

COMMONWEALTH OF MASSACHUSETTS

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

May 6, 2014
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

Agenda

Time	#	Item	Exhibits	Staff Contact
8:30	I.	CALL TO ORDER		
8:35	II.	APPROVAL OF AGENDA		
8:40	III.	APPLICATIONS 1. Caring Health Center Pharmacy, Inc. , 1145 Main Street, Springfield New Community Pharmacy, MOR Victor Fournier 2. OncoMed , 150 Bear Hill Road, Waltham (DS89702) Application for Transfer of Ownership	Applications and supporting documentation	R. Harris
9:20	IV.	APPROVAL OF BOARD MINUTES Draft April 1, 2014 Regular Session Minutes		
9:25	V.	REPORTS Applications approved pursuant to Licensure Policy 13-01 Plans of correction approved pursuant to Policy 13-02	Reports	R. Harris K. Barnes
9:30	VI.	EMERGENCY REGULATIONS 1. Proposed amendments to 247 CMR 8.00 and 247 CMR 9.00 pertaining to the handling and dispensing of hydrocodone-only extended release medications that are not in an abuse deterrent form 2. Proposed amendments to 244 CMR 4.00 (Board of Registration in Nursing) – consultation per M.G.L. c. 112, § 80E		H. Engman
10:00	VII.	POLICIES Board Delegated Complaint Review		D. Sencabaugh
10:15	VIII.	FLEX SESSION 1. Recent stakeholder meeting to discuss USP 797 Sterile Compounding inspection tool. 2. Revisions to routine pharmacy inspection tool. 3. Dispensing of Naloxone Rescue Kits by standing order		D. Sencabaugh
10:30		BREAK		

10:45	IX.	M.G.L. c. 112, 65C SESSION	CLOSED SESSION	
12:00		LUNCH BREAK		
1:00	X	M.G.L. c. 112, 65C SESSION	CLOSED SESSION	
2:00	XI.	<p>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.</p> <ol style="list-style-type: none"> Specifically, the Board will discuss and evaluate the <u>Good Moral Character</u> as required for registration for pending applicants. Approval of prior executive session minutes in accordance with M.G.L. ch.30A, § 22(f) for sessions held during the December 3, 2013 meetings. 	CLOSED SESSION	
3:00	XII.	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)		H. ENGMAN
	XIII.	ADJOURNMENT		

COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE REGULARLY SCHEDULED MEETING

239 Causeway Street, Fourth Floor ~ Room 417A
Boston, Massachusetts 02114

Tuesday, May 6, 2014

Board Members Present

Karen Ryle, RPh, President
Patrick Gannon, RPh, MS, President-elect
(arrived @ 8:55)
Edmund Taglieri, RPh, MSM, NHA,
Secretary
James DeVita, RPh (left @ 4:40)
Jane F. Franke, RN, MHA
Richard Tinsley, MBA, MEd
Joanne Trifone, RPh
Anita Young, RPh, EdD

Board Members Not Present

Anthony Perrone, MD

Board Staff Present

David Sencabaugh, RPh, Executive Director
James Lavery, Division Director, DHPL
Heather Engman JD, MPH, Board Counsel
Vita Berg, DHPL Legal Counsel
Kelly Barnes, JD, RPh, Quality Assurance
Richard Harris, Administrative Assistant
Samuel Penta, RPh, Investigator
Leo McKenna, RPh, PharmD, Investigator
Anthony Bartucca, RPh, Investigative Consultant
David Dunn, RPh, Investigative Consultant
Christina Mogni, RPh, Investigative Consultant
Paul Seed, Investigator
Joseph Sceppa, Consultant

Board Staff Not Present

Cheryl Lathum, RPh, PharmD, Investigator
William Frisch, Jr., RPh, Director of
Compliance

TOPIC:

I. CALL TO ORDER

DISCUSSION: A quorum of the Board was present. President, K. RYLE chaired the meeting and asked if anyone in the audience was recording the meeting; no one indicated that they were recording the meeting. K. RYLE also announced that the Board was recording the meeting.

ACTION: At 8:36 a.m. K. RYLE, called the May 6, 2014, meeting of the Board of Registration in Pharmacy to order.

TOPIC:

II. APPROVAL OF AGENDA

DISCUSSION: Approval of the minutes will be deferred to a future meeting.

ACTION: Motion by, J. DEVITA, seconded by R. TINSLEY, and voted unanimously to approve the agenda with the noted change. P. GANNON was not present for the vote.

TOPIC:

III. APPLICATIONS

A. Application for New Community Pharmacy

1. Caring Center Pharmacy, 1049 Main Street, Springfield

RECUSAL: J. TRIFONE recused herself and was not present during the discussion or votes for this matter.

DISCUSSION: Victor Fournier, MOR and Frank Kostek (CEO/owner) indicated that Caring Center Pharmacy would be a non-profit corporation, open weekdays from 8:30 a.m. to 6:00 p.m. This would be the first retail pharmacy of Caring Health Center. They are currently looking for a new MOR and plan to open in July or August. They will have access to 340B pricing and plan to actively use the Prescription Monitoring Program. As business increases, the pharmacy will expand hours of operation toward those of the Health Center.

Mr. Fournier indicated that the Pharmacy will not engage in compounding sterile or non-sterile pharmaceuticals, and requests a waiver from the following requirements:

1. 247 CMR 6.01:(5)(a)4 : A balance capable of accurately weighing quantities as small as 13 milligrams, which balance shall be tested and sealed by the state or local sealer of weights and measures annually.
2. 247 CMR 6.02:(4): The pharmacy or pharmacy department shall maintain on the premises at all times a sufficient variety and supply of medicinal chemicals and preparations which are necessary to compound and dispense commonly prescribed medications in accordance with the usual needs of the community.
3. 247 CMR 9.01:(16): A pharmacist shall not refuse to compound customary pharmaceutical preparations except upon extenuating circumstances.

ACTION: Motion by J. DEVITA, seconded by E. TAGLIERI, and voted unanimously to approve the Application to Manage and Operate a New Community Pharmacy and to approve the 3 requested waivers.

P. GANNON was not present for the discussion or vote for these matters.

TOPIC:

III. APPLICATIONS

B. Application for Transfer of Ownership

1. OncoMed Pharmaceutical Services of MA, Inc. (DS89702), 150 Bear Hill Road, Waltham, MA

DISCUSSION: As a result of a conversion from a corporation to a limited liability company, the corporate name, OncoMed Pharmaceutical Services of MA, Inc. has changed to OncoMed Pharmaceutical Services of MA, LLC and the officers have changed (noted as part of the application).

The Application did not indicate the intent to dispense Schedule II and III narcotics. MOR, Pamela Mortland submitted an Attestation of Intent to Conduct Nonsterile Compounding (USP <795> “simple” preparations).

ACTION: Motion by A. YOUNG, seconded by, E. TAGLIERI, and voted unanimously to approve the Application for Transfer of Ownership of Community Pharmacy.

Executive Director, David Sencabaugh will confirm the requested categories (Schedule II

and Schedule II narcotics) on the Application.

TOPIC:

V. REPORTS

A. Applications Approved Pursuant to Licensure Policy 13-01

DISCUSSION: R. HARRIS noted that during the past month there has been thirty-five (35) change of managers, one (1) relocation of a community pharmacy, two (2) renovation/expansion, and one (1) store closing.

ACTION: So noted.

B. Plans of Correction Approved Pursuant to Policy 13-02

DISCUSSION: K. BARNES noted that one (1) Plan of Correction (New England Home Therapies, DS3486, PHA-2014-0034) was approved.

ACTION: So noted.

TOPIC:

VII. POLICIES

A. Board Delegated Complaint Review Pursuant to Policy 14-02.

DISCUSSION: D. SENCABAUGH indicated that since March 25, 2014 there have been three (3) sessions in which three (3) different Board members met with the Executive Director, Legal Counsel, and other Board staff to review and dispose of staff assignments and complaints pertaining to quality related events and CE deficiencies. He indicated that 44 files were reviewed. As a result, there were 9 closed Complaints, 7 closed Staff Assignments (and 6 opened Complaints), 11 referred to the Office of Prosecution or Consent Agreements, and 17 referred to the full Board, and 3 cases reviewed and disposition pending Board approval of policy revisions.

He further indicated that the process worked smoothly, that various Board members had generously donated their time, and that policy revisions would be proposed to further enhance the process.

ACTION: So noted.

TOPIC:

VII. POLICIES

B. Board Delegated Complaint Review, Proposed Revisions to Policy 14-02

DISCUSSION: D. SENCABAUGH distributed a draft of proposed changes to Board Delegated Complaint Review, Policy 14-02. He proposed adding a category of Consumer Grievances, further defined each of the Quality Related Event Categories (include “or otherwise introduced into the patient’s body”), and included criteria (successful completion of CE or successful implementation a plan of correction) to resolve a staff assignment or complaint. Board members felt that theses would be important changes and would help streamline the process.

ACTION: Motion by J. TRIFONE, seconded by E. TAGLIERI, and voted unanimously, to approve the proposed changes to Board Delegated Complaint Review, Policy 14-02.

TOPIC:

VIII. FLEX SESSION

D. SENCABAUGH introduced Paul Seed, a new Board inspector and Gabrielle Dall, a pharmacy intern from Northeastern University.

A. Recent stakeholder meeting to discuss USP <797> Sterile Compounding Inspection tool

DISCUSSION: D. SENCABAUGH indicated on April 10, 2014, he coordinated a stakeholders meeting at Northeastern University to present a draft USP <797> inspection tool. Invitations were extended to MPhA, MCPC, MIPA, MSHP, MCPHS, NHIA, NU, WNEC, MA Board President Karen Ryle, and the FDA.

Board investigators C. LATHUM, S. PENTA, and W. FRISCH reviewed the tool in depth and entertained questions and concerns of attendees. Attendees were also encouraged to submit additional comments to the Board.

Eric Kastango, a USP consultant helped design the tool. Certain criteria exceed those of USP <797>, and will be considered “Best Practices”, and not subject to discipline at this time. Pending state legislation requires the Board to develop guidelines.

Once finalized, the tool will be shared with stakeholders and available on the Board’s website.

Mr. Sencabaugh also noted that a tool for USP <795> (non-sterile compounding) is under development. Board members felt that this would help pharmacies that may be hesitant to compound these products.

ACTION: So noted.

B. Revisions to the routine pharmacy inspection tool

DISCUSSION: D. SENCABAUGH distributed copies of the MA BORP *Compliance Inspection Report*. The Report has undergone many iterations and now includes a section for compounders of simple” non-sterile products (USP <795>).

After each item there is the reference (e.g., 247 CMR, USP <795>, Board policy#).

A copy of the final report is left with the pharmacy following an inspection.

Board members had not previously seen the Report and praised staff for the quality and readability.

ACTION: So noted.

C. Dispensing of Naloxone Rescue Kits by standing order

DISCUSSION: D. SENCABAUGH indicated that an example Naloxone Standing Order, a Naloxone Pamphlet, and a letter outlining the steps to safely dispense naloxone (with contact name & phone #), are now available on the Board’s website under “News, Updates, & Alerts”. H. ENGMAN noted that standing orders may need to be pharmacy-specific. The MOR needs to sign for the pharmacy, and a copy filed with the Board.

A. YOUNG mentioned that a physician from Brockton Hospital had agreed to sign standing orders for pharmacies. Members were concerned about logistics.

She also passed around a trainer of Evzio, the first auto-injector for naloxone. The auto-injector is pre-programmed with audible instructions for use.

ACTION: So noted.

VI. EMERGENCY REGULATIONS

1. Proposed amendments to 247 CMR 8:00 and 247 CMR 9:00 pertaining to the handling and dispensing of hydrocodone – extended release medications that are not in an abuse deterrent form.

DISCUSSION: D. SENCABAUGH and V. BERG distributed proposed amendments to the Board's regulations and a supporting memorandum on actions in response to the Governor's Declaration of a Public Health Emergency on March 27, 2014, include

emergency regulations promulgated by the Board of Registration in Medicine (BORIM) on April 22, 2014 regarding the prescribing of hydrocodone-only extended release medications that are not in an abuse deterrent form. The amendments proposed to the Board's regulations at 247 CMR add in new clauses at 247 CMR 8.05(3) and 247 CMR 9.04(8). If promulgated, the new provisions would prohibit pharmacy technicians, pharmacy technician trainees and pharmacy interns from handling, transporting or performing data entry relating to hydrocodone-only extended release medication that is not in an abuse deterrent form. The new provisions would also establish requirements for the dispensing of this medication, including: dispensing with a child proof safety cap or in a locked box, dispensing to patients with a letter of medical necessity corresponding to new BORIM regulations, dispensing with a written warning and mandatory counseling.

V. BERG noted that the Department of Public Health (DPH) recommended that the Board promulgate these emergency regulations as part of a coordinated effort by DPH, BORIM and other Boards of Registration (Dentistry, Physician Assistants, Nursing and Podiatry).

V. BERG provided the context and rationale for promulgating the proposed amendments on an emergency basis at this time, based on the convergence of two factors: First, Massachusetts is facing a broadening epidemic of opioid abuse with an unprecedented rate of unintentional opioid related overdose deaths. Second, the FDA has recently approved a new opioid medication into the prescription drug market: hydrocodone-only extended release medications that are not in an abuse deterrent form. The FDA advisory committee commented in December 2012 that if this medication were approved, it would be associated with higher levels of abuse than hydrocodone combination products currently in the market.

V. BERG noted that the first of these two factors warrants broad action and described actions taken towards that end. The Governor declared a Public Health Emergency on March 27, 2014 empowering the Commissioner of DPH to take necessary actions to address the crisis. The Commissioner has convened a task force to review, from an interdisciplinary perspective, measures to appropriately address opioid abuse, misuse and overdose generally. However, in considering such measures, DPH is cognizant that abrupt changes applicable to the prescribing and dispensing of opioid medications on a general basis may have a disruptive impact on persons with therapeutic regimens already in place that include such medications. This disruption is why the second factor - the recent introduction of this particular medication - warrants emergency action now. Specifically, with the introduction of a new medication, there is a short window of opportunity to implement measures intended to reduce the potential for abuse, misuse and overdose *before* widespread initiation of therapy with this medication. The hope is that the Commonwealth would be able to proactively meet the anticipated impact of this addition to the prescription opioid market rather than react after the fact. Thus these measures are presented on an emergency basis, because unless the measures are set prior to broad based commencement of treatment with this medication, the opportunity would be lost, to the detriment of the public health, safety and welfare. Board members discussed the particular provisions. With respect to the new 247 CMR 8.05(3), Board members generally agreed with the proposed limitations on physical handling of hydrocodone-only extended release medications that are not in an abuse deterrent form, as an appropriate means to reduce the potential for diversion of this medication. However, they noted that the restriction on data entry would not serve this purpose. Recognizing that in many pharmacies, there is only one pharmacist on staff at

one time, they were concerned that limiting all stages of prescription processing to a single person would pose a greater risk for both diversion and medication error. Board members emphasized it is safer to have two persons process the prescription and that data entry, by itself, would not significantly increase the opportunity for diversion. Board members also considered the impact of the restriction that only pharmacists transport the medication. They pointed out that transporting medications outside of the pharmacy (e.g., to a nursing home or assisted living facility) is a task frequently performed by persons with no registration at all (store clerks, delivery persons). Board members felt that transport of medications by unlicensed personnel and transport to facilities were topics that warranted additional discussion and consideration. Accordingly, Board members reached consensus on the proposed amendment at 247 CMR 8.05(3), with changes: removing "or transport" from the first sentence and removing the second sentence.

With respect to the new provisions at 247 CMR 9.04(8), Board members generally agreed that the proposed requirements would address the potential for abuse, misuse and overdose of hydrocodone-only extended release medication that is not in an abuse deterrent form. Board members noted gaps in the regulations as proposed. Specifically, Board members discussed the need for secure storage of the medication while on the pharmacy premises. They reached consensus that it should be securely stored as described in 247 CMR 6.02(6)(c) and not dispersed in general inventory. They also discussed storage during after the prescription has been processed but before the patient picks it up, noting that medications are usually stored in unsecure bins during that period. They agreed that this medication should be in locked storage during this period. Board members also reviewed the requirement that the prescriber supply a letter of medical necessity with components in compliance with recently promulgated BORIM regulations. They noted a lack of a record keeping provision on the part of the pharmacy. They also noted while the prescriber had a requirement to check the PMP, there was no corresponding requirement for the pharmacist, which would be necessary to check for any activity between the time the prescription was issued and when it was presented for filling. Lastly, the Board members considered the source for an appropriate written warning for hydrocodone-only extended release medication that is not in an abuse deterrent form, settling on the FDA medication guide for that product. V. BERG summarized the additions suggested by Board members, noting that the storage provision would become the new 9.04(8)(a), proposed 9.04(8)(a) through (d) would become 9.04(8)(b) through (e), with the new (c) including the requirement of keeping the letter of medical necessity in a readily retrievable manner, and a new 9.04(8)(f) requiring the pharmacist to check the patient's PMP history.

ACTION:

- a. Motion by J. DEVITA, seconded by P. GANNON, and voted unanimously, to promulgate proposed amendment 8.05 (3), with changes (removing "or transport" and the second sentence), on an emergency basis .
- b. Modifications to proposed amendment 9:04 (8):
 - i. Motion by P. GANNON, seconded by E. TAGLIERI, and voted unanimously, to add the requirement that the medication is stored in a securely locked and substantially constructed cabinet at all times while on pharmacy premises;
 - ii. Motion by P. GANNON, seconded by J. FRANKE, and voted unanimously, to add the requirement that the pharmacist checks the patient's history on the online Prescription Monitoring Program;

- iii. Motion by A. YOUNG, seconded by P. GANNON, and voted unanimously, to add the requirement that the pharmacist keep the Letter of Medical Necessity in a readily retrievable manner;
 - iv. Motion by K. RYLE, seconded by J. DEVITA, and voted unanimously, to approve the FDA Medication Guide for Zohydro ER as an acceptable “written warning” for distribution by a pharmacist.
- c. Motion by P. GANNON, seconded by E. TAGLIERI, and voted unanimously, to promulgate proposed amendment 9:04 (8), with changes as voted, on an emergency basis.

BREAK 10:58 – 11:12 a.m.

2. Proposed amendments to 244 CMR 4:00 (Board of Registration in Nursing) – consultation per M.G.L. c. 112 § 80E

DISCUSSION: V. BERG mentioned that the emergency regulations regarding the prescribing of hydrocodone-only extended release medications that are not in an abuse deterrent form, adopted by the Board of Registration in Medicine on April 22, 2014 do not address those prescribers controlled by other Boards. Other Boards that control prescribers will need to promulgate their own emergency regulations.

The Board of Registration in Nursing regulations require review of these emergency regulations by the Board of Registration in Pharmacy.

ACTION: Motion by P. GANNON, seconded by J. FRANKE, and voted unanimously, to concur with the BORN in adopting proposed emergency regulations for advanced practice nurses, that are identical to those of the BORIM.

LUNCH 11:50 – 1:04 p.m.

TOPIC:

IX. M.G.L. c. 112 §65C SESSION

DISCUSSION: None

ACTION: At 1:04 p.m., motion by, A. YOUNG, seconded P. GANNON, and voted unanimously to enter into M.G.L. c. 112 65C Session.

TOPIC:

X. EXECUTIVE SESSION (M.G.L. c. 30A, §21(a)(1))

DISCUSSION: K. RYLE noted that the Board would not return to open session following closed session.

ACTION: At 2:17 p.m., motion by P. GANNON, seconded by R. TINSLEY, and voted unanimously by roll call to enter Executive Session. K. RYLE: yes; J. DEVITA: yes; J. TRIFONE: yes; J. FRANKE: yes; A. YOUNG: yes; P. GANNON: yes; R. TINSLEY: yes. E. TAGLIERI was not present for the vote.

TOPIC:

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

DISCUSSION: None.

ACTION: At 2:50 p.m., motion by P. GANNON, seconded by J. FRANKE, and voted

unanimously to enter into Adjudicatory Session.

TOPIC:

XII. ADJOURNMENT

DISCUSSION: None.

ACTION: At 5:02 p.m., motion by P. GANNON, seconded by K. RYLE, and voted unanimously to adjourn.

LIST OF EXHIBITS USED DURING THE MEETING

1. Preliminary Agenda for the May 6, 2014 Regularly Scheduled Meeting
2. Application to Manage and Operate a New Community Pharmacy, Caring Health Center Pharmacy
3. Application for Transfer of Ownership of Community Pharmacy OncoMed Pharmaceutical Services of MA
4. Applications approved pursuant to Licensure Policy 13-01, May 2014
5. Plans of Correction approved pursuant to Policy 13-02
6. Memo: Emergency Regulations regarding Hydrocodone-Only Extended Release Medications that are not in an Abuse Deterrent Form, May 6, 2014
7. Proposed Amendment: 247 CMR 8:00
8. Proposed Amendment 247 CMR 9:00
9. Medication Guide, Zohydro (issued October 2013, approved by US FDA)
10. Revised Proposed Amendments to 247 CMR 8:05 (3) and 247 CMR 9:04 (8)
11. Board Delegated Complaint Reviews pursuant to Policy 14-02, March 25 – May 1, 2014
12. Board Delegated Complaint Review Policy 14-02, Draft of Proposed Revisions

Respectfully submitted,

Edmund Taglieri, RPh, MSM, NHA, Secretary