BOARD OF REGISTRATION IN PHARMACY MEETING AGENDA TUESDAY JUNE 23, 2009 239 CAUSEWAY STREET, ROOM 206 BOSTON, MA 02114

Present: James T. DeVita, R.Ph., Joanne Trifone, R.Ph., George Cayer, R.Ph., Kathy Fabiszewski, Ph.D. N.P., Michael Tocco, R.Ph., M.Ed., Stanley Walczyk, R.Ph., Steven Budish, Public Member

Absent: Donald Accetta, M.D., William Gouveia, R.Ph., M.S., Sophia Pasedis, R.Ph. **Staff:** James D. Coffey, R.Ph., Director, Margaret C. Cittadino, Associate Director, Susan Manning, Counsel, Leo McKenna, R.Ph., Pharm.D., CQI Surveyor, Carolyn Reid, Admin. Asst., Samuel Penta, R.Ph., Superv., James Emery, Inv., Cheryl Lathum, Inv.

- 8:30 a.m. CALL TO ORDER
 Pres. DeVita called meeting to order.
- 2. Introduction of Despina Ioannidis, Pharm.D. Candidate 2010 NEU APPE Student
- 3. 8:35 a.m. REVIEW/ADOPTION OF BOARD MINUTES

 Motion/Walczyk to approve January 27, 2009 minutes. Second/Tocco. All in favor.
- 4. 8:40 a.m. LICENSING: Pharmacy/Wholesale Distributor Applications

New Store

Walgreens 11998, 225R King Street, Northampton 01060 CVS 8972, 285 Columbus Avenue, Boston 02116 CVS 1603, 104 Washington Street, Norwel02061

Change of Manager

CVS 114, 12 Harvard Street, Waltham (DS2821)

CVS 1206, 240 Newbury Street, Boston (DS2033)

CVS 861, 355 Centre Street, Brockton (DS3550)

CVS 6505, 978 Boylston Street, Newton (DS3522)

CVS 0023, 978 241 Lincoln Avenue, Haverhill (DS23965)

CVS 73, 978 194 Main Street, Amesbury (DS2366)

CVS 1184, Route 1, Rowley (DS2123)

Rite-Aid 10054, 1504 Northampton Street, Holyoke (DS2396)

Rite-Aid 10213, 510 Wilbur Ave., Swansea (DS2612)

Stop & Shop 2403, 56 Shank Painter Road, Provincetown (DS89644)

Stop & Shop 055, 932 North Montello Street, Brockton (DS3290)

Wal-Mart 10-2184, 1180 Fall River Ave., Seekonk (DS2755)

Wal-Mart 10-2902, 121 Worcester Road, Framingham (DS3181)

Wal-Mart 10-2228, 555 Hubbard Avenue, Pittsfield (DS2746)

Wal-Mart 10-2629, 100 Valley Parkway, Northbridge (DS3508)

Walgreens 10427, 35 Central Street, Leominster (DS3611)

Walgreens 2738, 571 John Fitch Highway, Fitchburg (DS2095) Osco Pharmacy 7584, 115 Great Road, Stow (DS3061)

Relocations

CVS 1551, 272 Highland Ave., Salem FROM 263 Highland Ave., Salem

Controlled Substance Registration – Wholesale Distributor G Medical, LLC dba Pharmaceutics, 2383 Centre Street, W. Roxbury (WD471) request to add Schedule II controlled substances

Motion/Walczyk to approve applications, subject to compliant inspections and noted conditions. Second/Budish. All in favor with exception of DeVita and Tocco recused from all above CVS applications; Trifone recused from all above Walgreens applications.

5. 8:45 a.m. LEGAL/REPORT OF OFFICE OF INVESTIGATIONS Pending Legal Matters - Susan Manning, Board Counsel

Closed Session – M.G.L. c. 112, s. 65C (Pending Complaints)
M.G.L. c. 30A, s. 11A (Adjudicatory)
Policy Development

8:45 a.m. Motion/DeVita to enter Closed Session. Second/Trifone. All in favor.

9:30 a.m. Motion/Cayer to end Closed Session. Second/Fabiszewski. All in favor.

6. 9:30 a.m. INVESTIGATIVE CONFERENCE

Injured Workers Pharmacy LLC ("IWP"), 9 Branch St., Methuen (Drug Store Permit No. 3279) / Roger Scandura, R.Ph., Manager of Record (License No. 18853): Complaint Docket No. 20081006-DS-021

Cayer and Tocco recused/exited meeting room.

Complaint alleged that on diverse dates from January 5, 2007 through September 10, 2008, the pharmacy failed to report thefts or losses of a significant amount of controlled substances to the Board by submitting a copy of "Report of Theft or Loss of Controlled Substance" (DEA BND Form 106), within seven days of such thefts or significant losses, in accordance with 247 CMR 6.02(10).

Present: MOR Scandura

MOR Scandura acknowledged the pharmacy failed to report thefts or losses of a significant amount of controlled substances to the Board within seven days of such thefts or significant losses and stated he was not aware of reporting requirement. Scandura described corrective action taken to date to minimize losses.

Motion/DeVita to issue an Advisory Letter with four Pharmacy Law CEs. Second/Walczyk. All in favor.

7. 10:00 a.m. REVIEW OF PUBLIC HEARING COMMENTS

Proposed amendments to 247 CMR new sections 6.14 and 15.05 (Pharmacy to Report Certain Improper Drug Dispensing to the Board), mandated by M.G.L. c. 112, s. 39D.

Board reviewed comments on proposed regulations and made revisions to proposed regulations after discussion, including implementation date of 1/1/10 to facilitate education outreach on new reporting requirement and finalize reporting form.

Motion/Walczyk to adopt proposed regulations, revised as discussed. Second/Cayer. All in favor.

8. 11:00 a.m. PHARMACY TECHNICIAN Applicant / Appearance

Present: Matthew Austin

Applicant reviewed history noted on application with Board.

After discussion, Motion/DeVita for MPRS assessment. Second/Cayer. All in favor.

9. 11:15 a.m. TRANSPER OF OWNERSHIP APPLICATION/Appearance

Anderson Holdings, Inc. dba.J.E. Pierce Apothecary – Proposed: 1180 Beacon Street, Brookline, MA 02446 – transfer from J.E. Pierce Apothecary (same location)

Walczyk recused/exited meeting room.

Present: Derick Anderson, R.Ph., Owner/proposed MOR; Paul Gabrabini, Esq.

Anderson described renovations to premises (photographs and other) and other action taken to comply with 247 CMR and USP requirements. Board discussed concern regarding compounding volume and ongoing square footage and ventilation limitations. Anderson described hood to be installed and identified two professional staff members who will continue under his ownership. Board noted concerns that the premises not be a preceptor site until approved by the Board and that ad wince notice of any change in ownership be provided to Board

Motion/DeVita to take matter under advisement. Second/Trifone. In Favor: DeVita, Trifone, Fabiszewski, Tocco, Budish Opposed: Cayer

After review and discussion of information presented, Motion/DeVita to approve transfer application subject to conditions of complaint inspection; no preceptor site for information and year period; 15 day notice to Board in advance of any

change in ownership, review of transaction documents. Second/Tocco. All in favor.

Motion/Budish to enter into Close Session. Second/Tocco. All in favor.

Motion/DeVita to enter into Open Session. Second/Trifone. All in favor.

Matter of Ralph Mastriano, R.Ph. (Registration No. 19070): Complaint Docket No. PH-08-027)

After discussion of complaint, Motion/Cayer to propose one year suspension period; probation (4) following, professional evaluation minimum one year; refer to presecutions if not resolved by agreement. Second/Tocco. All in favor.

Matter of Renee M. Collins (Registration No. 25229): Complaint Docket No. PHA-2009-0023 - review of MPRS evaluation.

Motion/Cayer to propose Reprimand, for four Live Law continuing education credits. Second/Walczyk. All in favor.

10. 12:00 p.m. LUNCH

11. 1:00 p.m. PHARM/CY INTERNSHIP REQUIREMENTS

Continuation of discussion (March 31, 2009) regarding Massachusetts College of Pharmacy and Health Sciences (MCPHS) request for Board review of 247 CMR pactions 3.01(3) and 8.01 regarding internship requirements for pharmacist registration.

Present: MCPHS - Dennis Lyons, Douglas Pisano, Catherine Simonian, Kathy Keough, Paul DiFrancesco.

Continuation of discussion regarding current internship hour requirement for licensure. Board expressed concern regarding monitoring of training at preceptor sites and value of pharmacy work setting experience. MCPHS representatives described preceptor oversight and evaluation process; curriculum and training requirements at the Boston and Worcester campuses. Northeast: in University (NU) School of Pharmacy representative Mark Yorra described the NU pharmacy student work experience requirements.

Catherine Simonian stated MCPHS visit sites annually when possible, communicates with preceptors and reviews manuals. She tells students to contact her and utilizes a student evaluation form after the experience.

Dennis Lyons indicated the Board requires 1500 hours of total internship; 1000 of which (graded hours) are recognized in affiliation with Accreditation Council of Pharmacy Education (ACPE) accredited pharmacy programs. MCPHS currently provides 1740 hrs. of cupervised (preceptor) internship in Boston and 1780 hrs. in Wordester to meet and or exceed the ACPE standard. Lyons stated certain MCFHD graduates, have recently experienced difficulty completing the additional 500 hours required to be completed outside the academic curriculum.

Mark Yorra, although not representing the NU pharmacy program in an official capacity, stated the NU experience can vary dependent upon the preceptor but the additional 500 hours of internship is beneficial to prepare as professionals to practice. NU conducts regular site visits to each pharmacy to assess students rotation experiences.

Pres. DeVita stated the Board values student experiences and learning from both the academic and work settings. He stated his understanding that no student had petitioned the Board or colleges/schools regarding completion of the 500 hours requirement due to hardship.

Paul DiFrancesco stated the 500 hours of internship required can interfere with student academic achedules. He concurred that work offers valuable practical experience.

Dean Pisano stated MCPHS follows the 1500 hour requirement of 247 CMR. He noted precapions are evaluated and that MCPHS might also do an audit of pharmacy sites.

Charles Young stated that National Association of Boards of Pharmacy (NABP) and ACPE set standards for student rotations. In his opinion, the Board should review the curriculum and MCPHS evaluation tools and compare with ACPE standards.

After discussion, Motion/Budish to recognize the ACPE standard of 1740 internable rotation hours as satisfactory completion of practical experience required by the Board for personal registration as a pharmacist. The motion was not accorded.

Motion/Tocco to take matter under advisement. Second/Cayer. All in favor.

12. 2:30 p.m. INVESTIGATIVE CONFERENCE

DeVita and Tocco recused/exited meeting room.

CVS/pharmacy #433, Lenox (Drug Store Permit No. 1870); Robyn F. Graham, R.Ph., Manager of Record (License No. 20393); Mary O. Smith, R.Ph. (License No. 24152); Complaint Docket Nos. 20080916-DS-017and PHA-2009-0001

Complete that on July 28, 2008 the pharmacy dispensed Valtrex 500mg rather than Keflex 500mg as prescribed.

Present: MOR Graham, R.Ph., Mary O. Smith, R.Ph., William Irvin, CVS District Manager, Michael Hankley, Esq., Craig Jones, R.Ph. (son of complaint)

Board reviewed original prescription (handwritten) and follow up by pharmacists. Smith stated she will take greater care to verify any prescription that is questionable. Manager of Record (Graham) acknowledged the prescription was not clearly written and apologized for the medication error.

Pharmacist (Smith) Motion/Cayer to seek Reprimand, complete two hours of continuing education related to Medication Error Prevention and 15 hours Live CEs. Second/V/alcyzk. All in favor.

Drugstore: Motion/Cayer to issue Advisory Letter. Second/Walczyk. All in favor.

13. 2:45 p.m. INVESTIGATIVE CONFERENCE

CVS/pharmacy #979, South Boston (Drug Store Permit No. 2133); Kristopher D. Getzik, R.Ph., Manager (License No. 25503); Omoizele Okoawo, R.Ph. (License No. 23999) - Complaint Docket Nos. 20081023-DS-025 and HA-2009-0005

Complaint alleged that on September 17, 2008, the pharmacy dispensed Metadate CD 30m 3/24hr capsules rather than Metadate CD 10mg/24hr capsules as prescribed.

Present: Kristopher D. Getzik, MOR, Omoizele Okoawo, R.Ph., William Irvin, CVS District Manager, Complainant, Counsel to complainant

Pharmacist Okoawo stated he was a floating pharmacist and that in effort to assist, he performed incorrect entry and failed to fill correctly or follow checking procedures. Complainant described her concerns regarding her child's ingestion of the incorrect medication; complainant's counsel noted concern that stated company policies were not followed. Okoawo and CVS representatives applicated to occupationant.

Pharm soist: Melion/Tallone to propose Reprimand with two continuing education credits in medication errors. Second/Cayer. All in favor.

Drugstore: Motion/Cayer take matter under-advisement contingent on site Visit. Second/Walcyzk. All in favor.

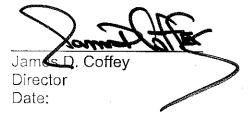
14. FLEX DISCUSSION - New Business

- a) Kelly Jo Frank, Pharmacy Intern Applicant Motion/Cayer to approve application. Second/Walczyk. All in favor.
- b) Sriggitte Anderson, Pharmacy Technician Applicant

 Motion/Trifone to approve application. Second/Tocco. All in favor.
- c) Janed Ochmita, Flushmany Intern Applicant
 M. Bon/Trifone to approve application. Second/Cayer. All in favor.
- d) Let le Ann Min, Reciprocal Pharmacist Applicant Motion/Walczyk to approve application. Second/Cayer. All in favor.
- e) Peter J. McFarland, Reciprocal Pharmacist Applicant Motion/Walczyk to approve application. Second/Tocco. All in favor.
- f) Rence Lucaroni, Pharmacy Technician Applicant Motion//DeVita schedule appearance. Second/Tocco. All in favor.
- g) In the matter of David Reardon, Pharmacy Intern Applicant Id trion/Walczy's to approve application. Second/Cayer. All in favor.
- i) End insetting July 14, 2009.

15. 4:00 p.m. Motion/Tritione to adjourn meeting. Second/Walczyk. All in favor.

Respectfully submitted by:



Reviewed by Counsel: September 15, 2009

Draft approved: September 15, 2009 **Board approved:** November 17, 2009