

COMMONWEALTH OF MASSACHUSETTS

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

August 4, 2015
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 <ul style="list-style-type: none">Pharmacy Intern Introductions		
8:40	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">Draft of July 16, 2015 Regular Session MinutesDraft of June 30, 2015 Regular Session Minutes		
8:45	IV	APPLICATIONS <ol style="list-style-type: none">Bravo Pharmacy – New Community PharmacyMedminder Systems , Inc. – New Community PharmN-Molecular, Inc – Transfer of Ownership of a Nuclear Pharmacy		
9:30	V	REPORTS Applications approved pursuant to Licensure Policy 13-01	Reports	R. Harris
9:35	VI	REGULATIONS: Proposed amendments to 247 CMR 8.00: Pharmacy Interns and Technicians. Proposed new regulation, 247 CMR 17.00: Sterile Compounding.		H. Engman; D. Sencabaugh; K. Barnes; W. Frisch

11:15	VII	FILE REVIEW <ol style="list-style-type: none"> 1. PHA-2014-0245, Walgreens 2063, DS1741 2. PHA-2015-0075, Carmen Marie Iannuzzi, PH233061 3. PHA-2015-0076, Tiffany Leigh Bartke, PH233537 4. PHA-2015-0047, CVS 913, DS3437 5. PHA-2015-0093, Matthew Lariviere, PH233579 6. SA-INV-6752, Rite Aid 10151, DS3122 	
12:30		LUNCH BREAK	
1:30	VIII	EXECUTIVE SESSION <p>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> <p>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 violation of probation.</p>	CLOSED SESSION
2:30	IX	M.G.L. c. 112, 65C SESSION	CLOSED SESSION
5:00	X	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**

August 4, 2015

Board Members Present

Patrick Gannon, R.Ph., MS, President
Edmund Taglieri, Jr. R.Ph., President-Elect
Richard Tinsley, MBA, M.Ed., Secretary
Timothy Fensky, R.Ph, FACA
Garrett Cavanaugh, R.Ph.
Catherine Basile, Pharm D, R.Ph.
Susan Cornacchio, JD, RN.
William Cox CPht
Michael Godek, R.Ph.
Karen Conley, DNP, RN
Andrew Stein, Pharm D, R.Ph.
Phillippe Bouvier, R.Ph.

Board Members Not Present

Board Staff Present

David Sencabaugh, R.Ph, Executive Director
David Dunn, R.Ph, Associate Executive Director
Heather Engman, JD, MPH Board Counsel
Kelly Ann Barnes, JD, R.Ph, Director of Pharmacy
Quality Assurance
William Frisch, R.Ph, Director of Pharmacy Compliance
Richard Harris, Program Analyst
Monica Vasquez, Compliance Officer
Colleen Collins, PharmD, R.Ph. Contract Investigator
Christina Mogni, R.Ph. Investigator

TOPIC: I

CALL TO ORDER

DISCUSSION: P. GANNON called the meeting to order.

ACTION: At 8:30 AM on August 4, 2015, the regularly scheduled Meeting of the Board of Pharmacy was called to order. P. GANNON asked if anybody was recording the meeting. No one indicated that they were recording the meeting. P.GANNON indicated

that the Board was recording the meeting. Quorum was established by a roll call: P. GANNON; yes, E. TAGLIERI; yes, T. FENSKY; yes, S. CORNACCHIO; yes, C. BASILE; yes, K. CONLEY; yes, W. COX; yes, A. STEIN; yes, R. TINSLEY; yes, M. GODEK; yes, G. CAVANAUGH; yes, P. BOUVIER; yes.

TOPIC II.

APPROVAL OF AGENDA

Time: 8:33AM

DISCUSSION: W.FRISCH noted that the matter of Rite Aid 1051 would be deferred to a future meeting.

ACTION: Motion by C. BASILE, seconded by K. CONLEY and voted unanimously to approve the Agenda with the noted changes.

TOPIC III.

APPROVAL OF BOARD MINUTES

Time: 8:34 AM

Draft July 16, 2015, Regular Session Minutes

DISCUSSION: None

ACTION: Motion by M. GODEK, seconded by P. BOUVIER, and voted unanimously to approve the Draft of July 16, 2015, Regular

Draft June 30, 2015, Regular Session Minutes

DISCUSSION: K. CONLEY noted that her credentials were missing from cover page. A.STEIN noted typos of his name on pages 4 and 12.

ACTION: Motion by A. STEIN, seconded by C. BASILE and voted unanimously to approve the Draft June 30 , 2015 Regular Session Minutes with the noted changes.

TOPIC IV.

APPLICATIONS:

1. Bravo Pharmacy New Community Pharmacy Time:8:35 AM

DISCUSSION: Bravo was represented by owner Dimiti Linkov, MOR Richard Simon, R.Ph., and Attorney Paul Garbarini. This is an application for an independent, traditional community pharmacy, located in an urban area near the Jamaica Plain / Roxbury line. The plan is to open 6 days a week with on-call coverage, and they seek no waivers.

ACTION: Motion by M. GODEK, seconded by T. FENSKY, and voted unanimously to approve the Bravo application to Manage and Operate a New Community Drug Store, pending a successful compliance inspection.

2. Medminder New Community Pharmacy Time:9:00AM

DISCUSSION: A decision was made to defer this application discussion to a future meeting, considering Board member Phillippe Bouvier was identified as the MOR applicant. According to Board Counsel Heather Engman, the other 11 Board members need to notify the Ethics Commission before taking a vote involving a fellow Board member

ACTION: The Medminder representatives were given an apology. Every effort will be made for a swift resolution, and to get scheduled on the September 1, 2015 agenda.

3. N-Molecular, Inc. Transfer of Ownership Time: 9:23AM

DISCUSSION: N-Molecular was represented by VP of QAREHS Mr. David Pellicciarini, and Mr. Philip Nielson, R.Ph., who is the MOR of N-Molecular, which is located in Haverhill, MA. N-Molecular was previously owned by IBA Molecular North America, Inc. On 7/23/15, the company had an inspection by NABP, and currently, FDA is inspecting the facility, therefore Director of Compliance W. FRISCH pointed out that there would be no need to hold up the approval of the ownership change for a BOP inspection.

ACTION: Motion by C. BASILE, seconded by T. FENSKY and voted unanimously to approve the transfer of ownership of N-Molecular, Inc.

TOPIC V.
REPORTS

Applications Approved Pursuant to Licensure Policy 13-01 Time: 9:32AM

DISCUSSION: R HARRIS noted that during the past month there have been twenty (20) Change of Managers, one (1) renovation/expansions and two (2) nuclear pharmacist, approved by staff action.

ACTION: So noted

TOPIC VI.
REGULATIONS

TIME: 9:32AM- 10:01AM

1. Draft amendments to 247 CMR 8.00: Pharmacy Interns and Pharmacy Technicians.

DISCUSSION: The draft of the proposed amendments to 247 CMR 8.00 was presented to the Board for review. The document was displayed on the screen for the Board members and audience to see. H.ENGMAN captured the Board requests via track changes. The Board had discussion regarding the hours requirement for Pharmacy Intern and the fact that all the hours would be provided through the college of pharmacy

experiential programs. Board member C. BASILE reviewed the Board 2012 language on Pharmacy Intern hours. Board staff did seek to strengthen the need for a Pharmacy Intern to be enrolled and pursuing a PharmD degree. The new draft regulation also provided an opportunity for Pharm D graduates enrolled in a residency program at a Massachusetts facility the avenue to be licensed as a Pharmacy Intern without being enrolled in a college of Pharmacy. The new draft regulation also seek licensure for Pharmacy Technician Trainees and increased the maximum number of hours a Pharmacy Trainee could work from 1000 to 1200 hours prior to becoming to being licensed as a Pharmacy Technician.

ACTION: Motion by M. GODEK, seconded by T. FENSKY, and voted unanimously to approve the proposed amendments to 247 CMR 8.00 with incorporated changes made on August 4, 2015, (2) proceed with the administrative review process, and (3) if substantive changes are not required by the administrative review process, send the proposed amendments to 247 CMR 8.00 out for public comment and hearing.

2. Draft proposed new section 247 CMR 17.00 Sterile Compounding

DISCUSSION: Work continued on the draft of the proposed new section 247 CMR 17.00 was presented to the Board for review. The document was displayed on the screen for the Board members and audience to see. H.ENGSMAN captured the Board requests via track changes. K. BARNES and W. FRISCH lead the discussion with the Board members on the new sections that Board staff had worked on since the July 16th meeting. The new sections focused on clean room standards and the certification of those rooms and the engineering controls involved in the compounding process.

TOPIC VII (Kelly)

FILE REVIEW:

1. PHA-2014-0245; WALGREENS 2063, DS1741 TIME: 10:53AM

RECUSAL: M. GODEK recused himself, and was not present for the discussion or vote of this matter.

DISCUSSION: C. COLLINS presented and summarized the pertinent facts of the investigation. Routine compliance inspections conducted with multiple deficiencies noted by Investigators (June 20, 2014, October 8, 2014, February 23, 2015 and April 30, 2015). The inspections noted deficiencies that included: evidence of rodents, refrigerator maintenance issues, record keeping, and outdated medications. Former MOR Iannuzzi was the MOR during the first and second inspections (left as MOR on December 4, 2014). Current MOR Bartke was the MOR during the third and fourth inspections. The Board wanted to see more supervisory oversight and an updated Plan of Correction to for the store to attain and maintain full compliance.

ACTION: Motion E. 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 and

to authorize resolution of the matter with a consent agreement for a reprimand of Walgreens 2063 drugstore license.

TOPIC IX.

FILE REVIEW:

2. PHA-2015-0075; Carmen Marie Iannuzi , PH233061

Time: 10:59

RECUSAL:M. GODEK himself and was not present for the discussion or vote on this matter.

DISCUSSION: C. COLLINS presented and summarized the pertinent facts of the investigation. Routine compliance inspections conducted with multiple deficiencies noted by Investigators (June 20, 2014, October 8, 2014, February 23, 2015 and April 30, 2015).The inspections noted deficiencies that included: evidence of rodents, refrigerator maintenance issues, record keeping, and outdated medications. Former MOR Iannuzzi was the MOR during the first and second inspections (left as MOR on December 4, 2014). Current MOR Bartke was the MOR during the third and fourth inspections. The Board wanted to see more supervisory oversight and an updated Plan of Correction for the store to attain and maintain full compliance

ACTION: Motion E. TAGLIERI, seconded by K. CONLEY, and voted unanimously to refer the matter to the office of prosecution for the issuance of an order to show cause and authorize resolution of the matter with a consent agreement for a non-disciplinary stayed probation with terms to include; (a) 2 hours of pharmacist continuing education in the area of Pharmacy Law or Pharmacy Management; (b) Attest to reading 247 CMR section (6): Registration, Management and Operation of a Pharmacy or Pharmacy Department ; Section (9) Code of Professional Conduct; Professional Standards for Registered Pharmacist, Pharmacies and Pharmacy Departments; Section (15) Continuous Quality Improvement Program.

TOPIC VII

FILE REVIEW

3. PHA-2015-0076 Tiffany Leigh Bartke, PH233537

RECUSAL: M. GODEK recused himself and was not present for the discussion of vote on this matter.

DISCUSSION: C. COLLINS presented and summarized the pertinent facts of the investigation. Routine compliance inspections conducted with multiple deficiencies noted by Investigators (June 20, 2014, October 8, 2014, February 23, 2015 and April 30, 2015).The inspections noted deficiencies that included: evidence of rodents, refrigerator maintenance issues, record keeping, and outdated medications. Former MOR Iannuzzi was the MOR during the first and second inspections (left as MOR on December 4, 2014). Current MOR Bartke was the MOR during the third and fourth

inspections. The Board wanted to see more supervisory oversight and an updated Plan of Correction to for the store to attain and maintain full compliance.

ACTION: Motion E. TAGLIERI, seconded by K. CONLEY, and voted unanimously to refer the matter to the office of prosecution for the issuance of an order to show cause and authorize resolution of the matter with a consent agreement for a non-disciplinary stayed probation with terms to include; (a) 2 hours of pharmacist continuing education in the area of Pharmacy Law or Pharmacy Management; (b) Attest to reading 247 CMR section (6) Registration, Management and Operation of a Pharmacy or Pharmacy Department ; Section (9) Code of Professional Conduct; Professional Standards for Registered Pharmacist, Pharmacies and Pharmacy Departments; Section (15) Continuous Quality Improvement Program.

TOPIC VII

FILE REVIEW

4.. PHA-2015-0047; CVS 913, DS3437

RECUSAL: S. CORNACCHIO recused herself and was not present for the discussion or vote on this matter.

DISCUSSION: C. COLLINS presented and summarized the pertinent facts of the investigation. Pharmacy Compliance Investigators noted inspectional deficiencies on a routine retail compliance inspection on 8/8/14) deficiencies included: no counseling sign, pharmacist technician ratios, name tags, balance not sealed, incomplete compounding logs, no certified thermometers, temp logs inconsistently filled out, outdated CII not reconciled. A second retail compliance inspection conducted on 12/3/2014 resulted in inspectional deficiencies which included; balance not sealed, supervisory ratios, temp logs inconsistently filled out; vaccine temp logs inconsistently filled out; refrigerator temps out of range multiple times, Technician-in-training having worked greater than 1000 hours; corrosion sink faucet, 76 baskets stacked on counter. CVS 913 did submit a satisfactory Plan of Correction from the Pharmacy Supervisor. The board was concern that the store attain and remain in compliance in the future.

ACTION: Motion by T. FENSKY, seconded by C.BASILE and voted unanimously to Refer the matter to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter with a consent agreement for reprimand of CVS 913 drugstore license.

TOPIC VII

FILE REVIEW

5. PHA-2015-0093 Mathew Lariviere, PH233579

RECUSAL: S. CORNACCHIO recused herself and was not present for the discussion or vote on this matter.

DISCUSSION: C. COLLINS presented and summarized the pertinent facts of the investigation. Pharmacy Compliance Investigators noted inspectional deficiencies on a

routine retail compliance inspection on 8/8/14) deficiencies included: no counseling sign, pharmacist technician ratios, name tags, balance not sealed, incomplete compounding logs, no certified thermometers, temp logs inconsistently filled out, outdated CII not reconciled. A second retail compliance inspection conducted on 12/3/2014 resulted in inspectional deficiencies which included; balance not sealed, supervisory ratios, temp logs inconsistently filled out; vaccine temp logs inconsistently filled out; refrigerator temps out of range multiple times, Technician-in-training having worked greater than 1000 hours; corrosion sink faucet, 76 baskets stacked on counter. CVS 913 did submit a satisfactory Plan of Correction from the Pharmacy Supervisor. The board was concern that the store attain and remain in compliance in the future.

ACTION: Motion T. FENSKY, seconded by C. BASILE, and voted unanimously to refer the matter to the office of prosecution for the issuance of an order to show cause and authorize resolution of the matter with a consent agreement for a non- disciplinary stayed probation with terms to include; (a) 2 hours of pharmacist continuing education in the area of Pharmacy Law or Pharmacy Management; (b) Attest to reading 247 CMR sections (6) Registration, Management and Operation of a Pharmacy or Pharmacy Department ; Section (9) Code of Professional Conduct; Professional Standards for Registered Pharmacist, Pharmacies and Pharmacy Departments; Section (15) Continuous Quality Improvement Program.

TOPIC VII
FILE REVIEW

6.SA-INV-6752; Rite Aid

DS3122

DISCUSSION: This Case is deferred to future meeting

LUNCH 12:07AM- 1:28PM

TOPIC VIII.
EXECUTIVE SESSION

DISCUSSION: P. GANNON called the session to order. At 11:07AM, P. GANNON informed the public that the Board would be in closed session for the remainder of the day. He read the reason why the Board would be in Executive Session.

However, to accommodate the schedule of those planning to appear during Executive Session, the Board went into 65C

ACTION: At 1:28PM motion by W. COX, seconded by P. BOUVIER and voted unanimously by roll call vote. P. GANNON; yes, E. TAGLIERI; yes, T. FENSKY; yes, S. CORNACCHIO; yes, C. BASILE; yes, K. CONLEY; yes, W. COX; yes, A. STEIN; yes, R. TINSLEY; yes, M. GODEK; yes, G. CAVANAUGH; yes, P. BOUVIER; yes.

TOPIC

IX M.G.L. c 112 §65 C Session

DISCUSSION: P. GANNON called the session to order.

ACTION: At 11:09AM motion by E TAGLIERI, seconded by C. BASILE, and voted unanimously to enter into M.G.L. c 112 §65 C Session. At 11:50AM the Board suspended M.G.L. c 112 § 65C Session

DISCUSSION: P GANNON called the session to order.

ACTION: At 2:27PM motion by T. FENSKY, seconded C. BASILE and voted unanimously to re-enter M.G.L. c 112 §65 C Session.

TOPIC

X ADJOURNMENT

DISCUSSION: None

ACTION: At 3:38PM motion by M. GODEK, seconded by G. CAVANAUGH, and voted unanimously to adjourn the meeting.

LIST OF EXHIBITS USED DURING THE MEETING

1. Draft Agenda for the August 4, 2015 Regularly Scheduled Meeting General Session
2. Draft June 30, 2015 Regular session Minutes
3. Draft July 16, 2015 Regular Session Minutes
4. Application to Manage and Operate a New Community Pharmacy, Bravo Pharmacy
5. Application to Manage and Operate a New Community Pharmacy, Medminder Systems.
6. Application for Transfer of Ownership, N-Molecular, Inc.
7. Reports of Applications approved pursuant to Licensure Policy 13-01.
8. Draft proposed amendments to 247 CMA 8.00: Pharmacy Interns, Pharmacy Technicians
9. Draft proposed amendments to 247 CMR 8.00: Pharmacy Interns, Pharmacy Technicians with track changes
10. Draft proposed new section 247 CMR 17.00: Sterile Compounding.
11. Draft proposed new section 247 CMR 17.00: Sterile Compounding with track changes.
12. Investigative Report in the matter of Walgreens 2063; DS1741, PHA-2014-0245.
13. Investigative Report in the matter of Carmen Marie Iannuzzi; PH233061, PHA-2015-0075
14. Investigative Report in the matter of Tiffany Leigh Burk; PH233537, PHA_2015-0076

15. Investigative Report in the matter of CVS 913; DS3437,PHS-2015-0093
16. Investigative Report in the matter of Matthew Lariviere; P233579, PHA-2015-0093
17. Investigative Report in the matter of Rite Aid 10151; DS3122, SA-INV-6752

Respectfully submitted by:

Richard Tinsley, MBA, M.Ed., Secretary