 9.01 (16): "A pharmacist shall not refuse to compound customary pharmaceutical preparations except upon extenuating circumstances." Attorney Garbarini indicated that waiver was being requested due to size limitation and the cost of compliance with USP standards. Board members questions Cure-Aid Pharmacy representatives that the waiver request meant that all compound prescription requests would need to be refused. Board members wanted to be clear that the Application to Manage and Operate a New Community Pharmacy only assumed simple and moderate compounding activities. Cure-Aid Pharmacy Representatives indicate that there was confusion regarding the requirement and that Attorney Garbarini would file an amended application withdrawing the waiver request.

Board members were concerned that the clientele of the proposed pharmacy would be Spanish speaking. Proposed MOR Grolchotou indicated that he was learning Spanish and that the technician hired would be Spanish speaking. The Board concern was that patient counseling take place correctly. Proposed MOR Grolchotou indicated that he would be providing the after hours services along with immunization. Proposed MOR Grolchotou indicated that he is an active user of the prescription monitoring program (PMP).

ACTION:

Motion by E.TAGLIERI, and seconded by K.CONLEY and voted unanimously to approve the Cure-Aid Pharmacy, Inc., Application to Manage and Operate a New Community Pharmacy pending an amended application withdrawing the waiver to compound and successful inspection

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TOPIC:

**IV. REPORTS**

**10:52 AM**

**1. Applications Approved Pursuant to Licensure Policy 13-01**

DISCUSSION: R. HARRIS distributed a December 15, 2014 report which noted the five (5) new community pharmacies, one hundred and six (106) change of managers, five (5) Renovation / Expansion Requests, five (5) pharmacy closures and three (3) pharmacy relocations that had been approved pursuant to Licensure Policy 13-01.

ACTION: So noted.

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BREAK 9:54 – 10:03 AM

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TOPIC:

**V. Regulations**

**10:25AM-12:00 PM**

**1. Proposed amendments to 247 CMR 6.00 Licensure of Pharmacies**

DISCUSSION: Executive Director D.SENCABAUGH advised new Board members on the review for the proposed amendments to 247 CMR and the line by line review process with on screen edits that has been utilized to date. Board Counsel H.ENGMAN, educated the Board on the regulation approval process. The Board learned about the EO485 Small Business impact process, Public Comment period and review, Revised regulation, Board vote, and Secretary of State for registering. The Board recommended the addition of Nuclear Pharmacy to the licensing section. The replacing of the term “medication” with controlled substance “ to be consistent with statute. Section 6 now included Suitability language as standard for licensure and continued licensure of pharmacy. The proposed amendments also streamlined the section focusing on the licensure of facilities. Professional Practice standards and reporting requirements will be relocated to other sections of 247 CMR. Edits recommend by Board members and Board members comments captured with track changes during the meeting.

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LUNCH 12:00 – 1:17 PM

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TOPIC:

**V. Regulations**

**Reconvene**

**1:17PM**

Proposed amendments to 247 CMR 6.00 Licensure of Pharmacies

K. BASILE rejoins at 1:18PM

A line by line review continues until completion of 247 CMR 6.00. Executive Director informs the Board that the changes made at the December 15, 2014, meeting will be incorporated along with the additions indicated by the Board will be made and will be brought back for a vote at the January 6, 2015 meeting.

TOPIC:

**VI. EXECUTIVE SESSION**

**2:04 PM to 3:43 PM**

DISCUSSION: P.GANNON noted that the Board would not return to open session following closed 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 the 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.



1. Specifically, the Board will discuss and evaluate the Good Moral Character as required or
- ~~1.2.~~ registration or pending applicants.
- ~~2.3.~~ Specifically, the Board will discuss and evaluate petitions for the Termination of Probation.

ACTION: At 2:08 PM., motion by E.TAGLIERI, seconded by W.COX, and voted unanimously by roll call to enter Executive Session.

P. GANNON: yes; E. TAGLIERI: yes; R. TINSLEY: yes; W. COX: yes; K.CONLEY: yes; K. BASILE: yes; G.CAVANUAGH: yes; M.GODEK: yes;

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TOPIC:

**VII. ADJUDICATORY SESSION (M.G.L. c. 30A, §18)**

**3:44PM**

DISCUSSION: None.

ACTION: At 3:44 PM., motion by E.TAGLIERI, seconded by R.TINSLEY, and voted unanimously to enter into Adjudicatory Session.

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TOPIC:

**VIII. M.G.L. c. 112 §65C SESSION**

**4:07 PM**

DISCUSSION: None

ACTION: At 4:07 PM., motion by E.TAGLIERI, seconded by C.BASILE, and voted unanimously to enter into M.G.L. c. 112 65C Session.

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TOPIC:

**IX. ADJOURNMENT**

**5:18 PM**

DISCUSSION: None.

ACTION: At 5:18 PM., motion by P.GANNON, seconded by E.TAGLIERI, and voted unanimously to adjourn.

LIST OF EXHIBITS USED DURING THE MEETING

1. Preliminary Agenda for the December 15, 2014 Scheduled Meeting
2. Applications approved pursuant to Licensure Policy 13-01, December 15, 2014
3. Application to Manage and Operate a New Community Pharmacy, Central Street Pharmacy
4. Application to Manage and Operate a New Community Pharmacy, Cure-Aid Pharmacy, Inc.
5. Application for the Operation of a Wholesale Distributor, Johnson & Johnson Health Care Systems
6. Application for a Renovation / Expansion of a Community Pharmacy, Partners Pharmacy of MA, LLC
7. Draft proposed amendments to 247 CMR 6.00: Licensure of Pharmacies
8. Draft proposed amendments to 247 CMR 6.00: Licensure of Pharmacies with track changes from Board meeting discussion
9. Board meeting dates for 2015

Respectfully submitted,

Richard Tinsley MBA, MEd, Secretary