

COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE REGULARLY SCHEDULED MEETING

239 Causeway Street, Fourth Floor Room 417A
Boston, MA 02114

Tuesday, March 3, 2015

Board Members Present

Patrick Gannon, RPh, Present (arrives @ 9:02AM)
Edmund Taglieri Jr., RPh, President-elect
Richard Tinsley, MBA, MEd, Secretary
Catherine Basile, PharmD, RPh
K. Conley, DNP, RN, AOCN, NEA-BC
Susan Cornacchio, JD, RN
Timothy Fensky, RPh, FACA
Michael Godek, RPh

Board Member Not Present

Garrett Cavanaugh, RPh.
William Cox, CPhT

Board Staff Present

James Lavery, JD, Director, Health Professions Licensure
David Sencabaugh, RPh, Executive Director
David Dunn, RPh, Assistant Executive Director
Heather Engman, JD, MPH, Board Counsel
Kelly Ann Barnes, RPh, JD, Director of Pharmacy Quality Assurance
William Frisch Jr., RPh, Director of Pharmacy Compliance
Samuel Penta, RPh, Senior Pharmacy Investigator
Christina Mogni, RPh, Pharmacy Investigator
Monica Vasquez, Compliance Office
Colleen Collins, RPh, Contract Pharmacy Investigator
Richard Harris, Program Analyst

TOPIC I.

CALL TO ORDER

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

ACTION: At 8:36 AM E.TAGLIERI, called the March 3, 2015, meeting of the Board of Registration in Pharmacy to order. Board member attendance was indicated by roll call: E. TAGLIERI; yes, R.TINSLEY; yes, C.BASILE; yes, K. CONLEY; yes, S. CORNACCHIO; yes, T FENSKY; yes; M GODEK; yes, P GANNON was not present at the time of roll call.

TOPIC II.

APPROVAL OF AGENDA

Time 8:38AM

DISCUSSION: D. SENCABAUGH asked that the Pharmacist Re-Entry Policy be removed from the Flex Session portion of the Agenda

ACTION: Motion by R.TINSLEY, seconded by K. CONLEY, and voted unanimously to accept the agenda with the noted change. P. GANNON was not present for the discussion or vote of this matter.

TOPIC III.

APPROVAL OF MINUTES

1. Draft, September 30, 2014, Regular Session Minutes

DISCUSSION: None

ACTION: Motion by R. Tinsley, seconded by T. FENKY, and voted unanimously to approve the September 30, 2014, Regular Session Minutes. C. BASILE, K. CONLEY, S. CORNACCHIO, M. GODEK, abstained from the vote. P. GANNON was not present for the discussion or vote on this matter.

2. Draft, October 9, 2014, Regular Session Minutes

DISCUSSION: None

ACTION: Motion by R. Tinsley, seconded by T. FENKY, and voted unanimously to approve the September 30, 2014, Regular Session Minutes. C. BASILE, K. CONLEY, S. CORNACCHIO, M. GODEK, abstained from the vote on this matter. P. GANNON was not present for the discussion or vote on this matter.

3. Draft, December 15, 2014, Regular Session Minutes

DISCUSSION: None

ACTION: Motion by C. BASILE, seconded by M. Godek, and voted unanimously to approve the December 15, 2014, Regular Session Minutes. S. CORNACCHIO, K. CONLEY, T. FENSKY abstained from the vote on this matter. P.GANNON was not present for the discussion or vote of this matter.

TOPIC IV.

REPORTS

TIME 8:42 AM

Applications Approved Pursuant to Licensure Policy 13-01

DISCUSSION: R HARRIS noted that during the past month there has been eleven (11) change of managers, and one (1) pharmacy closure.

ACTION: So noted

P.GANNON was not present for the presentation of the report.

TOPIC: V.
FLEX SESSION

1. Introduction of Pharmacy Intern James Kidd.
Was already completed during the call to order.

2. March 24, 2015 evening meeting

D. SENCABAUGH informed the Board that a regulations meeting has been scheduled for March 24, 2015 from 5:30 – 8:30 pm. The attendance of Board members is vital.

3. March 27, 201 Advisory Committee meeting

D. SENCAUGH informed the Board that the meeting would discuss the purpose and mechanics of the advisory committee and encouraged Board members to attend and meet the members of the Pharmacy Advisory Committee.

4. Board member involvement in NABP

D. SENCABAUGH encouraged Board members to become active with NABP, noting that a gap had been left with the departure of prior Board members who had represented the Massachusetts Board at the NABP. The services NABP provides to the Board were noted.

5. Ratification of the Plan of Correction (POC) policy 13-02

DISCUSSION: W. FRISCH explained Policy 13-02 and asked the Board for ratification. There was no further discussion.

ACTION: Motion by T. FENSKY, seconded by K. CONLEY and voted unanimously to approve Policy 13-02 Plan of Correction. P GANNON was not present for the discussion or vote on this matter.

6. Update on pharmacy practice inquiries to the Board

K. BARNES explained the inquiry process and tracking tool and provided data regarding email inquiries received by Board staff from April through December of 2014. The Board was shown on the screen a break-down for the four hundred and Sixty four (464) responded to and review by K. BARNES and her APPE rotation students. K. BARNES acknowledged the work of Pharmacy Intern Emily Walker for her organization of the data and formation of the slide. K. BARNES indicated that practice inquiries process has proven to be beneficial for both the students and licensees, providing timely and consistent answers to licensees' questions. K. BARNES indicated that she would continue the tracking program looking to incorporate a tracking of phone calls handled by Board Staff.

7. Guidelines for pharmacist continuing education: Sterile & Non-Sterile Compounding

K. BARNES presented the Board with a draft Policy Guidelines for Pharmacist Continuing Education Requirements: Sterile & Non-Sterile Compounding. The purpose

of the policy is clarify for pharmacist the educational requirements established by chapter 159 of the Acts of 2014. The Board discussed which pharmacists should be considered “engaged in” compounding, which Continuing Education (CE) would meet the requirement for compounding, and how compounding CEs would be monitored. It was agreed that the term “engaged in” in the statute is vague and it is necessary to include a definition in the regulations along with legislative intent. The guidelines were not acted on and would be brought back to the Board at a future meeting

BREAK

9:35-9:47

TOPIC VI.
APPLICATIONS

VI. APPLICATIONS

1. Application for Licensure as a Wholesale Distributor 9:48 AM

Rotem, Inc. 461 Boston Road, Unit 4D Topsfield, MA

DISCUSSION: Peter Foti, Director of US Operations, and Kathy Ceifert, Director of Regulatory Affairs, presented this application. Rotem, Inc. is seeking licensure as a limited service wholesale distributor of sodium chloride and sterile water for injection, to manufacturers and nuclear pharmacies.

Currently, Rotem plans only to carry C-VI drugs, but they were asked to submit information to the Board if, and when, that should change.

ACTION: Motion by R. TINSLEY, seconded by E. TAGLIERI, and voted unanimously to approve the application, pending a successful inspection.

TOPIC:

VI. APPLICATIONS

2. Application for Transfer of Ownership of a Community Pharmacy

Crawford Drug, LLC. 1735 Dorchester Ave, Dorchester, MA

DISCUSSION: AED David Dunn reported to the Board that Crawford Drug LLC has submitted a transfer of ownership request. Owner / MOR Norman Kinan has transferred ownership to his son MOR Steven Kinan and grandson Michael Wilson, RPh. There will be no changes to the name of the facility or policies and procedures of Crawford Drug.

ACTION: Motion by C. BASILE, seconded by, M. GODEK, and voted unanimously, to take approve the transfer of ownership conditioned on a successful re-inspection.

TOPIC:

VI. Applications

9:59AM

Review of Application for renovation / expansion and review of request to initiate sterile compounding

Boulevard Compounding Center, 149 Shrewsbury Street, Worcester, MA

Joseph Rossetti, Owner / MOR presented the case for Boulevard Compounding Center, to perform sterile compounding. Although they had done sterile compounding in the past, they have not done so since the full scale inspection of sterile compounders back in late 2012 and early 2013. They voluntarily ceased sterile compounding in approximately October 2012 and commenced plans to renovate their facility, so as to conform to USP 797 guidelines before resuming sterile compounding.

W. FRISCH presented and summarized a memorandum and timeline regarding Boulevard. The timeline indicated Mr. Rossetti and Mr. Gene Svirsky presented the renovation plans at the October 1, 2013 Board of Pharmacy Meeting. The Board approved the plans for the renovation at that time, pending successful inspection.

On June 27, 2014, Senior Investigators Penta and McKenna inspected Boulevard Compounding Center and found them sufficiently compliant for non-sterile (<795>) compounding, but the sterile component was not ready at that time. Beginning sometime in September of 2014, OPP was contacted by a consultant for Boulevard (BLVD), to trigger the final approval process. However, Director of Pharmacy Compliance, William Frisch, noted a number of outstanding issues, including training of staff, formulation worksheet questions, environmental testing, BUD dating, and other items required to demonstrate the competency required for sterile compounding, particularly for high-risk sterile compounding, as was described in BLVD's business model.

Director Frisch made it clear that Mr. Rossetti and BLVD have been very cooperative in responding to requests, but that still, there were issues to resolve, including the training required for MOR Rossetti and RPh Arakelian.

MOR Rossetti has been given a list of items to complete, and was asked by Board President Gannon if he understood what he needed to do in order to begin sterile compounding. MOR. Rossetti responded in the affirmative, and it was made clear by the Board, that that he would still need final approval before commencing "high-risk" sterile compounding.

ACTIONS: Motion by T. FENSKY, seconded by, M. GODEK, and voted to APPROVE initiation of low and medium risk level sterile compounding, provided the following conditions are met:

Minutes of the Regularly Scheduled Meeting held March 3, 2014
Approved April 7, 2015.

1. Boulevard submits documentation satisfactory to Board staff demonstrating that pharmacists Joseph Rossetti and Geraldine Arakelian, and any technician that will engage in sterile compounding, underwent formal training regarding sterile compounding and United States Pharmacopeia General Chapter 797 (“USP 797”). The training must include, but should not be limited to, Aseptic Technique, Hand Hygiene and Garbing, and Cleaning and Disinfecting.
2. Boulevard submits documentation satisfactory to Board staff demonstrating that pharmacists Joseph Rossetti and Geraldine Arakelian, and any technician that will engage in sterile compounding, successfully pass media fill tests and gloved fingertip/thumb sampling, in accordance with USP 797. The media fill tests shall represent the most challenging conditions encountered during sterile compounding at the pharmacy.
3. Boulevard submits documentation satisfactory to Board staff demonstrating that pharmacists Joseph Rossetti and Geraldine Arakelian, and any technician that will engage in sterile compounding, are successfully trained in the storage, handling, and disposal of hazardous drugs, in accordance with USP 797.
4. Boulevard enters into an Agreement with the Board that requires Boulevard to refrain from all high risk level sterile compounding until the pharmacy: (a) validates the sterility, stability, and beyond use dates of its high risk level products in accordance with USP 797; (b) submits complete formulation worksheets; (c) submits documentation demonstrating that all personnel engaged in high risk level sterile compounding completed formal training in high risk level sterile compounding and media fill tests in accordance with USP 797; and (d) receives written approval from the Board to engage in high risk level sterile compounding.

Boulevard *may not* engage in any low or medium risk level sterile compounding until the conditions described above are met and Boulevard receives written approval from the Board to begin low and medium risk level sterile compounding.

Final vote was YES by a majority vote of 5 in the affirmative and 3 in the negative. Board Members K. CONLEY, P. GANNON, and E. TAGLIERI opposed.

TOPIC

VI. APPLICATIONS

Update Change in Business Model

Soleo Health, 5 Shawmut Rd., Suite 103, Canton, MA

DISCUSSION:

The Board received a letter from MOR Smith regarding a change in the business model for Soleo Health. At the February 3, 2014, the approved Soleo Health's application to operate a New Community Pharmacy pending receipt of waivers and a successful inspection. In her letter MOR Smith indicates that construction of the new facility has been delayed impacting the ability to service patients. MOR Smith indicates that Soleo Health desires to lease a space adjacent to the new pharmacy in order to provide patients with non-compounded product Immunoglobulin and Factor products.²

ACTION: Motion by R. TINSLEY, seconded by K. CONLEY, and voted unanimously to approve the use of the temporary space, until such time as the permanent space has been completed, subject to successful inspection. The space can be used temporarily for six (6) months maximum. Any additional time needed would have to be approved by the Board.

TOPIC

VII. FILE REVIEW

1. SA-INV-4430, Gary Drug, DS3937

10:47 AM

Investigation report Presented and Summarized by: M. VASQUEZ

DISCUSSION: On July 5, 2013, the OPP was notified by the Florida Attorney General, that Greenfield Enterprises, Inc. DBA Gary Drug Company, had purchased pharmaceuticals from Countrywide Distributors, which was change with, "Trafficking in Contraband Prescription Drugs, Conspiracy to Traffic in Contraband Prescription Drugs, Organized Scheme to Defraud, and Money Laundering. OPP investigators inspected the facility in July of 2013 and found no evidence of purchases of pharmaceuticals from Countrywide Distributors by the licensee. H. ENGMAN added that the Florida Attorney Generals office was also unable to provide evidence of purchases by the Gary Drug.

Action: Motion by M. GODEK, seconded by C. BASILE, and voted unanimously to close the Staff Assignment SA-INV-4430 due to insufficient evidence.

2. SA-INV-5084, CutisPharma, Inc. WD466,

Investigation report Presented and summarized by: M. VASQUEZ

DISCUSSION: Staff Assignment was opened in response to concerns that convenience compounding kits manufactured by CutisPharma were not in compliance with USP <795>. On April 11, 2014, OPP investigators conducted a relocation compliance inspection and found no deficiencies of Board regulations. W. FRISCH offered that the Cutis Pharma, Inc., is a manufacturer, possessing both FDA and Drug Control Program licensure. W. FRISCH noted that it is not necessary to have both a DCP and Board

wholesale distributor license. The Board of Pharmacy Wholesale Distributor license subsequently expired.

ACTION: Motion by T. FENSKY, seconded by C.BASILE, and voted unanimously to close Staff Assignment SA-INV-5084 with no violation.

3. SA-INV-5082, Medicine Shoppe, DS89894

Investigation report Presented and summarized by: C. MOGNI

DISCUSSION: The OPP was notified by the Drug Control Program, that during an inspection of a clinic it was found that the Medicine Shoppe had provided Massachusetts controlled substance to the clinic without a valid prescription. A routine compliance inspection was conducted in March 2014. MOR Patel purchase the Medicine Shoppe in November of 2013. A review of the records, during a March 2013 compliance inspection indicated that the process of supplying the clinic with medication took place from March of 2012 thru September of 2013 under the previous owner. The compliance inspection yielded multiple deficiencies which were addressed by MOR Patel via a plan of Correction. The Medicine Shoppe was inspected for routine compliance in April 2014 and was deemed to be satisfactory.

ACTION : Motion by C. BASILE seconded by K. Conley, and voted unanimously to close Staff Assignment SA-INV-5082 , discipline not warranted because process of supplying clinic with medication occurred prior to the involvement of current owner/MOR.

4. PHA-2014-0212; Richard Tilton, PH14138 10:49AM

Investigation report Presented and Summarized by C. MOGNI

DISCUSSION: Pharmacist Tilton was the former Owner/ MOR of the Prescription Shoppe in Beverly. In response to the companion complaint Pharmacist Tilton admitted to supplying Massachusetts controlled substances (antivirals and antibiotics) to a clinic for dispensing to patients, in violation of 247 CMR 7.02 (1).

ACTION: Motion by Taglieri, seconded by T.FENSKY, and voted unanimously to refer the matter to the Office of Prosecution for the issuance of an Order to Show Cause authorizing resolution of this matter with a Consent Agreement for non disciplinary stayed probation with terms to include, five (5) contact hours of continuing education and an attestation that the registrant has read and review M.G.L c. 94-C.

5. SA-INV-5112, Walgreens 15390, 10:58AM

Investigation report Presented by Christina Mogni

Recusal: Michael Godek recused himself and was not present for the discussion or vote on this mater.

DISCUSSION: The Board discussed the nature of the complaint against the Walgreens Well Experience model regarding confidential patient information and mentioned concerns about controlled substances security. The complaint was dismissed because it

was about the model itself and not about specific deficiencies at the drug store in question, which showed no evidence or concern of unauthorized PHI disclosure.
ACTION: Motion by E. TAGLIERI, seconded by C. BASILE, and voted unanimously to Close Staff Assignment SA-INV-5112 with no violation

6. SA-INV-5202, The Whittier Pharmacist, DS3587 11:01AM

Investigation report Presented and summarized by Colleen Collins
RECUSAL: Board Member Ed Taglieri recused himself from this discussion and vote.
DISCUSSION: On 12/20/2013, The Office of Public Protection received a mandatory self-report of a Disclosure of Abnormal Results from The Whittier Pharmacist. Specifically, it was reported that on November 14, 2013, one air impaction sample obtained in one pharmacy barrier isolator, had exceeded the recommended quantity for colony forming units (CFU's) as recommended by USP 797.

According to MOR Luciano, The Whittier Pharmacist did not use PEC1 per protocol when notified of the Abnormal Result from B & V Testing and that PEC1 was not used from 12/3/13 until 1/9/14, when preliminary reports came back showing no growth.

On 3/9/14, was inspected for <797> Compliance by the OPP, and was assessed as satisfactory. On April 30, 2014, the OPP received the Plan of Correction, which indicated that 10 specific corrective measures had been implemented.

ACTION: Motion by R.TINSLEY, seconded by T. FENSKY and voted unanimously to close the Staff Assignment with discipline not warranted.

7. PHA-2014-0097, Home Solutions, DS89639 11:04AM

Investigation report Presented and Summarized by: C. MOGNI
DISCUSSION: Pharmacy failed to conduct viable air sampling after cleanroom modifications in violation of USP<797>, discovered upon inspection. Pharmacy voluntarily closed and conducted proper environmental monitoring and had successful inspection prior to re-opening.

MOR Norcross voluntarily ceased compounding and initiated remediation efforts. POC submitted included retraining on recertification requirements and viable sand non-viable environmental monitoring. W.Frisch noted: Pharmacy has recently undergone a major overhaul to HVAC and other physical plant improvements.

Board staff noted remediation and POC were sufficient, no further remediation is necessary and recommended the complaint be closed discipline not warranted.

ACTION: Motion by C. BASILE, seconded by E.TAGLIERI, and voted unanimously to dismiss complaint PHA-2014-0097, with discipline not warranted.

**TOPIC VIII.
REGULATIONS**

Time:11:08 AM- 12:35PM

1. Proposed amendments to 247 CMR 9.00 Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies, and Pharmacy Departments.

DISCUSSION: The draft proposed regulation was displayed on screen for Board members and the audience to view. Board Counsel H. ENGMAN captured Board members concerns and changes to the Draft document via track changes on screen for Board members and the audience to view.

LUNCH BREAK 12:35PM – 1:35PM

TOPIC IX.

Executive Session (M.G.L. c. 30A, §21(a))

TIME: 1:36PM

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

ACTION: Motion by E. TAGLIERI, seconded by C. BASILE, and voted unanimously by roll call to enter into Executive Session. P.GANNON; yes, E. TAGLIERI; yes, R.TINSLEY; yes, C. BASILE; yes, K. CONLEY; yes, S.CORNACCHIO; yes, T.FENSKY; yes, M.GODEK; yes.

TOPIC X.

M.G.L c. 112§ 65C SESSION

TIME: 1:54PM

DISCUSSION: None

ACTION: Motion by T.FENSKY , seconded by M.GODEK, and voted unanimously to enter into M.G.L. c. 112 65C Session.

TOPIC XI.

ADJOURN MEETING

TIME: 4:45PM

DISCUSSION: NONE

ACTION: Motion by, E.TAGLIERI, seconded by T. FENSKY, and voted unanimously to adjourn the meeting

Respectfully submitted,

Richard J. Tinsley, MBA, M.Ed.
Secretary

LIST OF EXHIBITS USED DURING THE GENERAL SESSION

1. Preliminary Agenda for the March 3, 2015, Scheduled Meeting
2. Draft Regular Session Minutes, September 30, 2014 Meeting
3. Draft Regular Session Minutes, October 9, 2014 Meeting
4. Draft Regular Session Minutes, December 15, 2014 Meeting
5. Application Wholesale Distributor, Rotem Inc.
6. Notice of Transfer of Ownership, Crawford Drug
7. Application for Renovation / Expansion and request to initiate sterile compounding- Boulevard Pharmacy
8. Soleo Health, Inc. letter
9. Report licenses approved pursuant to Licensure Policy 13-01
10. Draft Guidelines for pharmacist Continuing Education : Sterile and Non-Sterile Compounding
11. Plan of Correction Policy 13-02
12. Investigative report in the matter of Gray Drug; DS3937, SA-INV-4430
13. Investigative report in the matter of Cutis Pharma; WD466, SA-INV-5084
14. Investigative report in the matter of The Medicine Shoppe 500; DS89894, SA-INV-5082
15. Investigative report in the matter of Richard Tilton; PH14138, PHA-2014-0212
16. Investigative report in the matter of Walgreens 15390; DS89867, SA-INV-5112
17. Investigative report in the matter of The Whittier Pharmacist; DS3587, SA-INV-5202
18. Investigative report in the matter of Home Solutions; DS89639, PHA-2014-0097
19. Proposed Regulations 247 CMR 9:00: Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies and Pharmacy Departments.
20. Proposed Regulations 247 CMR 9:00 Code of Professional Conduct: Professional Standards for Registered Pharmacists, Pharmacies and Pharmacy Departments with track changes.