

COMMONWEALTH OF MASSACHUSETTS

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

April 1, 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. Benams Pharmacy , 96 Long Pond Road, Plymouth Maureen Idehen, PH1977, Owner and MOR Reconsideration of Application for New Community Pharmacy 2. CVS 2162 Children’s Hospital , 300 Longwood Ave. Boston (DS2687) Renovation/Expansion Request to include 795 Compounding 3. Johnson & Johnson Health Care Systems , 50 Scotland Blvd, Bridgewater Arthur Raymond, Distribution Manager Application for Licensure as a Wholesale Distributor	M. Cittadino	Applications and supporting documentation
10:00	IV.	APPROVAL OF BOARD MINUTES 1. Draft March 4, 2014 Regular Session Minutes		
10:05	V.	REPORTS Applications approved pursuant to Licensure Policy 13-01	Reports	M. Cittadino
10:10	VI.	FILE REVIEW 1. PHA-2013-0153, CVS Pharmacy 498, DS3349 2. PHA-2013-0079, David Young, PH22919 3. SA-INV-3273, IntegriScript, Inc., DS89726 4. SA-INV-3980, Jeanne Sz wajkowski, PH27446 5. SA-INV-5204, Coram Specialty Infusion Services, DS3601 6. SA-INV-4452, Critical Care Systems, DS3330 7. PHA-2013-0163, J.E. Pierce Apothecary, DS89745		

11:30	VII.	POLICIES 1. PMP Continuing Education Required by Chapter 244 2. Board Delegated Complaint Review		D. Sencabaugh
	VIII.	FLEX SESSION 1. Board Updates 2. Board of Medicine Quality and Patient Safety Committee 3. Emergency Regulations regarding Hydrocodone Bitartrate products in a hydrocodone-only formulation 4. Governor Patrick's Declaration of a Public Health Emergency: prohibition on prescribing and dispensing hydrocodone bitartrate products in a hydrocodone-only formulations and increased access to naloxone		D. Sencabaugh K. Ryle
12:00	IX.	BREAK		
12:20	X	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)	CLOSED SESSION	
12:30	XI.	M.G.L. c. 112, 65C SESSION	CLOSED SESSION	
2:30	XII.	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, April 1, 2014

Board Members Present

Karen Ryle, RPh, President
Edmund Taglieri, RPh, MSM, NHA,
Secretary
James DeVita, RPh (left @ 4:30 pm)
Jane F. Franke, RN, MHA
Richard Tinsley, MBA, MEd
Joanne Trifone, RPh
Anita Young, RPh, EdD

Board Members Not Present

Patrick Gannon, RPh, MS, President-elect
Anthony Perrone, RPh, MD, MBA

Board Staff Present

James Lavery, JD, Director, DHPL
David Sencabaugh, RPh, Executive Director
Margaret Cittadino, MEd, Associate Director
Vita Berg, JD, Chief Board Counsel
Heather Engman JD, MPH, Board Counsel
Kelly Barnes, JD, RPh, Dir. Quality Assurance
William E. Frisch, Jr., RPh, Investigator Supervisor
Leo McKenna, RPh, PharmD, Investigator
Cheryl Lathum, RPh, PharmD, Investigator
Samuel Penta, RPh, Investigator
John Murray, RPh, Investigator
Christina Mogni, RPh, Investigative Consultant
Anthony Bartucca, RPh, Investigative Consultant
David Dunn, RPh, Investigative Consultant
Richard Harris, Program Analyst

Board Staff Not Present

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. Karen Ryle stated that the Board of Pharmacy was recording.

ACTION: At 8:32 a.m. K. RYLE, called the April 1, 2014, meeting of the Board of

Registration in Pharmacy to order.

TOPIC:

II. APPROVAL OF AGENDA

DISCUSSION: Board members reviewed the tentative agenda.

ACTION: Motion by, A. YOUNG, seconded by J. FRANKE, and voted unanimously to approve the agenda with no changes.

TOPIC:

III. APPLICATIONS

A. Reconsideration of Application for New Community Pharmacy

1. Benams Pharmacy, 96 Long Pond Road, Plymouth

Maureen Idehen, PH1977, Owner and MOR

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

DISCUSSION: Ms Idehen had appeared before the Board in February, 2014 with this same application, but at the time, the Board voted to table the application. The Board cited several concerns, and believed that she was not ready to petition at that time. In February, she was unable to identify her planned wholesaler or her pharmacy system, nor was she able to effectively convince the Board that she understood the requirements related to compounding.

Ms. Idehen identified a company named “Harvard” as a wholesaler, as well as HD Smith. The Board shared concerns that Harvard provides only generics, and is not local, although they are VAWD certified. She mentioned that she plans to register for the PMP program and, although she herself is not certified as an immunizer, her partner is, and she plans to train soon.

Questions about certain entries in her attestation re: intended non-sterile compounding, resulted in the Board’s decision to require specific action steps prior to conducting any compounding; to familiarize herself with USP <795> and the corresponding “Gap Analysis”, and resend the attestation with appropriate answers to all questions.

ACTION: Motion by J. DEVITA, seconded by K. RYLE, and voted unanimously (J. Trifone had recused herself) to approve the application, conditioned upon Board’s receipt of a 795 non-sterile compounding attestation indicate that the pharmacy would not conduct compounding and conditioned upon a successful inspection.

TOPIC:

III. APPLICATIONS

B. Renovation/Expansion Request for the Non-Sterile Compounding Area

1. CVS 2612 Children’s Hospital (DS2687), 300 Longwood Avenue, Boston
CVS VP Peter Simmons, MOR Judy YU, Pharmacy District Supervisor Lulu Phan, and Consultant Ernest Gates presented for CVS.

RECUSAL: J. DEVITA recused himself and was not present during the discussion or votes for these matters.

DISCUSSION: CVS 2612 is currently located on the first floor at Children’s Hospital. Children’s informed CVS that they needed to permanently vacate the current space to accommodate a remodel of the building, and they were offered a location on the second floor. Additionally, Children’s requested that CVS offer compounding services (USP

<795>).

CVS was asking for space planning approval in order that they could go forward with construction, with a planned date for opening the new pharmacy on or about 7/1/2014. Once open, CVS plans to implement a comprehensive training program for their pharmacy staff at this location, with plans to begin compounding on or about 9/1/2014. The new design, scheduled to begin construction in May, 2014, will also include additional staff and expanded hours of operation. There will be 740 square feet of pharmacy space with no “front store”.

The goal is to work in uniformity with Children’s so that formulas and recipes for products dispensed to discharged patients will be identical to compounds used in treatment as inpatients. Head Investigator, W. FRISH commented that he would expect that the entire staff at CVS 2612, both existing and new, receives formal training in compounding, and that assurance was given by Mr. Gates.

ACTION: Motion by E. TAGLIERI, seconded by, A. YOUNG, and voted unanimously (J. DEVITA had recused) to approve the renovation request pharmacy and the addition of the non-sterile compounding area, pending successful inspection at the completion of the pharmacy move for current business, AND a prior full 795 audit before commencing compounding activities.

ACTION: Motion by E. TAGLIERI, seconded by, J. TRIFONE, and voted unanimously to approve the Renovation/Expansion Request for the Non-Sterile Compounding Area, subject to a successful inspection, and another prior to nonsterile compounding (a full USP <795> audit).

TOPIC:

III. APPLICATIONS

C. Application for Licensure as a Wholesale Distributor

**1. Johnson and Johnson Health Care Systems, 50 Scotland Blvd., Bridgewater
Arthur Raymond, Distribution Manager**

Board Member J. Devita stepped out of the room for much of this discussion.

DISCUSSION: Mr. Raymond described the facility as a “shared service” warehouse, that distributes mostly medical devices. There is one device, however, which comes with a scheduled drug, lidocaine (Xylocaine). Because of this one drug, Mr. Raymond was advised that he may need a Massachusetts BORP-issued Wholesale Distribution permit.

According to Mr. Raymond, the device and package containing lidocaine is owned by the HCS Division of Johnson & Johnson, and that his warehouse takes custody only to ship it to hospitals.

Board Counsel Heather Engman requested Mr. Raymond to provide written description of who the applicant is and applicant’s business. The Board to determine if there is already a permit in place, either with the BORP or perhaps DCP.

ACTION: Motion by E. TAGLIERI, seconded by J. TRIFONE, and voted to defer this matter pending further information. J. DEVITA abstained from voting.

BREAK 10:06 to 10:17

TOPIC:

IV. APPROVAL OF BOARD MINUTES

March 4, 2014 Regularly Scheduled Meeting

DISCUSSION: H. ENGMAN presented the minutes of the March 4, 2014 Regularly Scheduled Meeting.

ACTION: Motion by J. TRIFONE, seconded by, J. DEVITA, and voted unanimously to approve the minutes of the March 4, 2014 Regularly Scheduled Meeting with no changes.

TOPIC:

V. REPORTS

A. Applications Approved Pursuant to Licensure Policy 13-01

DISCUSSION: M. CITTADINO noted that during the past month there have been twenty-five (5) changes of managers, one (1) relocation of a distributor, one (1) renovation/expansion, and two (2) store closings.

ACTION: So noted.

TOPIC:

VI. FILE REVIEW

1. PHA-2013-0153, CVS Pharmacy #498 (DS3349)

RECUSAL: J. DEVITA recused himself and was not present during the discussion or votes for these matters.

DISCUSSION: This complaint was presented by C. LATHUM.

This CVS Pharmacy is very busy, filling approximately 3400 prescriptions per week. The second pharmacist arrives at 1 pm.

On October 16, 2013 during an unannounced compliance audit, it was observed that the ratio of pharmacist to supportive personnel was 1:6, in violation of 247 CMR 8.06(3)(a) and the same as what was observed during a March 3, 2011 inspection. Investigators also noted the name of the MOR (Christina Yesu) was not displayed and there was no evidence of annual CQI training (both cited in the 2011 inspection). The pharmacy was noted to be unsanitary (dust and dirt), there were incomplete refrigerator temperature logs (vaccine refrigerator monitored once daily), no designated compounding area, and expired compounded medications were observed.

A December 9, 2013 plan of correction addressed all of the compliance audit findings.

A January 30, 2014 compliance audit noted that the plan of correction was substantially implemented.

Board members expressed serious concerns about the familiarity of the MOR with 247 CMR, especially the staffing issues and felt stronger action was necessary.

ACTIONS:

1. Motion by R. TINSLEY, seconded by J. FRANKE, and voted unanimously, to reject the December 9, 2013 plan of correction.
2. Motion by R. TINSLEY, seconded by A. YOUNG, and voted unanimously, to refer the complaint to the Office of Prosecution for the issuance of an Order to Show Cause and to authorize resolution of the matter with a consent agreement for a three-year probation. Special terms to include no students on rotation, and an acceptable plan of correction with a commitment from CVS corporate to address staffing issue, or a potential cease and desist within 30 days.

TOPIC:

VI. FILE REVIEW

2. PHA/2013-0079 David Young, PHA22919 was deferred to a future Board meeting due to lack of quorum.

VI. FILE REVIEW

3. SA-INV-3273, **IntegriScript, Inc. #498** (DS89726), West Springfield
4. SA-INV-3980, **Jeanne Szwajkowski**, PH27446

DISCUSSION: This staff assignment was presented by S. PENTA.

In response to an unannounced sterile compounding assessment on December 13 & 14, 2012, the facility was closed and patients were transitioned to a Coram facility. A comprehensive corrective action plan was accepted.

On September 17, 2013, Board inspectors conducted a USP <797> re-inspection to assess progress in completion of the corrective action plan. Particle board was exposed and needed to be sealed with epoxy paint, and a stained HEPA needed replacement, resulting in the need to clean and re-test the PEC, anteroom and buffer room.

On January 16, 2014, a re-inspection was conducted by Board investigators. The plan of correction was significantly implemented and sterile compounding of low and medium-risk admixtures resumed on January 17, 2014. TPNs continue to be prepared at the Coram facility in Norwood.

ACTIONS:

3. Motion by J. DEVITA, seconded by R. TINSLEY, and voted unanimously, to close the staff assignment on IntegriScript, discipline not warranted.
4. Motion by J. DEVITA, seconded by R. TINSLEY, and voted unanimously, to close the staff assignment on former manager, Jeanne Szwajkowski, discipline not warranted.

TOPIC:

VI. FILE REVIEW

5. SA-INV-5204, **Coram Specialty Infusion Services** (DS3601), Norwood

DISCUSSION: This staff assignment was presented by S. PENTA.

On January 10, 2014, the Board received the results of a clean room certification (conducted November 5, 2013) in which viable bacillus and micrococcus organisms were identified. The certification results had been received by Coram on December 4, 2013. Board regulation 247 CMR 6.15(2) requires reporting of non-routine notices within 7 business days. MOR Gary Mills indicated that the results were forwarded up the chain of command and was not aware of the 7 day requirement.

As a result of the testing, Coram instituted a comprehensive corrective action plan on December 4, 2013.

ACTIONS: Motion by A. YOUNG, seconded by J. FRANKE, and voted unanimously, to close the staff assignment on **Coram Specialty Infusion Services** without prejudice, discipline not warranted and to send an advisory letter reminding pharmacy of its mandatory reporting requirements.

TOPIC:

VI. FILE REVIEW

6. SA-INV-4452, **Critical Care Systems** (DS3330), Shrewsbury

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

DISCUSSION: This staff assignment was presented by S. PENTA.

On August 14, 2013, the Board received notification from Critical Care Systems (CCS) in Shrewsbury of abnormal results (gram negative rods) from the ante room and a biological safety cabinet in which oncology drugs were being compounded. This was attributed to hand washing by an employee during testing.

The routine certification was done by BV Testing on July 23, 2013. A volumetric air sample from the ante room yielded gram negative rods. Another volumetric air sample of the biologic safety cabinet (PEC) yielded gram negative rods and mold. As a result, sterile compounding was halted and patients requiring sterile compounded products were transferred to other CCS facilities.

All 5 patients who received compounded oncology medications within 14 days of August 6, 2013, and their physicians were contacted. CCS replaced medication for the 3 patients who had not yet received the medication.

On August 16, 2013, Board investigators held a conference call with the MOR and senior corporate individuals. All agreed to a comprehensive plan to stratify patients into 3 groupings and to contact them.

A jointly-developed plan of correction for comprehensive cleaning, investigational testing, light reconstruction, review of protocols (garbing/gowning, flow of materials and supplies) and final testing was approved.

On October 15, 2013, investigators PENTA and McKENNA reviewed the plan of correction with MOR Matthew McLaughlin and found it to be substantially implemented. S. PENTA recommends closing the staff assignment.

ACTIONS: Motion by A. YOUNG, seconded by J. DEVITA, and voted unanimously, to close the staff assignment on **Critical Care Systems**, no violation.

TOPIC:

VI. FILE REVIEW

7. PHA-2013-0163, **J. E. Pierce Apothecary** (DS89745)

DISCUSSION: This complaint was presented by D. DUNN.

It alleges that Anderson Holdings, Inc. (d/b/a J.E. Pierce Apothecary Compounding Lab failed to conform to the requirements of 247 CMR 6.09 (1) and (2).

On October 13, 2013, the Board received notification of the June 12, 2013 closure of Anderson Holdings, Inc. (d/b/a J.E. Pierce Apothecary Compounding Lab, DS89745, 1093 Beacon St., Brookline) and that all prescription records, controlled and non-controlled substances, and required DEA record keeping had been transferred to Anderson Holdings, Inc. (d/b/a Wingate's Pharmacy, 129 Main St., Nashua, NH)

On September 9, 2013, the Board received notification from MOR Derek Anderson, owner of Anderson Holdings, Inc. of the intention to close J.E. Pierce Apothecary on September 27, 2013. It incorrectly indicated the license number and address (DS89745, 1093 Beacon St., Brookline) for J.E. Pierce Apothecary Compounding Lab. The correct information is DS89681, 1180 Beacon Street, Brookline. Inventory and files were transferred to CVS (DS17582), Brookline.

On November 26, 2013, MOR Anderson apologized to the Board for the oversight.

ACTIONS: Motion by J. DEVITA, seconded by J. FRANKE, and voted unanimously, to dismiss the complaint against J. E. Pierce Apothecary, discipline not warranted.

NB:

TOPIC:

VII. POLICIES

1. PMP Continuing Education Required by Chapter 244

DISCUSSION: D. SENCABAUGH distributed a draft of the policy, PMP Training for Pharmacists. It would fulfill the requirement in Section 8, Chapter 244 of the Acts of 2012 that all pharmacists licensed by the Board be trained in the use of the PMP. The policy sets out the specific requirements of the training as well as the recommended course requirements. Board members felt that the draft policy contained all of the elements recommended from prior discussions.

ACTION: Motion by J. DEVITA, seconded by A. YOUNG, and voted unanimously, to adopt Policy 14-03, PMP Training for Pharmacists.

TOPIC:

VII. POLICIES

2. 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 section (3c) that would allow or closure of a staff assignment or dismissal of a complaint if the licensee acknowledges any violation or error in writing and provides evidence of remediation.

ACTION: Motion by J. DEVITA, seconded by J. FRANKE, and voted unanimously, to adopt the proposed changes to Board Delegated Complaint Review, Policy 14-02.

TOPIC:

VIII. FLEX SESSION

1. Board Updates

DISCUSSION: D. SENCABAUGH introduced Kelly Barnes, the Director of Quality Assurance and John Murray, a Pharmacy Investigator.

He also indicated that Margy Cittadino would be retiring and that this would be her last Board meeting. On behalf of the staff, he thanked her for 25 years of dedicated service to the State, and with the Board of Registration in Pharmacy for the last 9 years.

ACTION: So noted.

2. Board of Registration in Medicine, Quality and Patient Safety Committee

DISCUSSION: The Board of Registration in Medicine (BORIM) sent President, RYLE a letter requesting a Board of Registration in Pharmacy member to be part of their Quality and Patient Safety Committee. Ms. RYLE had previously served.

Members felt that Kelly Barnes, Director of Quality Assurance would be a good choice. K. RYLE will follow-up with BORIM to see if a Board staff member would be acceptable.

ACTION: So noted.

3. Emergency Regulations regarding Hydrocodone Bitartrate products in a hydrocodone-only formulation

DISCUSSION: V. BERG distributed copies of an April 1, 2014 memo, Emergency Regulations to 247 CMR 10.00. The memo describes actions taken by the DPH pursuant to the Governor's Declaration of Emergency Detrimental to the Public Health.

The Department recommends the Board amend 247 CMR 10.03 to add “Violation of, or failure to comply with, an Order by the Commissioner of the Department of Public Health pursuant to a Declaration of Emergency Detrimental to the 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” as a grounds for discipline by the board.

ACTION: Motion by J. DEVITA, seconded by A. YOUNG, and voted unanimously, to approve the amendments to 247 CMR 10:00 on an emergency basis.

4. **Governor Patrick’s Declaration of a Public Health Emergency: Prohibition of prescribing and dispensing of any hydrocodone bitartrate product in hydrocodone-only extended release formulation**

DISCUSSION: D. SENCABAUGH and H. ENGMAN presented and discussed Governor Patrick’s Declaration of a Public Health Emergency on March 27, 2014. As a result of the Declaration, the DPH Commissioner and Public Health Council issued an order prohibiting practitioners from prescribing or dispensing hydrocodone-only extended release medications that are not in an abuse deterrent formulation until such time as the Commissioner determines adequate measures are in place to safeguard against diversion, overdose, and abuse. The Commissioner and PHC also issued an order expanding access to naloxone for persons in a position to assist an individual experiencing an opiate related overdose. The PHC also adopted emergency regulations expanding first responders’ access to naloxone.

ACTION: So noted.

Additionally, D. SENCABAUGH presented a circular letter, DHCQ 14-3-610, March 31, 2014, regarding the prohibition on prescribing and dispensing hydrocodone-only extended release medications that are not in an abuse deterrent formulation. The Division of Health Care Quality prepared the letter and requested the Board to adopt.

ACTION: Motion by K. RYLE, seconded by J. DEVITA, and voted unanimously to adopt the circular letter.

5. **Agenda Items for Future Flex Sessions**

- Enhancement of Policy 14-02 (Board Delegated Complaint Review)
- Self-reporting of CE deficiencies
- MA Law CE (A. YOUNG)

IX. LUNCH 12:28 p.m. – 1:04 p.m.

TOPIC:

X. ADJUDICATORY SESSION

DISCUSSION: None

ACTION: At 1:04 p.m., motion by, J. DEVITA, seconded P. GANNON, and voted unanimously to enter into ADJUDICATORY Session.

TOPIC:

IX. M.G.L. c. 112 §65C SESSION

DISCUSSION: None

ACTION: At 1:05 p.m., motion by, A. YOUNG, seconded P. GANNON, and voted

unanimously to enter into M.G.L. c. 112 65C 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 April 1, 2014 Regularly Scheduled Meeting
2. Application to Manage and Operate a New Community Pharmacy, Benams Pharmacy (Reconsideration)
3. Application for Renovation/Expansion Request for the Non-Sterile Compounding Area, CVS 2162, Children's Hospital
4. Application for Licensure as a Wholesale Distributor, Johnson & Johnson Health Care Systems
5. Regular Session Minutes of March 4, 2014
6. Applications approved pursuant to Licensure Policy 13-01, April 2014
7. Investigative Report in the Matter of PHA-2013-0153, CVS Pharmacy 498, DS3349
8. Investigative Report in the Matter of PHA-2013-0079, David Young, PH22919
9. Investigative Report in the Matter of SA-INV-3273, IntegriScript Inc., DS89726; SA-INV-3980, Jeanne Szwajkowski, PH27446
10. Investigative Report in the Matter of SA-INV-5204, Coram Specialty Infusion Services, DS3601
11. Investigative Report in the Matter of SA-INV-4452, Critical Care Systems, DS3330
12. Investigative Report in the Matter of SA-INV-0163, J.E. Pierce Apothecary, DS89745
13. Proposed Policy: PMP Continuing Education Required by Chapter 244, Policy 14-03
14. Proposed Policy Revisions: Board Delegated Complaint Review, Policy 14-02
15. Memorandum: Emergency regulations to 247 CMR 10.00
16. Circular Letter DHCQ 14-3-610: Prohibition of Prescribing and Dispensing of Any Hydrocodone Bitartrate Product in Hydrocodone-Only Extended-Release Formulation

Respectfully submitted,

Edmund Taglieri, RPh, MSM, NHA, Secretary