COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY
239 Causeway Street, Fourth Floor ~ Room 417A
Boston, Massachusetts 02114

MINUTES OF THE REGULARLY SCHEDULED MEETING
Tuesday, January 8, 2013

Board Members Present
James T. DeVita, RPh
Karen Ryle, RPh, MS
Anita Young, RPh, Ed.D
Stanley Walczyk, RPh
Joanne Trifone, RPh
Kathy J. Fabiszewski, PhD, NP; left @ noon
Patrick Gannon, RPh, MS
Edmund Taglieri, RPh, MSM, NHA

Board Members Not Present
Donald Accetta, MD, MPH
Steven Budish, Public Member
Jane Franke, RN, MHA

Board Staff Present
Madeleine Biondolillo, MD,
Bureau Director, HCS&Q
Margaret Cittadino, MEd,
Associate Director
Louis Dell'Olio, RPh,
Director, SOPS
Joel Kanter, Consultant
Heather Engman JD, MPH, Board Counsel
Vita P. Berg, assisting Board Counsel
Iyah Romm,
Director of Policy, Health Planning &
Strategic Development, HCS&Q
Carolyn Reid, Adm. Asst
Joseph Sceppa, RPh, Consultant

Board Staff Not Present
Leo McKenna, RPh, PharmD,
Quality Assurance (QA) Coordinator
Samuel Penta, RPh,
Investigator Supervisor
Cheryl Lathum, RPh, PharmD,
Investigator
William E. Frisch, Jr., RPh, Investigator

TOPIC:
I. **Call to Order**

DISCUSSION:
A quorum of the Board was present.

ACTION:
At 8:32 a.m. J. DEVITA, President, called the January 8, 2013, meeting of the Board of Registration in Pharmacy to order.

TOPIC:
II. **Approval of Agenda**

DISCUSSION: Board members reviewed the tentative agenda. K. Ryle asked that a discussion of Chapter 244 of the Acts of 2012 be added to the Flex Session (Item X).

ACTION: Motion by S. WALCZYK, seconded by E. TAGLIERI , and voted unanimously to approve the agenda with the additional topic.

TOPIC:
III. **Approval of Prior Board Minutes:**

November 20, 2012 Scheduled Meeting
December 11, 2012 Regularly Scheduled Meeting
December 11, 2012 Adjudicatory Session
December 11, 2012 M.G.L. c. 112, § 65C Session
December 20, 2012 Scheduled Meeting
December 20, 2012 Executive Session

DISCUSSION: V. Berg presented minutes from Board meetings of November 20, 2012, December 11, 2012, and December 20, 2012

ACTIONS:

Motion by J. TRIFONE, seconded by P. GANNON, and voted unanimously to correct and approve the minutes from the November 20, 2012 Scheduled Meeting.

Motion by J. TRIFONE, seconded by P. GANNON, and voted unanimously to approve the minutes from the December 11, 2012 Adjudicatory Session and M.G.L. c. 112, § 65C Session.

Motion by J. DEVITA, seconded by K. RYLE, and voted unanimously to defer the minutes from the December 11, 2012 Regularly Scheduled Session for various corrections.

Motion by J. TRIFONE, seconded by P. GANNON, and voted unanimously to approve the minutes from the December 20, 2012 Scheduled Meeting and Executive Session.

TOPIC:
IV. Regulations
Emergency Regulations at 247 CMR promulgated November 1, 2012

DISCUSSION:
H. Engman presented the revised emergency regulations for Board approval and noted that upon approval, they will be filed and made effective on February 1, 2013. K. Ryle noted that the draft regulations refer to 94C for a definition of a "prescription", and that Section 2 of 247 CMR is more appropriate (and easier to access) definition.

ACTIONS:
Motion by A. YOUNG, seconded by K. RYLE, and voted unanimously to change the reference for the definition of a prescription from 94C to 247 CMR,

Motion by S. WALCZYK seconded by A. YOUNG, and voted unanimously to approve the revised the Emergency Regulations at 247 CMR.

TOPIC:
V. POLICY
V. A.1. **Proposed Licensure Policy 13-01: Staff Action on Applications and Notices**

V. Berg distributed a draft of proposed Policy 13-01 which would authorize Board staff to approve and process certain applications or notices concerning individual licensure, or changes in the operation of licensed pharmacies, provided that the application or notice meets criteria specified in this policy.

DISCUSSION: Rather than waiting for a formal Board meeting, this policy would allow immediate action by a designated individual, on registration of a nuclear pharmacist, change in manager of a pharmacy, and notice of closing of a community pharmacy or pharmacy department. The Board requested two clarifications (no unresolved adverse history, specific designated authorization).

ACTION: Motion by S. WALCZYK, seconded by K. RYLE, and voted unanimously to (1) adopt Licensure Policy 13-01 as a pilot policy with the minor clarifications noted above, and (2) to designate Associate Director Margaret Cittadino as the board staff person authorized to review and approve the applications and notices.

TOPIC:
V. POLICY
V.A.2. **Proposed Enforcement Policy 13-02: Implementation of Plans of Correction**

V. Berg distributed a draft of proposed Policy 13-02 which would allow for an expedited review and evaluation of a plan of correction (POC) submitted by a registrant in response to a notice of deficiencies issued by inspectors following an inspection.

DISCUSSION: The Board recognized the need to approve POCs so that non-compliant pharmacies may begin to make necessary changes without waiting for the next board meeting. The review of the POC would be conducted by a team consisting of the inspector, a designated Board member, the Board's QA coordinator, and the Board counsel or chief prosecutor. If there was no consensus agreement, the POC would come back to the Board.

ACTION: Motion by S. WALCZYK, seconded by J. TRIFONE, and voted unanimously to (1) adopt Enforcement Policy 13-02 as a pilot policy. The president of the Board will serve as the designated Board member for all POCs by pharmacies that receive a cease and desist order. For all other pharmacies, each Board member will serve as the designated Board member for a one month period on a rotating basis.

TOPIC:

VI. LEGAL REVIEW

CLAIMS AND INDEMNITY PROCEDURE FOR THE COMMONWEALTH, ITS MUNICIPALITIES, COUNTIES AND DISTRICTS AND THE OFFICERS AND EMPLOYEES THEREOF

DISCUSSION: H. Engman summarized the provisions of M.G.L. ch. 258, the Massachusetts Tort Claims Act as they apply to the Board. Board members are considered public employees. The Tort Claims Act places a cap of $100,000/claim, and that the state (not the individual) is liable. In case of a suit, the AGO defends the action.

ACTION: So noted.

TOPIC:

VII. UPDATE ON BOARD OPERATIONS

DISCUSSION: M. Biondolillo updated the Board with respect to recent activities that affect Board operations. She recognized that personnel changes and emergency inspections during the past few months have impacted usual activities of the Board. She advised that there are ongoing searches to fill the positions for both the Director of the Division of Health Professions Licensure and Executive Director for the Board of Registration in Pharmacy. She acknowledged the efforts of a number of individuals that had assumed temporary responsibilities, and outlined efforts to obtain additional personnel resources, especially inspectors. She noted that the unannounced inspections of sterile compounding pharmacies are coming to a close and updated the Board on results to date: few pharmacies had no deficiencies, most had POCs, and a few were issued partial or complete cease and desist letters. She praised the efforts of the internal inspectors and the consultants. She updated the board that she and L. Smith attended one of the FDA outreach conferences. Take-home messages included an FDA commitment to real-time communication with state boards of pharmacy, sharing training resources, and FDA consideration of a separate category for compounders of high-risk level products that are being shipped across state lines. Board members responded with their thoughts and recommendations.

ACTION: So noted.

TOPIC:

CLOSED SESSIONS

DISCUSSION:

J. DeVita announced the Board's intentions to enter into Adjudicatory Session, M.G.L. Ch. 65C Session, and Executive Session, all of which will be closed sessions, and noted that it was the Board's intent to return to Open Session following the conclusion of the closed sessions. He announced the topic to be discussed during Executive Session, specifically, the Open Meeting Law complaint filed by Todd Wallack of the Boston Globe on or about December 20, 2012 regarding the December 20, 2012 Board of Registration in Pharmacy meeting. He cited the purpose for holding this discussion in executive session as M.G.L. c. 30A, § 21(a)(1) - To discuss 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.

ACTION: So noted.

TOPIC:

VIII. **Adjudicatory Session**

DISCUSSION:
None

ACTION:
Motion by J. DEVITA, seconded by K. RYLE and passed by unanimous roll call vote to enter Adjudicatory Session at 10:55.

ADJUDICATORY SESSION (10:55 – 11:00)

TOPIC:
IX. **M.G.L. Ch. 65C Session**

DISCUSSION:
None

ACTION:
Motion by A. YOUNG, seconded by E. TAGLIERI and passed by unanimous roll call vote to enter M.G.L. Ch. 65C Session at 11:00.

M.G.L. Ch. 65C SESSION (11:00 – 12:25)

TOPIC:
X. **Executive Session**

DISCUSSION:
J. DeVita

ACTION:
Motion by J. DEVITA, seconded by K. RYLE and passed by unanimous roll call vote to enter Executive Session at 12:25.

EXECUTIVE SESSION (12:25 – 12:30)

TOPIC:
IX. APPLICATIONS AND NOTICES

DISCUSSION:
M. Cittadino recited a list of applications and notices previously determined by Board staff to be in compliance with Board regulations.

A. Application for Registration as a Nuclear Pharmacist
1. **Jaehwa Lee**, PH234387

C. Certificates of Fitness
1. **Acton Pharmacy**, 563 Mass Ave, Acton (DS2731)
3. **Keyes Drug Store**, 2090 Commonwealth Ave, Auburndale, (DS2125)
4. **Wegmans Pharmacy**, 9102 Shopsway, Northborough(DS89780)

D. Pharmacy Closings
1. **Big Y 67**, South Hadley, (DS3256)
2. **Blackwood Pharmacy**, 181 Parkingway, Quincy (DS3345)
4. **Fall River Prescription Ctr**, 187 New Boston Rd, Fall River (DS22684)
5. **MOMS Pharmacy**, 75 Armory Street, Boston (DS89828)

E. Renovation/Expansion
1. **Big Y Pharmacy 50**, Willimansett Street, South Hadley, (DS3178)
2. **BioRx**, 266 West Cummings Park, Woburn (DS89763)
4. **Greater Boston Long Term Care**, 1864 Centre Street, West Roxbury (DS3306)
5. **Rite Aid 10207**, 1383 Cove Road, New Bedford (DS2411)

ACTION:
Motion by A. YOUNG, seconded by E. TAGLIERI, and unanimously passed to approve the applications.

TOPIC:
IX. APPLICATIONS AND NOTICES
B. Community Pharmacy Relocations
2. **Walgreens #02738**, 571 John Fitch Ave, Fitchburg (DS02738) relocating to trailer at same address during full store renovation with a new store number #13983

RECUSAL:
J. Trifone exited the room prior to commencement of the discussion of this matter and returned following the vote.

DISCUSSION:
M. Cittadino recited a list of applications and notices previously determined by Board staff to be in compliance with Board regulations.

ACTION:
Motion by S. WALCZYK, seconded by P. GANNON and unanimously passed to approve the application.

TOPIC:
IX. APPLICATIONS AND NOTICES
C. Certificates of Fitness
2. **Critical Care Systems**, 191 Bay State Drive, Braintree (DS3327)

RECUSAL:
E. Taglieri exited the room prior to commencement of the discussion of this matter and returned following the vote.

DISCUSSION:
M. Cittadino recited a list of applications and notices previously determined by Board staff to be in compliance with Board regulations.

ACTION:
Motion by A. YOUNG, seconded by S. WALCZYK , and unanimously passed to approve the application.

TOPIC:
IX. APPLICATIONS AND NOTICES
F. Petition for Waiver of the Provisions of 247 CMR
1. **Southcoast Pharmacy**, 101 Page Street, New Bedford (DS2641) Waiver of 247 CMR 6.02 (8)(a)
2. **Southcoast Pharmacy**, 363 Highland Avenue, Fall River for a Waiver of 247 CMR 6.02 (8)(a). This new community pharmacy application has been approved by the Board but is pending a compliant inspection.

RECUSAL:
P. Gannon exited the room prior to commencement of the discussion of this matter and returned following the vote.

DISCUSSION:
M. Cittadino recited a list of applications and notices previously determined by Board staff to be in compliance with Board regulations. Board members noticed that the waiver request related to the hours of operation, but did not specify the appropriate regulation.

ACTION:
Motion by S. WAKLCZYK, seconded by E. TAGLIERI and unanimously passed to defer the applications until resubmitted with clarification.

TOPIC:
IX. APPLICATIONS AND NOTICES
B. Community Pharmacy Relocations
1. **CVS 73**, 194 Main Street Amesbury (DS2366) relocating to 5 May Street, Amesbury
3. **CVS 394**, 1475 Newman Avenue, Seekonk relocated to a new store built in front of the old store at the same address.
D. Pharmacy Closings
3. **CarePlus Pharmacy**, 35 Millbury St. Auburn (DS3219)
E. Renovation/Expansion
3. **CVS 2171**, 65 Canal Street, Millbury (DS2865)

RECUSAL:
J. DeVita exited the room prior to commencement of the discussion of this matter and returned following the vote.

DISCUSSION:
M. Cittadino recited a list of applications and notices previously determined by Board staff to be in compliance with Board regulations.

ACTION:
Motion by S. WALCZYK, seconded by K. RYLE, and unanimously passed to approve the applications.

IX. APPLICATIONS AND NOTICES (Cont.)

G. Application for a New Community Pharmacy
EASYCARE PHARMACY, LLC
Proposed Managers of Record:
a. Jennifer Wingate (PH24370) for 35 Millbury Street, Auburn
b. Robert Talbourdet (PH17706) for 370 Lunenburg St. Fitchburg
c. Joanne Williams, (PH19407) for 165 Mill St. Leominster
d. Charles Johnson (PH16275)for 176 West St, Milford
e. Kim Morese (PH22315) for 630 Plantation St. Worcester
f. George Knight, (PH19722) for 344 Thompson Road, Webster

RECUSAL:
J. DeVita exited the room prior to commencement of the discussion of this matter and returned following the vote.

DISCUSSION:
K. Ryle led the discussion (in Jim's recusal absence). Eric Howard R.Ph. (PH20071), Easy Care Director of Pharmacy Operations indicated that Easy Care is a new retail pharmacy chain of ten (10) stores. The Board was satisfied that ownership of the pharmacies complies with 247 CMR 6.01(3). Four (4) of the applications were previously approved by the Board.

ACTION:
Motion by E. TAGLIERI, seconded by S. WALCZYK, and unanimously passed to approve the application for the Auburn facility.
Motion by S. WALCZYK, seconded by A. YOUNG, and unanimously passed to approve the application for the Fitchburg facility.
Motion by A. YOUNG, seconded by P. GANNON, and unanimously passed to approve the application for the Leominster facility.
Motion by P. GANNON, seconded by A. YOUNG, and unanimously passed to approve the application for the Milford facility.
Motion by E. TAGLIERI, seconded by A. YOUNG, and unanimously passed to approve the application for the Worcester facility.
Motion by P. GANNON, seconded by A. YOUNG, and unanimously passed to approve the application for the Webster facility.

TOPIC:
IX. FLEX SESSION
IX.1. **Chapter 244 of the Acts of 2012 – An Act Relative to Prescription Drug Diversion, Abuse, and Addiction**

DISCUSSION:
The Board discussed the recent announcement of a delay in the implementation date of section 4 of Chapter 244 (restricting the filling of out-of-state schedule IIO narcotic prescriptions). In order to ease the transition of the implementation, the effective date has been pushed back from January 1, 2013 to May 1, 2013. Once this section becomes effective, pharmacies may only fill out-of-state schedule II narcotic prescriptions issued by providers licensed in Maine or a contiguous state (CT, RI, NH, NY, VT) and have been issued within the preceding 5 days.

ACTION:
The Board will help communicate the above by placing the notice on the website and sending a blast email to pharmacies. The Board will ask the various pharmacy schools and organizations to help communicate the changes.

TOPIC:
IX. FLEX SESSION
IX.2. **Agenda for the upcoming meetings:**

a. Chapter 244 of the Acts of 2012: CE Plan
b. Electronic Prescribing: prescriber's signature
c. Addressing the special commission's recommendations
d. Emergency Regulations: Implementing "in a format approved by the Board"
e. MA Law component of the NABP (MJPE) Exam
f. Specialty Compounding Pharmacies
g. Massachusetts Immunization Information System

TOPIC:
IX. FLEX SESSION
IX.3. **Scheduling Additional Meetings**:

DISCUSSION:
Concern was expressed about the backlog of work that the Board needs to address. Rather than holding additional meetings, members felt it would be better to expand the hours of the next regularly scheduled meeting (February 5, 2013) to 8:30 am until 4 pm. M. Cittadino will suggest a second date for file reviews and pending applications.

ACTION:
None

TOPIC:
Adjournment

DISCUSSION:
None

ACTION:
Motion by S. WALCZYK, seconded by A. YOUNG, and unanimously passed to adjourn at 1:38

Respectfully submitted,

Vita Palazzolo Berg, Assisting Board Counsel