

COMMONWEALTH OF MASSACHUSETTS

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

June 3, 2014
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

Agenda

Time	#	Item	Exhibits	Contact
8:30	I	CALL TO ORDER		
8:35	II	APPROVAL OF AGENDA		
8:40	III	EMERGENCY REGULATIONS 1. Post public hearing review and promulgation of permanent regulations at 247 CMR 10.03(1)(cc) inserting violation of a Commissioner's order into the list of grounds for discipline		H. Engman
8:45	IV	APPLICATIONS 1. Southcoast Specialty Pharmacy – New Community Pharmacy	Applications and supporting documentation	R. Harris
9:20	V	APPROVAL OF BOARD MINUTES Draft April 1, 2014 Regular Session Minutes Draft May 6, 2014 Regular Session Minutes		
9:30		EXECUTIVE SESSION The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(3) for the purpose of discussing strategy with respect to litigation because discussing in open session would have a detrimental effect on the litigating position of the board. Specifically, the board members will discuss pending litigation: <i>Zogenix, Inc. v. Patrick, et. al.</i> , United States District Court, District of Massachusetts, 1:14-CV-11689-RWZ.	Closed Session	
10:00	VI	REPORTS 1. Applications approved pursuant to Licensure Policy 13-01 2. Board Delegated Complaint Review	Reports	R. Harris

10:05	VII	FLEX SESSION <ol style="list-style-type: none"> 1. Automated Pharmacy Systems Joint Guidelines 2. Board Update <ol style="list-style-type: none"> a. Introduction of Board Intern, Shirley Yu b. Update on the Associate Executive Director Search Process 		J. Devita Kelly Barnes
10:30	VIII	FILE REVIEW <ol style="list-style-type: none"> 1. PHA-2013-0079, David Young, PH22919 2. PHA-2012-0124, Sudbury Pharmacy, DS3406 3. SA-INV-5182, Village Fertility Pharmacy, DS89358 4. SA-INV-5334, Village Fertility Pharmacy, DS89358 5. SA-INV-5139, Village Fertility Pharmacy, DS89358 6. SA-INV-5110, Village Fertility Pharmacy, DS89358 7. SA-INV-5698, Village Fertility Pharmacy, DS89358 		W. Frisch
11:00	IX	M.G.L. c. 112, 65C SESSION	CLOSED SESSION	
12:00		LUNCH BREAK		
1:00	X	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. <ol style="list-style-type: none"> 1. Specifically, the Board will discuss and evaluate the <u>Good Moral Character</u> as required for registration for pending applicants. 2. Approval of prior executive session minutes in accordance with M.G.L. ch.30A, § 22(f) for sessions held during the April 1, 2014 and May 6, 2014 meetings. 	CLOSED SESSION	
1:30	XI	M.G.L. c. 112, 65C SESSION	CLOSED SESSION	
4:00	XII	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)	CLOSED SESSION	
4:15	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, June 3, 2014

Board Members Present

Karen Ryle, RPh, President
Patrick Gannon, RPh, MS, President-elect
(Arrived @ 9:38 am)
Edmund Taglieri, RPh, MSM, NHA,
Secretary
Joanne Trifone, RPh
Anita Young, RPh, EdD (Left @ 4:25 pm)
Richard Tinsley, MBA, MEd
Anthony Perrone, MD

Board Members Not Present

James DeVita, RPh
Jane F. Franke, RN, MHA

Board Staff Present

Heather Engman JD, MPH, Board Counsel
Kelly Barnes, JD, RPh, Quality Assurance
Richard Harris, Administrative Assistant
William Frisch, Jr., RPh, Director of Compliance
Samuel Penta, RPh, Investigator
Leo McKenna, RPh, PharmD, Investigator
Anthony Bartucca, RPh, Investigative Consultant
David Dunn, RPh, Investigative Consultant
Christina Mogni, RPh, Investigative Consultant
John Murray, Investigator
Joseph Sceppa, Consultant

Board Staff Not Present

David Sencabaugh, RPh, Executive Director
Cheryl Lathum, RPh, PharmD, Investigator

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 indicated that the Board was recording the meeting.

ACTION: At 8:39 a.m. K. RYLE, called the June 3, 2014, meeting of the Board of Registration in Pharmacy to order.

TOPIC:

II. APPROVAL OF AGENDA

DISCUSSION: Board Counsel, H. ENGMAN indicated that the Southcoast Specialty

Pharmacy Application and the Automated Pharmacy System Joint Guidelines will be deferred to a future meeting. Membership on the BORIM Quality and Safety Committee will be added to the Flex Session.

ACTION: Motion by A. YOUNG, seconded by J. TRIFONE, and voted unanimously to approve the agenda with the noted changes. P. GANNON was not present for the vote.

TOPIC:

III. EMERGENCY REGULATIONS

DISCUSSION: Board Counsel, H. ENGMAN indicated that the Board published a Notice of Public Hearing on the emergency amendment to 247 CMR 10.00. This amendment inserted a new clause at 10.03(1)(cc): *Violation of, or failure to comply with, an Order issued by the Commissioner of the Department of Public Health pursuant to a Declaration of Emergency Detrimental to Public Health made in accordance with M.G.L. c.17, §2A or pursuant to such other authority as may be vested in the Commissioner.* There were no comments from the public.

ACTION: Motion by A. YOUNG, seconded by E. TAGLIERI, and voted unanimously to adopt the amendment of 247 CMR 10.00 by insertion of the clause at 10.03(1)(cc) as promulgated by the emergency filing on April 1, 2014, with no changes, and complete the process for the final promulgation by filing appropriate documentation with the Secretary of State's office. P. GANNON was not present for the vote.

TOPIC:

IV. APPLICATIONS

DEFERRED

TOPIC:

V. APPROVAL OF BOARD MINUTES

1. April 1, 2014 Regular Session of the Board

DISCUSSION: None

ACTION: Motion by J. TRIFONE, seconded by R. TINSLEY, and voted unanimously to approve the minutes of the April 1, 2014 Regular Session of the Board with no changes.

TOPIC:

V. APPROVAL OF BOARD MINUTES

2. May 6, 2014 Regular Session of the Board

DISCUSSION: None

ACTION: Motion by J. TRIFONE, seconded by R. TINSLEY, and voted unanimously to approve the minutes of the May 6, 2014 Regular Session of the Board with no changes.

TOPIC:

IX. M.G.L. c. 112 §65C SESSION

DISCUSSION: None

ACTION: At 9:08 a.m., motion by E. TAGLIERI, seconded by R. TINSLEY, and voted unanimously to enter into M.G.L. c. 112 65C Session.

P. GANNON was not present for the vote.

TOPIC:

EXECUTIVE SESSION (M.G.L. c. 30A, §21(a)(3))

DISCUSSION: The Board will meet in Executive Session for the purpose of discussing strategy with respect to litigation because discussing it in open session would have a detrimental effect on the litigating position of the board. Specifically, the board members will discuss pending litigation: *Zogenix, Inc. v. Patrick, et. al., United States District Court, District of Massachusetts, 1:14-CV-11689-RWZ.*

ACTION: At 9:30 a.m., motion by K. RYLE, seconded by A. YOUNG, and voted unanimously by roll call to enter Executive Session.

K. RYLE: yes; E. TAGLIERI: yes; A. PERRONE: yes; R. TINSLEY: yes; J. TRIFONE: yes; A. YOUNG: yes. P. GANNON was not present for the vote.

BREAK 10:28 – 10:40

TOPIC:

M.G.L. c. 112 §65C SESSION

DISCUSSION: None

ACTION: At 10:42 a.m., motion by P. GANNON, seconded by R. TINSLEY, and voted unanimously to return to M.G.L. c. 112 65C Session.

TOPIC:

VI. REPORTS

1. Applications Approved Pursuant to Licensure Policy 13-01

DISCUSSION: R. HARRIS noted that during the past month the following number of applications have been approved pursuant to Licensure Policy 13-01: seven (7) new community pharmacies, eleven (11) change of managers, one (1) renovation/expansion one (1) relocation of a community pharmacy, and one (1) store closing.

ACTION: So noted.

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

DISCUSSION: K. BARNES noted that on May 22, 2014, nine (9) cases were reviewed. The Board member present was A. YOUNG. There were three (3) cases of CE deficiencies, one (1) QRE case (that was sent to the full Board), and 5 grievances (staff assignments dismissed with either “insufficient evidence” or “no violation”).

ACTION: So noted.

TOPIC:

VII. FLEX SESSION

2. Board Update

a. Introductions

K. BARNES introduced Shirley Yu, a pharmacy intern from MCPHS.

H. ENGMAN introduced David Bazlewicz, a legal intern.

b. Update on the Associate Executive Director Search Process

DISCUSSION: We have received seventeen (17) applications for the Associate Executive Director position and seven (7) individuals were selected to be interviewed. Interviews were held the week of May 19th; background checks and references are being obtained. Some applicants are pharmacists. The name of a preferred candidate will be submitted within the next few weeks.

ACTION: So noted.

c. BORIM Quality and Safety Committee Membership

DISCUSSION: K. RYLE indicated that the Quality and Safety Committee of the BORIM meets monthly and discusses issues such as “Never Events” in hospitals. At the May meeting of the Board, in response to a request by Maureen Keenan at BORIM, it was recommended that Director of Quality Assurance, K. BARNES, represent the Board on the BORIM Quality and Safety Committee. BORIM has indicated that they would like a member of the Board.

ACTION: K. BARNES will scan Ms. Keenan’s letter to Board members. Interested members would contact Ms. Keenan to better understand time commitment and roles.

TOPIC:

VIII. FILE REVIEW

1. PHA-2013-0079, **David Young**, PH22919 10:20 a.m.

DISCUSSION: This complaint was presented by C. MOGNI.

As a result of a December 20, 2012 USP <797> inspection of Apothecare South Shore, on July 11, 2013, a complaint was issued against MOR, David Young for a October 17, 2012 Sterile Compounding Pharmacy Attesting of Compliance. In a January 27, 2014 email to OPP, pharmacist Young denies involvement with or signing the Attestation of Compliance. He resigned on November 2, 2012 with his last day of employment as November 12, 2012. There were conflicting opinions as to whether or not the signature was that of MOR Young.

ACTION: Motion by P. GANNON, seconded by A. PERRONE, and voted unanimously, to dismiss the complaint on **David Young** due to insufficient evidence.

TOPIC:

VIII. FILE REVIEW

2. PHA-2012-0124, **Sudbury Pharmacy**, DS3406

DISCUSSION: This complaint was presented by W. FRISCH and S. PENTA.

This is an older case, held until the sterile compounding pharmacies had been addressed. During a June 20, 2012 routine compliance inspection, investigators noted a number of serious deficiencies, some of which included: improper labeling of ingredients and final products in the non-sterile compounding area; expired compounding ingredients; no hot running water; inconsistencies in the 10 day inventories of Schedule II products; malfunctioning lock on the Schedule II drug storage cabinet; an electronic scale that was not sealed, and an uncertified hood used for weighing powders.

On February 13, 2014, Senior Investigator S. PENTA conducted a re-inspection and found Sudbury Pharmacy to have significantly implemented the plan of correction. Renovations have been made to the non-sterile compounding area and the pharmacy is being reorganized or a pending USP <795> inspection. Investigators FRISCH and PENTA indicated that the pharmacy had addressed all of their concerns.

ACTION: Motion by P. GANNON, seconded by A. PERRONE, and voted unanimously, to dismiss the complaint on **Sudbury Pharmacy** with no discipline warranted.

TOPIC:

VIII. FILE REVIEW

3. SA-INV-5182, **Village Fertility Pharmacy**, DS89358
4. SA-INV-5334, **Village Fertility Pharmacy**, DS89358

5. SA-INV-5139, **Village Fertility Pharmacy**, DS89358
6. SA-INV-5110, **Village Fertility Pharmacy**, DS89358
7. SA-INV-5698, **Village Fertility Pharmacy**, DS89358

DISCUSSION: These staff assignments were presented by W. FRISCH and S. PENTA. There were five (5) separate reports of abnormal sample results, self-reported by Village Fertility Pharmacy that reflect testing in the anteroom and the USP <795> and USP <797> buffer rooms. The pharmacy no longer does High-Risk Level compounding. However, yet they continue to maintain an increased frequency of testing (monthly) that exceeds the USP <797> requirements.

Village Fertility Pharmacy has implemented a comprehensive corrective action plan, submitted all requested documentation (policies, logs, training records), and on April 9, 2014, submitted the results of a B & V Testing certification report. The report shows that total bacterial count, total fungal (yeast/mold) count, and total microbial (bacterial & fungal) counts to be zero.

ACTION: Motion by A. YOUNG, seconded by J. TRIFONE, and voted unanimously, to close all five (5) staff assignments on **Village Fertility Pharmacy** with no violation.

LUNCH 11:59 a.m. – 1:04 p.m.

TOPIC:

IX. M.G.L. c. 112 §65C SESSION

DISCUSSION: None

ACTION: At 1:04 p.m., motion by P. GANNON, seconded by J. TRIFONE, and voted unanimously to return to M.G.L. c. 112 65C Session.

TOPIC:

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

DISCUSSION: None.

ACTION: At 1:15 p.m., motion by P. GANNON, seconded by R. TINSLEY, and voted unanimously by roll call to return to 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.

BREAK 2:31 – 2:44 p.m.

TOPIC:

IX. M.G.L. c. 112 §65C SESSION

DISCUSSION: None

ACTION: At 2:44 p.m., motion by P. GANNON, seconded by J. TRIFONE, and voted unanimously to return to M.G.L. c. 112 65C Session.

TOPIC:

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

DISCUSSION: None.

ACTION: At 5:23 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 5:25 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 June 3, 2014 Regularly Scheduled Meeting
2. Draft of Amendment to 247 CMR 10.00 [247 CMR 10.03(1)(cc)]
3. Draft Minutes of the Apr 1, 2014 Regularly Scheduled Meeting of the Board
4. Draft Minutes of the May 6, 2014 Regularly Scheduled Meeting of the Board
5. Applications approved pursuant to Licensure Policy 13-01, June 2014
6. Board Delegated Complaint Reviews pursuant to Policy 14-02, May 22, 2014
7. Update on the Associate Executive Director Search Process memo, May 30, 2014
8. Investigative Report in the Matter of David Young, PH22919, PHA-2013-0079
9. Investigative Report in the Matter of Sudbury Pharmacy, DS3406, PHA-2012-0124
10. Investigative Report in the Matter of Village Fertility Pharmacy, DS89358, SA-INV-5182, SA-INV-5334, SA-INV-5139, SA-INV-5110, and SA-INV-5698

Respectfully submitted,

Edmund Taglieri, RPh, MSM, NHA, Secretary