

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, February 3, 2015

Board Members Present

Patrick Gannon, RPh, Present (arrives @ 9:49AM)
Edmund Taglieri Jr., RPh, President-elect
Richard Tinsley, MBA, MEd, Secretary
Catherine Basile, PharmD, RPh
Garrett Cavanaugh, RPh
Susan Cornacchio, JD, RN (arrives @9:51AM)
William Cox, CPht
Timothy Fensky, RPh, FACA
Michael Godek, RPh

Board Member Not Present

Karen Conley, DNP, RN,
AOCN, NEA-BC

Board Staff Present

David Sencabaugh, RPh, Executive Director
David Dunn, RPh, Assistant Executive Director
Heather Engman, Board Counsel
Kelly Ann Barnes, 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 8:50AM E.TAGLIERI, called the February 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, G CAVANAUGH; yes, W COX; yes, T FENSKY; yes; M GODEK; yes;

P GANNON and S CORNACCHIO, were not present at the time of roll call

TOPIC II.

APPROVAL OF AGENDA

DISCUSSION: Approval of the minutes and the file review for Park Avenue Pharmacy will be deferred to a future meeting.

ACTION: Motion by R.TINSLEY, seconded by C. BASILE, and voted unanimously to accept the agenda with the noted change. P. GANNON and S. CORNACCHIO were not present for the discussion or vote of this matter.

TOPIC III.

9:05AM

REPORTS

Applications Approved Pursuant to Licensure Policy 13-01

DISCUSSION: R HARRIS noted that during the past month there has been twenty six (26) change of managers, and one (1) new community pharmacy.

ACTION: So noted, P.GANNON and S.CORNACCHIO were not present for the presentation of the report.

TOPIC IV.

FILE REVIEW

SA-INV-3639, Stat-Care Pharmacy,

Presented by: Christina Mogni, RPh, Pharmacy Investigator

DISCUSSION: The case was presented and summarized by Pharmacy Investigator MOGNI. The Staff Assignment was open based on information provided by the Drug Enforcement Agency (DEA) Boston office regarding an excessive amount of Schedule II narcotic emergency prescription requiring hard copy back-up self-reported by Stat Care Pharmacy. The Board was concerned regarding the high number of emergency schedule prescriptions, it was noted that emergency Schedule II prescriptions is common in the long term care setting for continuity of care. The Board was satisfied with efforts by Stat Care Pharmacy to obtain the outstanding prescriptions, Plan of Correction, and cooperation with the DEA.

ACTION: Motion by FENSKY, seconded by C.BASILE, and voted unanimously to close the staff assignment with no discipline warranted. P.GANNON and S. CORNACCHIO were not present for the discussion or vote of this matter.

FILE REVIEW

2.SA-INV-3691, Pharmacy Corporation of America

Presented by, Colleen Collins, RPh. Contract Investigator

DISCUSSION: C. COLLINS presented and summarized the Staff Assignment. The investigation was initiated as the result of a complaint by Ther-Rx that the Pharmacy Corporation of America's Brockton facility was compounding hydroxyprogesterone

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Approved April 7, 2015.

caproate injection, commercially available as Makena®. Pharmacy Corporation of America was able to provide records indicating that it had not compounded any hydroxyprogesterone caproate injection.

ACTION: Motion by R.TINSLEY, and seconded by M.GODEK, and voted unanimously, to close the staff assignment with no violation. P.GANNON and S. CORNACCHIO were not present for the discussion or vote of this matter.

TOPIC V.

APPLICATIONS

Application for a New Community Pharmacy

1. Soleo Health, 5 Shawmut Road, Canton

DISCUSSION: MOR Bridget Smith presented this application. Soleo Health will be a Home Infusion Pharmacy. MOR Smith indicated that there would be no USP <795> compounding and that Soleo is seeking waivers for compounding. It was noted that Schedule VI medications was not checked off on the application. MOR Smith indicated that she would amend the application.

ACTION: Motion by M.GODEK, seconded by T.FENSKY, and voted unanimously to approve Soleo Health Application and waivers pending a (1) successful inspection, (2) receipt of <795> and <797> Attestations (3) amended application. P.GANNON and S. CORNACCHIO were not present for the discussion or vote of this matter.

TOPIC V.

APPLICATIONS

9:36AM

Application for Renovation / Expansion Request for Board Approval

2. Integriscript, 95B Ashley Ave, west Springfield, DS89726

DISCUSSION: MOR Roman Szarek and Larry Kioski Operations Manager presented the application for expansion of Integriscripts facility. The proposed expansion indicates an increase of 3650 sq ft. Operations Manager Kioski noted that the increase space was need in order service the approximately 2000 long-term care beds. Board Counsel H.ENGSMAN advised the Board that there are currently open complaints against Integriscript that are pending board counsel. The Board authorized resolution of those matters with a consent agreement for probation. Board counsel indicated that pending complaints do not necessarily impact Board's decision on pending application. W. FRISCH was concerned regarding the impact of the construction on the compounding facility. W. FRISCH inquired regarding a containment plan for construction particulate matter, environmental monitoring of the classified space. W.FRISCH displayed concerns regarding the following items of the renovation request: policy and procedures for the night drop off box, Supervision of the new narcotic room, and supervision of the clean room. The representatives from Integriscript were able satisfactorily address each concern.

ACTION: Motion by C.BASILE, seconded by G. CAVANAUGH, and voted unanimously to approve the renovation pending successful inspection

TOPIC: VI.
REGULATIONS

Time: 9:17 – 9:47AM

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.

Break 9:47AM- 9:55AM

TOPIC VII.
APPLICATIONS

Application a Renovation / Expansion for Board Approval

Critical Care Systems a Walgreens Company, 191 Bay State Drive, Braintree DS 3327

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

DISCUSSION: MOR Kelvin Ma, presented this application. W. FRISCH and K. BARNES indicated that they have been involved in multiple discussions with MOR MA and Walgreens representatives. W. FRISCH noted that due to inspectional deficiencies Critical Care System of Braintree has been closed down since June of 2014. K. BARNES informed that Board that as a result of on-going collaboration Critical Care System was seeking the approval to remake its cleanroom.

ACTION: Motion by C.BASILE, seconded by R. TINSLEY, and voted unanimously to approve the Critical Care System's application for Renovation / Expansion pending a successful inspection.

TOPIC VIII.
FLEX SESSION

DISCUSSION:

D. SENCABAUGH introduced Pharmacy Intern Emily Walker from Northeastern University.

D. SENCABAUGH introduced new Board Member Susan Cornacchio, Public Member with expertise in Patient Safety and Quality Assurance.

D. SENCABAUGH made members aware of the need for additional meeting dates for possible day and evening meetings to keep Regulations and monthly Board activity on track.

D. SENCABAUGH addressed the audience to keep apprised of the website for future meeting dates.

LUNCH BREAK TIME 12:36PM- 1:30PM

TOPIC IX.

Executive Session (M.G.L. c. 30A § 21 (a) (1))

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

ACTION: At 1:49 PM Motion by E.TAGLIERI, seconded by M. GODEK, and voted unanimously by roll call to enter into Executive Session, P.GANNON; yes, E.TAGLIERI; yes, R.TINSLEY; yes, C.BASILE; yes, G.CAVANAUGH; yes, W. COX; yes, S. CORNACCHIO; yes, T. FENSKY; yes, M.GODEK; yes.

TOPIC X.

M.G.L. c 112, 65C SESSION

DISCUSSION: NONE

ACTION: At 2:46PM Motion by E. TAGLIERI, seconded by C.BASILE, and voted unanimously to enter into M.G.L. c 112, 65C. Session.

TOPIC XII.

AJOURNMENT of the Meeting

DISCUSSION: P.GANNON, extended his appreciation to fellow members and staff for their patience and understanding as many battled commuting issue. P.GANNON wanted recognize Board Staff for its dedication and hard work in support of the Board.

ACTION: At 4:51PM Motion by M.GODEK, seconded by G.CAVANAUGH, voted unanimously to adjourn the meeting.

Respectfully Submitted,

Richard J. Tinsley, M.B.A, M.Ed.
Secretary

List of Exhibits Referenced During the Meeting

1. Preliminary Agenda for the February 3, 2015 meeting.
2. Critical Care Systems Application for Renovation / Expansion Request for Board Approval
3. Soleo Health, Inc. Application to Operate and Manage a New Community Pharmacy
4. Integriscript, Application for Renovation / Expansion Request for Board for Board Approval
5. Report of Applications approved pursuant to Licensure Policy 13-01
6. List of proposed additional meeting dates
7. Board Policy 13-02 Plan of Correction
8. Investigative report SA-INV-3639 regarding the matter of Stat-Care Pharmacy
9. Investigative report SA-INV-3691 regarding the matter of Pharmacy Corporation of America
10. Draft Proposed Regulation: 247 CMR 9:00, Code of Professional Conduct; Professional Standards for Registered Pharmacist, Pharmacies, and Pharmacy Departments
11. Draft Proposed Regulation: 247 CMR9:00, Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies, and Pharmacy Departments –with track changes.