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NEW JERSEY STATE BOARD OF PHARMACY MINUTES OF THE OPEN SESSION December 14, 2011

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I. CALL TO ORDER

The Open Meeting of the New Jersey Board of Pharmacy was called to order by Board President Edward McGinley in the Somerset Room 6th Floor at 124 Halsey Street, Newark, New Jersey on December 14, 2011 at 9:18 a.m. All members were duly notified of the time and place and all pertinent materials were provided to the members.

II. SUNSHINE LAW ANNOUNCEMENT

Edward McGinley President, read a statement that the newspapers and appropriate elected officials had been notified of the meeting according to the requirement of the Open Public Meetings Act N.J.S.A., Chapter 231, PL 1975, /C. 10:4-8.

III. ROLL CALL

Edward G. McGinley, R.Ph.	President
Thomas Bender, R.Ph.	Vice President
Margherita Cardello, R.Ph.	
Richard Palombo, R.Ph.	
Mahesh Shah, R.Ph.	
Marc Sturgill, R.Ph.	Excused
Stephen Lieberman, R.Ph.	Excused

OTHERS IN ATTENDANCE

Susan Gartland	Acting Executive Director
Jodi Krugman	Deputy Attorney General
Maria Bertorelli	Administrator Assistant

IV. UPDATE BY EXECUTIVE DIRECTOR

1. The Executive Director reported that \$20,150.00 was collected in fines and penalties during the month of November 2011.

The following permits/licenses/registrations were issued during the month of November 2011:

- Technicians - 76
- Pharmacists - 39 (13 by examination/score transfer, 26 by reciprocity)
- Out of state pharmacies - 6
- In state pharmacies - 6
- Pharmacists receiving immunization approval - 97
- Interns (foreign graduates) - 5

V. OLD BUSINESS - Updates

1) Public Orders filed

- a) Randy O'Neal, R.Ph. - Consent Order 11/18/11
- b) Semiu Alli, R.Ph. - Consent Order 11/18/11
- c) Fredrick Burlakoff, R.Ph. - Consent Order 11/18/11
- d) William Mattioli, R.Ph. - Consent Order 11/18/11
- e) Neelam Chand, R.Ph. - Consent Order 11/30/11
- f) Theresa Freis, Technician - Consent Order 11/18/11
- g) Kyle Colalillo, R.Ph. - Consent Order to Reinstate 11/9/11
- h) Shafali Data, R.Ph. - Order of Summary Suspension 11/18/11
- I) Sheenavene Goodwin, Technician-Order of Summary Suspension 11/18/11
- j) Danielle L. Russo, Technician - Order of Summary Suspension 10/11/11

The Board reviewed public orders filed, and accepted as informational.

2) Michael J. Massaro, R.Ph., Director Pharmacy, Underwood Memorial Hospital, Woodbury, NJ – Regarding waiver requests to permit application

(This matter was last seen before the Board on 11/9/11, at that time it was advised that Underwood Memorial Hospital should submit an application for a retail license and that the Board would expedite the approval process.)

The Board reviewed correspondence submitted by Mr. Massaro, RPIC at Underwood Memorial Hospital relating to waiver requests to the permit application:

Thomas Bender moved, seconded by Richard Palombo to approve waiver requests. **Motion passed unanimously.**

3) Harriette Paradiso of Phormula Pharmacy - Regarding Certificate of Debt filed by the New Jersey Board of Pharmacy.

The Board reviewed correspondence from Ms. Paradiso's attorney regarding allegation that the Board filed erroneously two (2) certificates of debt naming her "individually" instead of in her corporate capacity as the State has done in previous years.

Richard Palombo moved, seconded by Thomas Bender to table this matter to allow DAG Krugman to further research matter. **Motion passed unanimously.**

4) Proposed Regulations - Regulatory Analyst, Maryann Sheehan

a) NJAC 13:39-7.1 - Valid Prescription

The Board discussed this proposed regulation as recommended by the Rules and Regulations Committee. Because of concerns with the scope of the regulation, particularly with respect to prescriptions resulting from legitimate telephone or internet consultation between doctor and patient, the Board asked that the matter be returned to the committee for further review and revision.

- b) NJAC 13:39-7.22 - Data Submission and Access for Prescription Monitoring Program (PMP)**

Thomas Bender moved, seconded by Richard Palombo to approve as amended. **Motion passed unanimously.**

- c) NJAC 13:39-11.1 - Compounding in retail and institutional pharmacies for sterile and/or non-sterile preparations.**

The Board was requested to approve this regulation for pre-proposal and comment. Concerns were raised about the Board's inclusion of a specific provision directing where the sink may be located, when USP 797 is silent as to the location of the sink.

Richard Palombo moved, seconded by Thomas Bender to approve the regulation for pre-proposal. **Motion passed unanimously.**

VI. NEW BUSINESS

- 1) Medco Health Solutions, Inc., Franklin Lakes, NJ -
Presentation by John Sisto and Jeff Mesaros - Non-Professional Data Entry**
Richard Palombo recused, due his affiliation with Medco.

The Board listened to Medco's presentation concerning its proposal to permit a third party to perform data entry functions which could be performed by unlicensed personnel. Following some questions,

Thomas Bender moved, seconded by Mahesh Shah to go into executive session for advice of counsel. **Motion passed unanimously.**

Margherita Cardello moved, seconded by Thomas Bender to go back into public session for further discussion. **Motion passed unanimously.**

Chair direct for DAG to research legal aspects of project and process.

- 2) Review of Joint application to conduct, Centralized Prescription Handling Pharmacy Service:**

- a) Port Richmond Pharmacy and Stokes Pharmacy**

The Board reviewed the joint application to conduct a centralized prescription handling pharmacy service.

Richard Palombo moved, seconded by Mahesh Shah to approve application. **Motion passed unanimously.**

- b) Med Prep Consulting Inc. and AHS Hospital Corp./Morristown Memorial Hospital.**

The Board reviewed the joint application to conduct a centralized prescription handling pharmacy service.

Richard Palombo moved, seconded by Thomas Bender to approve application, pending a satisfactory explanation of the audit trail and how it will be maintained.
Motion passed unanimously.

c) Med Prep Consulting Inc. and East Orange General Hospital Pharmacy

The Board reviewed the joint application to conduct a centralized prescription handling pharmacy service.

Richard Palombo moved, seconded by Thomas Bender to approve application, pending a satisfactory explanation of the audit trail and how it will be maintained.
Motion passed unanimously.

d) Solutions Homecare LLC, d/b/a Partner IV and Auxiliary Healthcare and A.C.C. Pharmacy Inc., d/b/a Discover Rx (Plainfield, NJ) and A.C.C. Pharmacy Inc., d/b/a/ Discover Rx (Bethlehem, PA)

Chair direct to request additional information from Solutions Homecare LLC as follows:

- a) Copy of Contract.
- b) Copy of policies and procedures governing the relationship between the parties.
- c) Clear explanation of their audit trail process and how the audit trail will be maintained.

3) Hamid Rahimtolla, R.Ph. - Regarding reinstatement application (expired 4/30/97)

The Board reviewed the reinstatement application.

Thomas Bender moved, seconded by Mahesh Shah that prior to the reinstatement of his license, he must satisfy the exam requirements of the NAPLEX and MPJE, pay the reinstatement fee (\$225.00), satisfactorily complete a criminal history background check, pay five (5) past renewal fees (\$840.00) plus the current renewal fee (\$140.00). Finally, he needs to submit the most recent continuing education credits completed. Once these are reviewed, the Board will determine what credit can be given toward the 75 hours required for reinstatement. **Motion passed unanimously.**

VII. MITIGATION/ HEARING REQUESTS

1) Karen Balcerzak, R.Ph. - CE (UPL)

The Board reviewed correspondence submitted in response to a Uniform Penalty

Letter.

Margherita Cardello moved, seconded by Richard Palombo to approve her request and allow her to place her pharmacist license in an inactive status. **Motion passed unanimously.**

2) Anna Park, RPIC, Duane Reade Pharmacy

Thomas Bender recused, due his affiliation with Walgreens.

The Board reviewed correspondence seeking mitigation of penalty submitted in response to a Uniform Penalty Letter.

Richard Palombo moved, seconded by Margherita Cardello to remove from inspection report #8-1217E-11-X the \$350.00 fine issued pursuant to CFR §1301.21, CFR §1301.44B.

Motion did not pass due to lack of quorum, 3-1. The matter will be reagendaized.

3) Kathryn M. Woge, RPIC - Walgreens Pharmacy, Penns Grove, NJ

Thomas Bender recused, due his affiliation with Walgreens.

The Board reviewed correspondence seeking mitigation of penalty submitted in response to a Uniform Penalty Letter.

Margherita Cardello moved, seconded by Richard Palombo to remove from inspection report #8-5623-11-X the \$25.00 fine issued pursuant to NJAC 13:39-7.18 & NJAC 13:39-6.2(f)7 and to denied mitigation request to the \$50.00 fine issued pursuant to NJAC 13:39-5.3(b). **Motion passed unanimously.**

VIII. INFORMATIONAL

1) A-4041 An act concerning tamper resistant opioid drugs

2) Correspondence from Jersey Shore University Medical Center - Regarding the use of an automated delivery device agreement.

The Board accepted as informational the one-month report required under the agreement.

3) FY2011 Budget Report

The Board accepted as informational.

4) Adopted New Rule NJAC 13:35-7A - Compassionate Use Medical Marijuana

The Board accepted as informational.

IX. COMMITTEE REPORTS

1) 3:00 p.m. Discussion regarding Committee assignments.

X. APPROVAL OF MINUTES

1) November 9, 2011

Margherita Cardello moved, seconded by Thomas Bender to approve the November 9, 2011 Open Session Minutes as amended. **Motion passed unanimously.**

X. ADJOURNMENT

At 11:50 a.m. Thomas Bender motioned, seconded by Margherita Cardello to move into Executive Session for the review of 4 complaints, 2 Old Business Items, 6 New Business Items, the Secretary's Report and Recommendation on Retail and Institutional Permits, the Secretary's Report and Recommendation on Inspection Reports, 2 Investigative Inquiries and the Approval of Minutes.