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BOARD OF PHARMACY OPEN SESSION MINUTES MONMOUTH CONFERENCE ROOM, 7TH FLOOR JANUARY 23, 2013

I. CALL TO ORDER

The Open Meeting of the New Jersey Board of Pharmacy was call to order by Board President Edward McGinley in the Monmouth Conference Room at 124 Halsey Street, Newark, New Jersey on January 23, 2013 at 9:07 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 9:36 a.m.
Marc Sturgill, R.Ph.	
Richard Palombo, R.Ph.	Excused Absence
Mahesh Shah, R.Ph.	Excused Absence
Stephen Lieberman, R.Ph.	

OTHERS IN ATTENDANCE

Anthony Rubinaccio	Executive Director
Linda Brodie	Customer Service Rep.
Matthew Wetzel	Government Rep.
Jodi Krugman	Deputy Attorney General
Rachel Glasgow	Regulatory Analyst

IV. UPDATES 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 December:

- Technicians registered - 171
- Pharmacists licensed - 31 (26 by examination and 5 by reciprocity)

- out of state pharmacies registered - 2
- in state pharmacies licensed - 2
- Pharmacists receiving immunization approval - 38
- Interns (foreign graduates) licensed - 4

V. OLD BUSINESS

1) Orders Filed

- Jennifer Miller, Pharmacy Technician (12/19/12)
- Amy Duffield, Pharmacy Technician (12/19/12)
- Thomas Wall, Pharmacy Technician (12/19/12)
- Nicole Ardite, R.Ph. (1/4/13)
- Calvin Osei, R.Ph. (1/10/13)
- Rachel Sohn, R.Ph. (1/10/13)

2) Geriscript, LLC, David Kozloski, RPIC - Compounding records per Board's request pursuant to Mr. Kozloski's mitigation request

Presented at the Open Session on August 22, 2012, the Board reviewed correspondence submitted by Geriscript, requesting mitigation of UPL. Richard Palombo moved, seconded by Mahesh Shah for the Board to obtain an affidavit from Geiscript to verify when compounding commenced, and provide compounding records post move and pre-inspection. Motion passed 5-1. Stephen Lieberman, opposed.

David Kozloski, R.Ph. for Geriscript submitted requested documentation pertaining to when compounding began at the new location.

At 9:18 am Marc Sturgill moved, seconded by Stephen Lieberman for the Board to go into Executive Session for advice of counsel to discuss a potential additional violation. **Motion passed 4-0.**

At 9:42 am Thomas Bender moved, seconded by Marc Sturgill to move back into Open Session. **Motion passed 4-0.**

Thomas Bender moved, seconded by Marc Sturgill to mitigate cite N.J.A.C. 13:39-11.19(d) with a fine of \$2,500.00, clean room has not certified as an ISO Class 6 environment; N.J.A.C. 13:39- 11.20(a) with a fine of \$2,500.00, anteroom not certified as an ISO class 7 environment; and N.J.A.C. 13:39- 11.14(b)4 with a fine of \$1,000.00, for air and surface sampling not being done at the new location. In addition the old UPL will be withdrawn and replaced with a new UPL to include N.J.A.C. 13:39-11.17(d) with a fine of \$500.00, for ceiling panels not being caulked, weighted or clipped to the frame and a warning for N.J.A.C. 13:39-11:4 and N.J.A.C. 13:39-11:4.7 compounding before inspection. **Motion passed 5-0**

3) Christopher Helvitson - POD to be finalized

Margherita Cardello moved, seconded by Marc Sturgill to issue a FOD on default (same terms). **Motion passed 5-0**

- 4) Mark Mankbadi - POD to be finalized

Thomas Bender moved, seconded by Marc Sturgill to issue a FOD on default (same terms). **Motion passed 5-0**

- 5) Jeremiah Burgert - POD to be finalized

Marc Sturgill moved, seconded by Stephen Lieberman to issue a FOD on default (same terms). **Motion passed 5-0**

- 6) Hanley Abraham - POD to be finalized

Thomas Bender moved, seconded by Marc Sturgill to administratively close matter, as license already fully reinstated in North Carolina. **Motion passed 5-0**

VI. NEW BUSINESS

- 1) Bill Comment Request - A-2541 (Asm. Ramos) reduces tasks that may be performed by pharmacy technicians

The Board reviewed A2541. The Board concluded that the bill went too far in limiting the tasks that technicians could perform to assist a pharmacist. It would increase a pharmacy's cost of operation if counting, weighing, measuring, pouring, and compounding of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system had to be performed by the pharmacist without assistance of a technician. The Board suggested other ways to amend the statute relating to technicians, such as requiring training and continuing education. At minimum, before a pharmacy or practice site hires a technician it should have a policy and procedure manual for technicians and go over it with them. There are some other changes in the Practice Act that the Board would like that are reflected in the draft of an alternative bill that was presented to the meeting.

The Board agreed the alternative provided added protection for the public. Thomas Bender moved, seconded by Marc Sturgill to move forward in supporting this draft as a replacement for Bill A2541. **Motion passed 5-0.**

2. Remote Processing of Prescriptions Pre-Proposal- Discussion on status of proposed regulations

The Board agreed to move forward with the proposal, but noted it will require additional review and updating in terms of better prefatory language and clarification to what types of functions would and would not be is not allowed. Marc Sturgill moved, seconded by Thomas Bender to address working on the regulation proposal with remote processing procedures. **Motion passed 5-0.**

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

This item was tabled in December to be addressed before the full Board in January.

Thomas Bender moved, seconded by Stephen Liberman to approve Pipeline's application to operate as an out-of -state pharmacy with a retail permit. The next step for Pipeline is to submit a completed central fill application(s) with it's New Jersey client(s) for review by the Board. If the central fill application(s) is/ are approved, the Board will outline additional items that pipeline will need to supply in order to be granted the ability to operate in New Jersey under a pilot program agreement. These items will include, but are not to be limited to: Pipeline supplying the Board with a policy and procedure manual for the remote handling of prescriptions; agreeing to quarterly reporting of patient services; and addressing security issues. **Motion passed 5-0.**

The point was raised that the Board may want to consider another type of classification for permits/registrations in addition to the two current types, retail and institutional. Additional permit/registration classifications will be placed on the Rules and Regulations Committee agenda for discussion.

4. Pharmacist Assessment for Remediation Evaluation (PARE) - Discussion of exam scope and use by the Board

The Board accepted the Pharmacist Assessment for Remediation Evaluation (PARE) as informational. The Board will use the PARE exam as an assessment tool on a case by case basis and will not apply the results strictly on a pass/ fail basis. The individual results of each licensee's particular situation. If the examination is taken in another state, the Board will need access to the score report in order to make their own determination.

5. Hackensack University Medical Center, Mobile Satellite Emergency Department (MSED) - Request for review of MSED truck and manual

The Board accepted this as Informational only.

6. Community Medical Center, Barnabas Health - Waiver request for speciality pharmacy license to service clinical drug study patients

N.J.A.C. 13:39-4:16 addresses the regulations governing the issuance of specialized permits. The Board will request a copy of the hospital's Standard Operating Procedures manual for Investigational New Drugs. This will cover among other things, where and how the drugs for studies are stored, and how they are handled and administered to patients.

The hospital's Investigational Review Board (IRB) sets the policy for research in their specific institution. The Board office is to request a copy of that document

Chair Direct: Community Medical Center should file a specialized permit application for a pharmacy license with the guidance of the Board office.

7. Twin City Specialty Pharmacy - Waiver request of square footage requirement

Chair Direct: The Board office will obtain additional information as to why a second permit has been requested. Twin City Specialty Pharmacy does not appear to have separate facilities, and it is not clear what services are going to be provided.

VII. MITIGATION/HEARING REQUEST

1. Salvatore Velez, RPIC - Medicap Pharmacy, Barnegat

Salvatore Velez RPIC, would like to mitigate the violation N.J.A.C. 8:65-5.7 (13:45H) fine of \$1,000.00 for the pharmacist not having access to the lock cabinet where the CDS inventory report was keep.

Thomas Bender moved, seconded by Stephen Liberman that the mitigation of \$1000.00 is pending until the Board office receives a copy of the inventory report.
Motion passed 5-0.

2. Bhargav K. Shukla, RPIC - Target Pharmacy, South Plainfield

Bhargav K. Shukla, RPIC, would like to mitigate the violations N.J.A.C. 13:39-6.12 fine \$50.00, 13:39-7.16(c) 2&3 fine \$75.00, 13:45H-7.5(a) fine \$50.00 and two warnings N.J.A.C. 13:39-5.8 and 13:39-5.9 (a). He has corrected all violations and were told by the inspector violations would not go before the Board.

Stephen Lieberman moved, seconded by Margherita Cardella to deny mitigation but remove the warning N.J.A.C. 13:39-5.9(a). **Motion passed 5-0.**

3. Jayesh Patel, RPIC- Park Dug, Linden

Jayesh Patel, RPIC would like to mitigate N.J.A.C. 13:39-5.9 fine of \$300.00 because weights and measures did not perform inspections.
Marc Sturgill moved, seconded by Margherita Cardello to mitigate the fine.
Motion passed 5-0

4. Patricia Cox, RPIC - Shop Rite Pharmacy Department, Chatham

Patricia Cox, RPIC would like to mitigate N.J.A.C.13:39-6.2(f) fine of \$500.00 she was unaware of the minimum work hours of 35 hours per week.

Margherita Cardello moved seconded by Marc Sturgill to deny mitigation.

Motion 5-0

5. Davis Miller, RPIC - Millers of Wyckoff Inc, Wyckoff

David Miller, RPIC would like to mitigate N.A.J.C. 13:39 -7.21(a)11 and 13:39-6.2(f)2&3 fine \$200.00 and 2 CE credits for labeling the prescription as directed instead of what was written.

Stephen Lieberman moved, seconded by Thomas Bender to mitigate the above fine. Margherita Cardello opposed. **Motion passed 4-1**

6. Monet Cabral- Duane Reade Pharmacy #14402, Jersey City

This item was moved from the Executive Session Agenda 3E (1), to the Open Session Agenda. The item originated as a complaint for failure of counsel but it is now a mitigation for Monet Cabral RPIC.

Monet Cabral, RPIC would like to mitigate N.J.A.C. 13:39-7.21(b) fine \$1000.00 noting that the technician didn't notify her the patient wanted to be counseled.

Margherita Cardello moved, seconded by Edward McGinley to deny mitigation request. Thomas Bender was recused due to his affiliation with Walgreens. **Motion passed 4-0.**

VIII. INFORMATIONAL

John Covello, of the Independent Pharmacists Association (IPA), discussed the Association's meeting with representatives from the Director's office to address concerns with the Division's "Best Practices for Pharmacy Security" document. Mr. Covello expressed concerns that it may potentially create HIPAA violations for retail pharmacists, the potential use by the DEA to take actions based on the Best Practices document, as well as actions that may potentially taken by Insurance Payers referencing the document.

The Board will ensure that the document clearly states that all the recommendations outlined in the document do not apply in their entirety to every situation; the document is not intended to be a "one -size fits all" set of guidelines. There is no intent for Insurance Payers to be able to utilize this document in order to recapture funds.

IX. COMMITTEE REPORTS

The Board's Law Enforcement Committee met on January 8, 2013

The electronic Enforcement Bureau Report was reviewed and approved by the committee. The Director's office of the Division of Consumer Affairs supports the creation of a self-assessment tool for the Board to make available to all pharmacies in New Jersey. Currently researching any legal constraints to use an assessment tool.

The Rules and Regulations committee met on January 15, 2013

The proposed updates to the compounding regulations are scheduled to be published in the New Jersey Register on March 4, 2013.

The proposed changes to regulations concerning container integrity will be presented to the Board at the February 27, 2013 meeting.

The pharmacy technicians rules were going to be published.

X. APPROVAL OF MINUTES

Marc Sturgill moved, seconded by Thomas Bender to approve December 12, 2012 Open Session Minutes as amended.

XI. ADJOURNMENT

At 12:02 p.m. Margherita Cardello moved, seconded by Thomas Bender to adjourn Public Session and move into Executive Session for review of 10 complaints, 3 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 December 12, Executive Session Minutes.