

COMMONWEALTH OF MASSACHUSETTS

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

September 9, 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		
8:45	III	APPLICATIONS <ol style="list-style-type: none"> 1. Sobi/Cardinal Health, Waltham – Wholesale Distributor 2. Boston Home Infusion, Dedham to Stoughton-Relocation 3. Coram CVS Specialty Infusion- Northborough- New Store 4. Village Fertility – Reconsideration of previous approved application 5. Johnson Compounding and Wellness Center- Renovation/Expansion 		
9:45	IV	APPROVAL OF BOARD MINUTES Draft August 5 , 2014 Regular Session Minutes		
9:50	V	REPORTS <ol style="list-style-type: none"> 1. Applications approved pursuant to Licensure Policy 13-01 2. Report of activities pursuant to Board Delegated Complaint Review Policy 14-02 	Reports	R. Harris D. Sencabaugh
9:55	VI	REGULATIONS: <ol style="list-style-type: none"> 1. Scheduling of additional meetings to discuss regulations required by c. 159 of the Acts of 2014 		D. Sencabaugh

	VII	POLICIES: <ol style="list-style-type: none"> Revisions to Administrative Policy 14-02, Board Delegated Complaint Review 		
10:30	VIII	FLEX SESSION <ol style="list-style-type: none"> Automated Pharmacy Systems Joint Guidelines: Policy 2010-02 Board Update <ol style="list-style-type: none"> Introduction of Sela Striligas and Nil Patel - Interns NABP Red Flag Video NABP Interactive Board member Forum-Dec 2-3 Electronic faxes (electronic prescriptions that get converted to faxes) National Drug Take Back Day 795 Compliance Inspection Tool- Final Draft 		J. Devita K. Ryle D.Sencabaugh
11:30	IX	FILE REVIEW <ol style="list-style-type: none"> SA-INV-3634, Smart Pak Equine, DS3320 SA-INV-4418, PharmaHealth Pharmacy, DS3056 SA-INV-4785, Walgreens 4393, DS2882 		W. Frisch
12:30		LUNCH BREAK		
1:30	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"> 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
3:30	XI	M.G.L. c. 112, 65C SESSION		CLOSED SESSION
4:45	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, September 9, 2014

Board Members Present

Karen Ryle, RPh, President
Patrick Gannon, RPh, MS, President-elect
Edmund Taglieri, RPh, MSM, NHA,
Secretary
James DeVita, RPh
Timothy Fensky, RPh (arrive @ 9:00AM)
Jane F. Franke, RN, MHA
Anthony Perrone, MD
Richard Tinsley, MBA, Med (arrive @ 8:55AM)
Anita Young, RPh, EdD

Board Members Not Present

Joanne Trifone, R.Ph.

Board Staff Present

David Sencabaugh, RPh, Executive Director
Heather Engman JD, MPH, Board Counsel
Kelly Barnes, JD, RPh, Dir. Quality Assurance
David Dunn, RPh, Assistant Executive Director
Richard Harris, Program Analyst
William Frisch, Jr., RPh, Director of Compliance
Samuel Penta, RPh, Investigator
Anthony Bartucca, RPh, Investigative Consultant
Christina Mogni, RPh, Investigator
Steven Horn, RPh, Investigator
John Murray, RPH, Investigator
Paul Seed, RPH, Investigator

Board Staff Not Present

Cheryl Lathum, RPh, PharmD, Investigator
Leo McKenna, RPH, PharmD, Investigator

TOPIC:

I. CALL TO ORDER

DISCUSSION: A quorum of the Board was present. President K. RYLE opened the meeting and asked if anyone in the audience was recording the meeting; one individual indicated that they were recording the meeting. K. RYLE she indicated that the Board was recording the meeting.

ACTION: At 8:46 a.m. K. RYLE, called the September 9, 2014, meeting of the Board of Registration in Pharmacy to order.

TOPIC:

II. APPROVAL OF AGENDA

8:48AM

DISCUSSION: Assistant Executive Director D. Dunn reported that approval of August 5, 2014 Board Minutes would be deferred to a future meeting. -Director of Compliance W. FRISCH noted that the file review of PharmaHealth Pharmacy SA-INV-4418 would be deferred. Board Member J. DEVITA deferred the discussion of Automated Pharmacy Dispensing devices until September 30, 2014 meeting.

ACTION: Motion by P. GANNON, seconded by A. YOUNG, and voted unanimously to approve the agenda with the noted changes. R. TINSLEY, and T. FENSK, were not present for the vote.

TOPIC:

III. APPLICATIONS

1. Application for a Wholesale Distributor

SOBI, 890 Winter St., Suite 115, Waltham, MA.

R.TINSLEY and T. FENSKY were not present at the start of the discussion.

DISCUSSION: Deanna Patton, Licensing Consultant, and Scott Brewster, SOBI presented this application for a new wholesale distributor. SOBI, (Swedish Orphan Biovitrum) is a Swedish based pharmaceutical manufacturer of orphan drugs. SOBI currently distributes three orphan drugs in the United States through a restricted pharmacy network. Currently, SOBI distributes 1 ultra-orphan product to a Specialty Pharmacy in St. Louis, Dohmen Life Sciences. All products are shipped via a third party logistics coordinator. SOBI seeks licensure as Massachusetts is the home state for the wholesaler and licensure is necessary for SOBI to obtain licensures in other states. SOBI indicates that it does not take possession of any product and all pedigree and product tracking is the responsibility of the third party logistics coordinator. The Board was concerned with issuing a wholesale license to a virtual wholesaler. Board Counsel H. Engman informed the Board that it currently licenses two virtual wholesalers. Consultant Patton was asked if SOBI would be VAWD (Verified-Accredited Wholesale Distributor) accredited. Consultant Patton indicated that SOBI was not planning on being VAWD accredited. SOBI Representative Brewster in response to the Board inquiry indicated that product flow took place from SOBI to Dohmen Life Sciences to the patient. The Board showed concern for the licensing of wholesaler of this model as there would be very little for inspectors verify.

ACTIONS: Motion by E.TAGLIERI, seconded by, J. DEVITA and voted unanimously to approve the application for new wholesale distributor pending a successful inspection. R.TINSLEY and T. FENSKY were not present for all of the discussion and abstained from voting.

TOPIC

III. APPLICATIONS

2. Application for a Relocation of a Community Pharmacy

Boston Home Infusion, 30 Buckley Road, Stoughton, MA

Discussion: Robert Simmons, owner, Rachael Gallagher, MOR, Paul Murray representing Boston Home Infusion along with contractor Patrick Beatrice representing Filter Sales and Service, presented this application for relocated community pharmacy. Mr.

Simmons noted that they have secured a 10,000 square foot building on one acre of land. Mr. Simmons noted that once licensed Boston Home Infusion would move from its current facility located at 110 Stergis Way in Dedham. Board member E. TAGLIERI noted that the application omitted the desire to dispense narcotic controlled substances. MOR Gallagher indicated that she would work with Board staff to amend. MOR Gallagher indicated that, Boston Home Infusion would not be compounding any NIOSH or chemotherapy drugs. The Board showed concern for the continuity of care for patients during the transition from the Dedham to the Stoughton facilities. MOR Gallagher indicated that this would not be a concern as the pharmacy software would be redundant making the prescription processing seamless. The Board was concerned with the construction of the new modular clean room. Patrick Beatrice of Filter Sales and Service the contractor for the modular clean room provided a packet for Board members review outlining the construction of the clean room. Mr. Beatrice also showed Board members a sample of the materials that would be used in the construction.

Applicant requested a waiver of the regulation regarding a patient consultation area.

Board staff informed representatives from Boston Home Infusion that any equipment movement or additions after the room is certified would necessitate that the room be recertified prior to the compounding and dispensing of any compounded products.

ACTIONS: Motion by R.TINSLEY, seconded by T. FENSKY, and voted unanimously to approve the Boston Home Infusion Application for Relocation of a Community Pharmacy, conditioned on a satisfactory inspection and to approve the requested waiver.

TOPIC:

III. APPLICATIONS

3. Application for a New Community Pharmacy

Coram Healthcare Corporation of Massachusetts, 367 West Main St., Unit F, Northborough, MA.

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

DISCUSSION: MOR, John Consoletti; and Erik Heikkenen, Director of Licensure and Certification for Coram / CVS presented this application for a new community pharmacy. MOR Consoletti indicated that this would be the second Massachusetts facility for Coram. The Northborough facility would be smaller than the current Norwood location. MOR Consoletti indicated that the new facility would provide expedited first dose response for patients located in central and western Massachusetts. MOR Consoletti indicated that the new Northborough facility would not be compounding NIOSH or chemotherapy drugs. MOR Consoletti indicated that the Norwood facility would be providing weekend coverage for the Northborough facility which will not operate on the weekends. The pharmacy will not engage in non-sterile compounding. There will be no walk-in patients. There was confusion on the part of Coram, regarding the issuance of waivers to 247 CMR due to the nature of the facility. Coram to request waivers for: 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. 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. 247 CMR 9.01 (16) A pharmacist shall not refuse to compound customary pharmaceutical preparations except upon extenuating circumstances. Board staff to work with Coram representatives to assist Coram with its' application for waivers.

ACTION: Motion by P.GANNON, seconded by, T. FENSKY, and voted unanimously to approve the Coram / CVS Specialty Infusion Application for a New Community Pharmacy, with waivers, conditioned upon a successful inspection and receipt of amended page 7 of the Application and formal written request for waivers.

TOPIC:

III. APPLICATIONS

**4. Reconsideration of previous approved application
Village Pharmacy, 355 Bear Hill Road, Suite B, Waltham, MA**

DISCUSSION: Stuart Levine, Owner, Julia Norowski, MOR, Charles Young, and Lori Bassinger (Gates HealthCare) presented a letter for reconsideration of a previous Board approval of Village Pharmacy license with probationary status.

On July 1, 2014 the Board had voted to approve Village Pharmacy's Application to Operate and Manage a New Community Pharmacy. The license was approved, but conditioned upon Village Pharmacy entering into a consent agreement for probation that would run congruently with the probation of its sister pharmacy, Village Pharmacy (DS89658) which would share a common wall and be owned by the same management team currently on probation. The Board voted to approve with the probationary status so to not permit other owners faced with Board discipline a means for avoid discipline by opening a new facility.

Representatives from Village Pharmacy informed the Board that there would be no compounding taking place at the new Village Pharmacy. Village Pharmacy representatives informed the Board that the sole reason for the new pharmacy was to provide continuity of care for Express Scripts commercial customers that they were currently servicing through their specialty pharmacy agreement with Express Scripts the specialty pharmacy provider agreement prevents Village Pharmacy from providing traditional prescription services to Express Scripts commercially insured customers that our patients of Village Pharmacy. Board member R. TINSLEY had concerns of setting precedent that removing the probationary requirement would allow others owners to avoid Board discipline. The Board was concerned with fragmenting of patient care and wanted to be consistent with other organizations that may have stores on probation while opening new locations noting chain pharmacies.

ACTION: Motion by A.YOUNG, seconded by, T. FENSKY and voted by majority. to rescind the July 1, 2014 vote regarding approval with probationary status for Village Pharmacy's Application to Operate and Manage a New Community Pharmacy. R.

TINSLEY opposed.

ACTION: Motion by A. YOUNG, seconded by T. FENSKY and voted by majority approve Village Pharmacy's Application to Operate and Manage a New Community Pharmacy conditioned upon receipt of an attestation by the MOR that she has read CMR 247 and a successful inspection. R. TINSLEY opposed.

Break 9:55AM – 10:07AM

TOPIC:

III. APPLICATIONS

5. Renovation/Expansion

**Johnson Compounding and Wellness Center, 577 Main St. Waltham, MA.
DS3579**

E TAGLIERI stepped out of the room and was not present during the discussion or vote for this matter.

DISCUSSION: Janelle Ogle, Johnson Compounding and Wellness Center, and Ernest Gates, consultant Gates HealthCare presented the Application for Renovation / Expansion. Ms. Ogle outlined that Johnson Compounding and Wellness Center operates in a former Bank of America building and has acquired the space formerly used for the automated teller machine (ATM). Johnson's plan is to incorporate this space as a NIOSH compounding room. Ernest Gates of Gates HealthCare provided a detailed construction plan. Mr. Gates reports that all work is taking place within the newly acquired space and no breach of the wall between the existing compounding area and the new NIOSH space will take place without the Board's approval of the application. Mr. Gates indicated that once the Board approves and construction is complete the wall separating the new from the existing space will be breached and a sealed door will be installed to create negative pressure environment in the new NIOSH compounding space. Johnson Compounding and Wellness Center has been cooperating with Board staff and will supply a containment strategy for the construction dust and agrees to conduct additional environmental monitoring of particulate counts. Director of Quality Assurance Kelly Ann Barnes and Director of Compliance William Frisch noted Johnson's collaboration and cited the increased environmental monitoring was out of an abundance of caution.

ACTION: Motion by J.DEVITA, seconded by A. YOUNG, and voted unanimously to approve the Johnson Compounding and Wellness Center Application for Renovation / Expansion. Inspection will be required following the renovation.

TOPIC

IV. APPROVAL OF BOARD MINUTES

1. August 5, 2014, Regular Session of the Board

DISCUSSION: Deferred.

TOPIC:

V. REPORTS

1. Applications Approved Pursuant to Licensure Policy 13-01

DISCUSSION: R. HARRIS distributed a September 9, 2014, report which noted thirteen (13) change of managers, seven (7) renovations and three (3) closing of community pharmacies that had been approved pursuant to Licensure Policy 13-01.

ACTION: So noted.

2. Applications Approved Pursuant to Licensure Policy 14-01

DISCUSSION: R. HARRIS distributed a September 9, 2014, report which noted the good moral character application for a pharmacist that had been approved pursuant to Licensure Policy 14-01.

ACTION: So noted.

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

DISCUSSION: D. SENCABAUGH distributed a report which noted that on August 26, 2014, thirty (30) Board Delegated cases were reviewed. The Board member present was E.TAGLIERI. There were 10 cases that resulted in discipline, eighteen (18) closed staff assignments or dismissed complaints; one (1) case was referred back to OPP for investigation.

Discussion: J.DEVITA desires to see an addition to the summary noting the number of cases that pertained to the policies of Board Delegated Complaint Review

ACTION: So noted.

4. Revisions to Administrative Policy 14-02

DISCUSSION: D. SENCABAUGH and H. ENGMAN proposed revisions to the Board Delegated Complaint Review policy that would allow BDCR to act on certain staff assignments and complaints regarding pharmacy controlled substances losses and confidentiality violations. J. DEVITA recommended some typographical and formatting changes.

VOTE: Motion by P. GANNON, seconded by J. FRANKE, and voted unanimously to approve the revised policy with suggested changes.

TOPIC:

VI. Regulations

1. The Scheduling of additional meetings to discuss regulations required by c.159 of the Acts of 2014

DISCUSSION: Executive Director, D.SENCABAUGH, distributed to Board members a list a proposed additional meeting dates for the Board to review. Board members were asked to select dates they were unable to attend and leave with Board staff at the conclusion of the meeting. The Board members were informed that Board staff would use the information to establish future Board meetings.

ACTION: So noted.

TOPIC:

VII. FLEX SESSION

1. Automated Pharmacy Systems Joint Guidelines: Policy 2010-02 deferred to a future

meeting

2.Board Update: Introductions

Executive Director D. SENCABAUGH, introduced Stella Striligas and Nil Patel, pharmacy interns from MCPHS and Northeastern University respectively,

3. NABP Red Flag Video

DISCUSSION: Board President K. RYLE introduced the NABP 12 minute video titled “Red Flag” Increasing Pharmacists’ Awareness of Drug Diversion’. The video presentation was shown on the projection screen. The video is designed for pharmacists and technicians to identify behaviors that maybe consistent with a patient seeking to divert controlled substances. Board member A.YOUNG commented that the video has been well received at Continuing Education Programs.

ACTION: So noted.

4. NABP Interactive Board Member Forum – December 2-3

DISCUSSION: Board President K. RYLE introduced the NABP Interactive Member Forum. NABP invites a Board member to their offices to review NABP program offerings. It was noted that board member J.TRIFONE had attended in the past. K. RYLE recommended that P.GANNON attend as in coming President of the Board. Executive Director D. SENCABAUGH noted that when notified by NABP board staff would coordinate with P.GANNON for his attendance.

ACTION: So noted.

5.National Drug Take Back Day

DISCUSSION: Assistant Executive Director D. Dunn provided materials to Board members for National Drug Take Back Day scheduled for September 27, 2014. Members were provided an overview and a list of collection sites throughout Massachusetts.

ACTION: So noted.

6.<795> Compliance Inspection Tool-Final Draft

DISCUSSION: Executive Director D.SENCABAUGH, updated the Board on the <795> Compliance Inspection Tool. Board members made aware that this new inspectional tool will be utilized by OPP Pharmacy Compliance Inspectors in two-weeks. W. FRISCH acknowledged the work of Joseph Sceppa and Erica Robinson in the development of the inspectional tool. The Board was concerned with the feedback Board staff had received regarding the new inspectional tool. Executive Director D. SENCABAUGH, informed the Board of three stake holder meetings that would be scheduled later in September to seek input on the new tool.

ACTION: So noted.

7.Electronic Faxes

DISCUSSION: President K. Ryle introduced the topic of electronic prescriptions from prescribers that do not conform to the electronic switch provider such as SureScript. President K. Ryle informed the Board that if the electronic prescription from the prescriber’s software does not meet format requirements the switch provider may convert the electronic

prescription to a fax document. The issue is that the fax document does not comply with the regulatory requirements of a prescription. Board members were informed that third party auditors were seeking to take back payments made to pharmacies for the non conforming prescriptions. T. FENSKY confirmed the take back by third party auditors for the non-conforming prescriptions. J.DEVITA and T. FENSKY agreed to obtain additional information on this topic and report back to the Board.

ACTION: So noted.

TOPIC:

VIII. FILE REVIEW

1. SA-INV-3634, **Smart Pak Equine**, Plymouth, DS3320

DISCUSSION: This complaint was presented by investigators A. BARTUCCA and S.PENTA. As a result of a February 19, 2014 retail and <795> compliance inspection, OPP investigators noted multiple deficiencies which included, lack of documentation to confirm staff competency, technician not gloved while compounding, lack of a quality assurance program for compounding, lack of procedures to prevent cross-contamination, lack of suitable equipment for compounding, lack of appropriate cleaning of compounding utensils after use, lack of Primary Engineering Controls to provide negative airflow with a minimum of twelve (12) air exchanges, lack of standards for operations for personnel and cleaning. Former MOR Gutierrez submitted a detailed plan of correction for the observed deficiencies. A re-inspection of the facility by OPP compliance investigators S.PENTA and L.MCKENNA, on May 10, 2014 yielded a satisfactory inspection.

ACTION: Motion by A.YOUNG, seconded by P.GANNON, and voted unanimously to close the staff assignment with discipline not warranted.

TOPIC:

VIII. FILE REVIEW

2. SA-INV-4393, **Walgreens #4393**, 54 Elliott St., Beverly, DS2882

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

As a result of a general inspection, the Board alleges that Walgreens Pharmacy #4393 failed to conduct pharmacy operations in accordance with 247 CMR 9.01, USP <795>, and 247 CMR 6.02. Specifically, Board investigators observed multiple compounded products of hazardous and non-hazardous powders without the use of a powder hood; an incorrect mask was used for compounding powdered APIs; lack of a dedicated sink; use of a soiled and rusted sink, an automated dispensing machine (ADM) with visible powder contamination, and multiple soiled ceiling tiles in the pharmacy dispensing area.

This pharmacy is a large volume, regional compounding center for Walgreens.

MOR Christina Muniz responded that: a powder hood is not required as hazardous APIs are no longer used; the personnel interviewed by the investigators were new and identified the wrong mask to the investigators; personnel protective equipment has been ordered (including ventilator masks and gowns); the sink has been replaced; more frequent cleaning rotation of the ADM, and ceiling tiles are being replaced.

Inspector PENTA plans a follow-up focused USP <795> inspection and plans to check with other states as to when to use powder hoods (e.g., not just for hazardous APIs).

ACTION: Motion by P. GANNON, seconded by T.FENSKY, and voted unanimously, to close the staff assignment on **Walgreens Pharmacy #4393**, with discipline not warranted.

