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Governor

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New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
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NEW JERSEY STATE BOARD OF PHARMACY MINUTES OF THE OPEN SESSION December 12, 2012

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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 Sussex Room at 124 Halsey Street, Newark, New Jersey on December 12, 2012 at 9:20 am. All members were duly notified of the time, place and all pertinent materials were provided to members.

II. SUNSHINE LAW ANNOUNCEMENT

President Edward McGinley, read a statement that the newspapers and appropriate elected officials had been notified of the meeting according to the requirements 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.	Late Arrival 9:42 am
Marc Sturgill, R.Ph.	
Richard Palombo, R.Ph.	Excused Absent
Mahesh Shah, R.Ph.	
Stephen Lieberman, R.Ph.	

OTHERS IN ATTENDANCE

Anthony Rubinaccio	Executive Director
Linda Brodie	Customer Service Rep I
Matthew Wetzel	Government Rep II
Megan Cordoma	Deputy Attorney General
Michael Westenberger	Enforcement Bureau

IV. UPDATE BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of November, \$7,750 were collected in fines and penalties. The following permits, licenses, and registrations were issued during the month of November:

- Technicians - 272
- Pharmacists -41 (36 by examination/score transfer, and 5 by reciprocity)

- Out of state pharmacies - 15
- In state pharmacies - 12
- Pharmacists receiving immunization approval - 50
- Interns (foreign graduates) -9

V. OLD BUSINESS

1) Orders Filed

- a. New England Compounding Center 11/20/12
- b. Kira Fedorenko, R. Ph. 11/28/12

2) Angelo J. Cifaldi, on behalf of his client **Nick Stamatiadis, R. Ph.** - Requesting reinstatement of license

Angelo Cifaldi sent in documentation showing that Mr. Stamatiadis has completed participation in Narcotics Anonymous and is in good standing with the PAPNJ. Dr. Washton, has found no evidence of impairment that would prevent Mr. Stamatiadis from returning safely to the practice of pharmacy if he continues to be monitored by Dr. Baxter, of PAPNJ.

Thomas Bender moved, seconded Marc Sturgill for the DAG to offer a Modified Consent Order for a two year suspension with one year active and the, second year stayed via petition by respondent, if all the Consent Order requirements are met. Mr. Stamatiadis will have to continue with PAPNJ monitoring until PAPNJ determines that he can be released. He will be required to show the modified Consent Order to employers, and he will not be able to be a, RPIC, an owner, or a preceptor until the end of his suspension in July of 2013. Mahesh Shah recused due to his affiliation with Mr. Cifaldi. **Motion passed 4-0.**

3) **Heidi Elzer** - Request for modification of Consent Order

Heidi Elzer has been offered a position to become the RPIC at the Stop and Shop in Flemington, NJ, but is prohibited from serving as a RPIC per the terms of her Consent Order. Ms. Elzer requested her Consent Order to be modified so she can be a RPIC and accept the position.

Thomas Bender requested this be reviewed in executive session for legal advice. At 10:22 a.m. Thomas Bender moved, seconded by Marc Sturgill to enter item into executive session for legal review. **Motion passed 6-0.** At 10:30 a.m. Thomas Bender moved, seconded by Stephen Lieberman to move back into open session.

Thomas Bender moved seconded by Stephen Lieberman to deny Ms. Elzer's request for a modification of her Consent Order, and allow her to serve as a RPIC. Ms. Elzer has only been practicing for six months, which the Board believes is not a sufficient amount of time

for the Board to render a decision on her ability to practice without restrictions. The Board would like to see her active as a pharmacist for two years without incidents and Ms. Elzer must continue participation with PAPNJ, before a modification is considered. **Motion passed 6-0**

4) Ruben Aguilar, R. Ph. - Requesting reinstatement of license

Mr. Aguilar is petitioning the Board for reinstatement of his pharmacist licence.

In accordance with Mr. Aguilar's Consent Order filed, October 13, 2010, Mr. Aguilar is required to appear before the Board before he is reinstated. Thomas Bender moved, seconded by Margherita Cardello for the Board to schedule Mr. Aguilar for an Investigative Inquiry. **Motion passed 6-0.**

5) Proposed Regulations - Compounding Sterile and Non-Sterile Preparations in Retail and Institutional Pharmacies

The proposed regulations were previously reviewed and approved by the Board. During the regulatory review process, several minor changes were made, but substantive changes were made to reporting requirements, when confirmed contamination is noted. The substantive changes necessitated another review and approval by the Board. Betsy Greenbalt appeared before the Board to detail each change that was made. The following changes have been made:

Sterile Compounding

- a) Proposed N.J.A.C. 13:39-11.12 (b) controlled temperatures terminology was changed to be consistent with United States Pharmacopeia (USP) 797. The Board requested that refrigeration be included in the terminology as well (next to control cold). Page 12
- b) Proposed N.J.A.C. 13:39-11.5 cashier proposal component has been added to the compounding regulations. Cashier proposal changed, RPIC is now responsible. Page 16
- c) Proposed N.J.A.C. 13:39-11.23 (b) 1 the RPIC is to report all confirmed contaminations to the Board within 48 hours of becoming aware of such incidents. Page 18

Non - Sterile Compounding

- d) Proposed N.J.A.C. 13:39-11A.10 the RPIC is to report all confirmed contaminations of non-sterile compounds to the Board within 48 hours of becoming aware of such incidents. Page 23
- e) Proposed language needs to be updated to something more preferable to reflect that

reporting requirements have been included. Page 27

- f) Proposed controlled temperatures terminology changed to be consistent with United States Pharmacopeia (USP) 797. The Board will like to see “refrigeration” included in terminology as well for “controlled cold”. Page 48
- g) The risk-management programs shall require that the pharmacist-in-charge report all confirmed incidents of sterile product contamination to the New Jersey Board of Pharmacy within 48 hours of becoming aware of such incidents. Page 63
- h) Any confirmed incidents of non-sterile product contamination shall be reported by the pharmacist in charge to the New Jersey Board of Pharmacy within 48 hours of becoming aware of any such incidents. Page 77

Thomas Bender moved, seconded by Marc Sturgill to accept the changes in the proposed regulations as presented and amended. **Motion passed 5-0.**

The proposal review has been completed by the Division of Law. It will be forwarded to Division of Consumer Affairs and then forwarded to the Governor’s office.

- 6) **Pipeline Health Holdings, LLC** -Out-of-state pharmacy applicant request for waiver to operate as a remote medication order entry service

Pipeline is requesting a waiver to operate from a private residence or request a pilot project be considered .

This item is tabled and will be discussed by the full Board in January as part of a discussion on remote processing regulations.

VI. NEW BUSINESS

- 1) Fernando Gonzalez, on behalf of **Arnold & Marie Schwartz College of Pharmacy** -Request on how to handle out-of-state pharmacy students internship in New Jersey

The Board accepted the submission as informational. Students who are registered in New York can do IPPE and APPE in New Jersey.

The Board noted that New Jersey is drafting a new law to allow internships to start at the end of the third year as opposed to the fifth. This would put New Jersey in line with the rest of the nation.

- 2) MedPrep Consulting Inc. - Request for Board approval to employ a pharmacist to pharmacy technician ratio greater than 1:2 as defined by N.J.A.C. 13:39-6.15(f)

Marc Sturgill moved, seconded by Margherita Cardello, that the Board finds the material submitted by MedPrep Consulting as the Policy and Procedures Training Manual to be insufficient. MedPrep is to make modifications to the training manual and outline how each of the statutory requirements are being met by its training manual. As presented, there are

deficiencies that do not meet the statutory requirements. MedPrep is not allowed to exceed the pharmacist to pharmacy technician ratio at this time, to continue will result in disciplinary action. MedPrep must cease and desist, exceeding the 2:1 ratio until their training manual has been reviewed and approved by the Board. **Motion passed 6-0.**

VII. MITIGATION REQUEST

1) **Angelika Vakhovsky, RPIC -CVS Pharmacy # 7105, Rochelle Park**

RPIC Vakhovsky would like to mitigate the fine of \$250, for violation of N.J.A.C. 13:39-7.18 of 10 misbranded medications found in the active drug stock inventory.

Thomas Bender moved, seconded by Marc Sturgill to mitigate the fine of \$250 for the above citation. The CVS procedure is to generate a return to stock label and place it over the original prescription label, and rubberband the return to stock bottle to the manufacture bottle on the shelf. **Motion passed 6-0.**

2) **Steven J. DeVane, RPIC- Wal-Mart Pharmacy # 10-5047, Audubon**

RPIC DeVane would like to mitigate the fine of \$225, for violation N.J.A.C. 13:39-7.18 of 9 misbranded medications found in inventory and the fine of \$25 for violation N.J.A.C. 19:39-6.2(f) 2 affixed label inconsistent with quantity prescribed.

Stephen Lieberman moved, seconded by Mahesh Shah to deny the mitigation request. Margherita Cardello recused herself due to her husband's affiliation with Wal-Mart. **Motion passed 5-0.**

3) **Sheeju George, RPIC- Rite Aid Pharmacy #10503, Yardville**

RPIC George would like to mitigate the fine of \$1,000 for violation of N.J.A.C. 13:39 - 6.2(f) 9 biennial CDS inventory completed but not documented correctly and the fine of \$50 for violation of N.J.A.C. 8:65-7(a) filled a schedule II CDS prescription missing required information.

Marc Sturgill moved, seconded by Thomas Bender to mitigate both violations. Margherita Cardello recused herself due to her affiliation with Rite Aid. **Motion passed 5-0**

4) **Lawrence H. Margolis - Digino's Apothecary, Wood Ridge**

RPIC Margolis would like to mitigate a fine of \$25.00 for N.J.A.C. 13:39-7.18 misbranded medication, the fine of \$50 for the violation of N.J.A.C. 13:39-2.10(b) RPIC current certificate not displayed, the fine of \$50 for violation of N.J.A.C. 13:39-6.3 no name tag worn by pharmacist, and the fine of \$250 for violation of N.J.A.C. 13:39-7.12(a) (b) 13i prescription label "Use By" deficiency.

Thomas Bender moved, seconded by Stephen Lieberman to deny the mitigation request. Marc Sturgill opposed. Mahesh Shah recused himself due to his affiliation with Mr. Cifaldi.
Motion passed 4-1.

VIII. INFORMATIONAL

IX. COMMITTEE REPORTS

X. APPROVAL OF MINUTES

Marc Sturgill moved, seconded by Margherita Cardello to approve November 28, 2012 Open Session Minutes as amended.

XI. ADJOURNMENT

At 10:47 a.m. Thomas Bender moved, seconded by Margherita Cardello to adjourn Public Session and move into Executive Session for the review of 3 Complaints, 2 Old Business Items, 2 New Business Items, the Secretary's Report and Recommendation on Retail and Institutional Permits, the Secretary's Report and Recommendation on Inspection Reports, and the approval of the November 28, Executive Sessions Minutes.