

KIM GUADAGNO Lt. Governor

# New Jersey Office of the Attorney General

Division of Consumer Affairs

Board of Pharmacy
124 Halsey Street, 6<sup>th</sup> Floor, Newark, NJ 07102



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## BOARD OF PHARMACY OPEN SESSION MINUTES MONMOUTH CONFERENCE ROOM, 7<sup>TH</sup> FLOOR May 29, 2013

## I. CALL TO ORDER

The Open Meeting of the New Jersey Board Of Pharmacy was called to order by the Board President Edward McGinley in the Monmouth Conference Room at 124 Halsey Street, Newark, New Jersey on May 29, 2013, at 9:07 a.m. 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 Open Public Meetings Act N.J.S.A., Chapter 231, PL 1975,C.10:4-8

#### III. ROLL CALL

Edward G. McGinley, R.Ph. Thomas Bender, R.Ph. Margherita Cardello, R.Ph. Marc Sturgill, R. Ph. Richard Palombo, R.Ph. Mahesh Shah, R.Ph. Stephen Lieberman, R.Ph. President Vice President Excused Absence Late Arrival 9:15 a.m.

## OTHERS IN ATTENDANCE

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

## V. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of April, \$12,150 was collected in fines and penalties. The following permit, licenses, and registrations were issued during the month of April:

- Technicians -94
- Pharmacists 25 (20 by examination / score transfer and 5 by reciprocity )
- Out-of- state pharmacies 4
- In-state-pharmacies 7
- Pharmacists receiving immunization approval -65
- Interns (foreign graduates) 9

## V. OLD BUSINESS

- 1. Orders Filed
  - a) MedPrep Consulting, Inc. (4/19/13)
  - b) Nick Stamatiadis, R.Ph. (4/30/13)
  - c) Tyrone Morgan, Pharmacy Technician (4/30/13)
  - d) John Hussey, Pharmacy Technician (4/30/13)
  - e) MedPrep Consulting, Inc. (5/2/13)
  - f) Pallimed Solutions, Inc. (5/2/13)

## 2. **Dia Woodford, Pharmacy Technician-** POD to be finalized

Dia Woodford was registered as a pharmacy technician in the state of New Jersey on June 7, 2012. On August 31, 2012, she gave a voluntary statement to CVS Pharmacy, admitting to stealing drugs from them between March 2012 and August 2012. On March 25, 2013 a POD was filed.

Thomas Bender moved, seconded by Richard Palombo to finalize the POD by default. **Motion passed 4-0** 

## 3. **Denise Roman, Pharmacy Technician** - POD to be finalized

Denise Roman was registered as a pharmacy technician in the of New Jersey on October 19, 2010. In February of 2012 she pled guilty in Superior Court of New Jersey in Essex County to (1) count of knowingly committing healthcare claims fraud in violation of N.J.S.A. 2c:21-4.3A and was convicted. On March 14, 2013 a POD was filed.

Thomas Bender moved, seconded by Richard Palombo to finalize the POD by default. **Motion passed 4-0** 

## 4. **Twin City Specialty Pharmacy** - Waiver request of square footage requirement

Twin City Specialty Pharmacy went before the Board January 23, 2013, for a waiver request for not having the minimum required square footage. The Board members issued a Chair Direct for the Board office to obtain additional information as to why another permit is needed.

Twin City Speciality Pharmacy responded with the following information:

- They will be a closed door pharmacy
- The proposed pharmacy will have a separate entrance, phone number, and address
- The computer system and software will be different, with separate filing systems
- The space will be used to pre-formulate, bioengineered injectables
- The goal is to transfer hospice prescriptions from the existing retail pharmacy to the new closed door pharmacy
- The new permit will allow this pharmacy to join certain buying groups to obtain specialty pharmacy medications

Richard Palombo moved, seconded by Marc Sturgill to table the waiver request pending additional information showing proof of undue hardship in accordance with <u>N.J.A.C.</u> 13:39-1.6. **Motion passed 6-0** 

5. Pamela Mandel, on behalf of her **client Michael Stavitski, R.Ph.**- Response to Boards's denial of reinstatement

Michael Stavitski reinstatement application went before the Board on April 24, 2013. Mr. Stavitski's license was revoked on March 14, 2002 for healthcare claims fraud. Richard Palombo moved, seconded by Margherita Cardello to deny his request for reinstatement at this time due to his egregious conduct and non-responsiveness to the POD issued on 12/12/03. **Motion passed 6-0** 

Thomas Bender moved, seconded by Marc Sturgill to move this item to be discussed last on the open agenda in order to go into executive session for advice of counsel. At 11:18 a.m. this item went into executive session. At 11:52 a.m. Marc Sturgill moved, seconded by Richard Palombo to returned to open session. Richard Palombo moved, seconded by Mahesh Shah to schedule Mr. Stavitski for an Investigative Inquiry. **Motion passed 6-0.** 

6. **Alan Kay, R.Ph.** - Consent Order of Reinstatement filed allowing reinstatement subsequent to compliance with requirements in ordered paragraph 1 (criminal history background check and submission of continuing education credits). This Item is an add on to the agenda; the purpose is for clarification of the Board's previous response on this request.

Mr. Kay has met the Consent Order requirements, requesting new Order granting an unrestricted license.

Marc Sturgill moved, seconded by Mahesh Shah to remove probation and reinstate his license without restrictions.

Thomas Bender was recused because Mr. Kay was a former employee of Walgreens. **Motion passed 5-0** 

1. **Pharmacy Technician Regulations**- Adoption by the Board

Marc Sturgill moved, seconded by Richard Palombo to adopt the Pharmacy Technician Regulations. **Motion passed 6-0** 

2. **St. Joseph's Healthcare System**, Paterson, NJ - Seeking approval for Electronic Display of Pharmacy Licenses and Certificates

Mitch Sobel of St. Joseph's Healthcare System is asking the Board for an interpretation of the regulations on the displaying of licenses, and approval to display licenses electronically in a photo frame which will perpetually scroll the images in accordance to public display rules.

Richard Palombo moved, seconded by Stephen Lieberman to approve the electronic display of pharmacist and pharmacy technician licenses and registrations as long as the original are available on site for patients to observe if requested.

This matter is also being referred to the Rules and Regulations Committee for clarification, and sent to the Enforcement Bureau as well. It will also be included as a Newsletter item. **Motion passed 6-0** 

3. **Martin Dix**, Akerman Senterfitt - Request for Board review of pharmacy business practices

Mr. Dix contacted the Board on behalf of a client to determine if New Jersey allows the payment by the pharmacy to the prescriber, or if this would be considered as a kickback/rebate/split fee.

Thomas Bender moved, seconded by Marc Sturgill, that under N.J.S.A.45.1-28 Veterinarians are considered health care professionals, and under statute N.J.A.C. 13:39-3.10, this proposed business model would be considered steering. **Motion passed 6-0** 

4(a). **Brain Furbush, R.Ph.**, HealthSouth Hospital, Toms River, NJ - Request for Board interpretation of N.J.A.C. 13:39-4.15(b)1 Security of Pharmacies and Pharmacy Departments

The security system described in the statute seems more appropriate for retail pharmacies rather than for hospital settings.

This item was tabled for DAG Cordoma to research the matter.

4(b). **Scott Angus, R.Ph.**, QPharma, Inc.- Requesting interpretation of who is allowed access alarm codes

Mr. Angus is asking if the pharmacy alarm/access codes can be given to someone other than a licensed pharmacist.

Chair Direct: The Board determined that the PIC shall be responsible for securing the

access and alarm codes, but others can have access to them. The Board office will send clarification to Mr. Angus.

5. **ASPN** retail permit application - Waiver request of certain retail pharmacy requirements

ASPN is a non-dispensing pharmacy and asked the Board to waive equipment and facilities of the prescription area requirements present under New Jersey pharmacy laws and regulations; the requirement to include copies of prescription and poison labels on the pharmacy permit application because ASPN will not be dispensing any drugs from its facility. ASPN also asked the Board to waive any other requirements the Board deems inapplicable to this pharmacy application.

Richard Palombo moved, seconded by Stephen Lieberman to grant ASPN a retail permit and to grant the waiver request of the applicant due to excessive hardship in requiring equipment/space, etc. which is not required in this type of pharmacy practice. The waiver will also include exterior signage requirements; the pharmacy name is required on outside door only. Also, a Central Fill application will be required upon execution of contracts with facilities/clients, etc. **Motion passed 6-0** 

6. **Bill Comment Request- A-3887** (Asw. Munoz) - requires emergency action plans for delivery of oxygen to patient residences during public health emergency

Richard Palombo moved, seconded by Stephen Lieberman to support Bill A-3887. **Motion 6-0** 

7. **Anthony Czaplick, R.Ph. -** Reciprocity applicant, review of work experience as a pharmacy consultant

Marc Sturgill moved, seconded by Mahesh Shah to proceed with reciprocity application . Motion passed 5-1

8. **Mary Bishay, R.Ph**. - Reciprocity applicant, review of work experience as a pharmacist in industry

Richard Palombo moved, seconded by Edward McGinley for the applicant to supply the Board with a detailed resume outlining her job responsibilities. **Motion passed 6-0** 

9. **Barbara Pesciotta, R.Ph.**- Request for reinstatement of license

Ms. Pesciotta is under a Consent Order filed January 25, 2006 for practicing pharmacy under a surrendered license and obtaining CDS through the use of stolen and forged prescription banks. Her license is surrendered and deemed a revocation with prejudice to any reapplication.

At 10:51 am Thomas Bender moved, seconded by Richard Palombo to move this item into executive session for further discussion and advice of counsel. **Motion passed 6-0** 

At 11:53 am Marc Sturgill moved, seconded by Richard Palombo to move back to open session. **Motion passed 6-0**.

Stephen Lieberman moved, seconded by Marc Sturgill to not consider Ms. Pesciotta's request for a pathway to reinstatement at this time. **Motion passed 6-0.** 

## VII. MITIGATION/HEARING REQUEST

1) Nahed Ahmed, Owner - **Organix Pharmacy**, Pompton Lakes, NJ

Organix Pharmacy was cited for violation of <u>N.J.S.A.</u> 45:14-65(e) unprofessional conduct (improper advertising) at October 3, 2012 Board Meeting.

Mr. Ahmed stated that he was unaware of the law and since this is his first time he asked the board to dismiss or reduced the fine.

Thomas Bender moved, seconded by Stephen Lieberman to deny the mitigation request. **Motion passed 6-0** 

2. Svetislav Milic, RPIC - Colonia Natural Pharmacy, Colonia, NJ

During the 11/7/12 inspection the RPIC and the staff pharmacist Kimberly Hansen were found not to have been annually trained in sterile product compounding laminar flow technology and quality assurance techniques. A violation was issued under **N.J.A.C.** 13:39-11.7, with a fine of \$1,000.00.

Angelo J. Cifald, Esq. responded for Colonia Natural Pharmacy, stating that the RPIC Svetislav Milic does not engage in the compounding of sterile preparations, even though he has academic training in sterile preparation compounding. His staff pharmacist Kimberly Hansen, is responsible for the compounding of sterile preparations for the pharmacy. Documentation was submitted demonstrating the training and testing that Ms. Hansen has completed.

Thomas Bender moved, seconded by Stephen Lieberman to deny the mitigation request. They have not provided proof of proper annual training; there were no media fill or fingertip testing documentation provided. **Motion passed 5-0** Mahesh Shah was recused due to his affiliation with A. Cifald.

3. Jeney Rasla, RPIC - Sav-On Pharmacy, Morris Plains, NJ

During the 4/18/12 inspection the pharmacy was cited for violation of N.J.A.C. 8:65-5.7 CDS biennial inventory not being available.

RPIC Rasla stated that the CDS biennial inventory was misfiled and found shortly after the inspection and provided. Company policy requires CDS inventory to be done annually.

Marc Sturgill moved, seconded by Stephen Lieberman to remove the cite for violating N.J.A.C. 8:65-5.7. **Motion passed 6-0** 

4. Salvatore Velez, RPIC - Medicap Pharmacy, Barnegat, NJ

During the February 22, 2012 inspection they were cited for violating N.J.A.C. 8:65-5.7 CDS biennial inventory not being available.

RPIC Velez stated that the CDS biennial inventory was locked in a cabinet that only the owner had access to, was later provided ro us.

Marc Sturgill moved, seconded by Thomas Bender to remove cite for violating N.J.A.C. 8:65-5.7. **Motion passed 6-0** 

#### VII. INFORMATIONAL

1. Rx Timer Cap- Suggesting a mandate of timer cap containers

Rx Timer Cap is a prescription bottle closure, which incorporates a digital timer that works like a stopwatch, automatically counting the time since medication container was last opened.

The Board accepted this as informational.

2. Codonics- Safe label system for patient safety

Codonics is currently focused on Safe Label System (SLS), a first of it's type FDA Class II medication safety device. The reason for the communication is to broaden the understanding and scope of solutions positioned to advance patient and medication safety.

The Board accepted this as informational.

3. Coram- Request to increase the NJ State Medicaid allowable reimbursement rate for the product, Factor Eight Inhibitor Bypass Agent, which is manufactured by Baxter Bioscience

The information does not fall under the pervue of the Board of Pharmacy and will be directed to the Department of Banking and Insurance.

- 4. Edward McGinley was elected Treasurer of NABP
- 5. Margherita Cardello give birth to a baby boy on May 28, 2013
- 6. Publication for Sterile Compounding Regulations is due on June 3.

- 7. The Executive Director is to obtain information regarding the Enforcement Bureau electronic tablets status
- 8. New Jersey Board of Pharmacy has contracted with NABP for additional support to inspect sterile compounding pharmacies in New Jersey. It is expected that this activity will begin in June 2013.
- 9. NABP held its 109<sup>th</sup> conference in St. Louis. Missouri. Discussion topics included compounding issues, NABP creating the ".pharmacy" domain to host only validated on-line internet pharmacies, and virtual pharmacies and wholesalers being able to compromise the integrity of the drug delivery system among other topics.

## IX. COMMITTEE REPORTS

## X. APPROVAL OF MINUTES

Marc Sturgill moved, seconded by Stephen Lieberman to approve the April 24, 2013 Open Meeting minutes as amended. **Motion passed 6-0** 

## XI. ADJOURNMENT

At 11:52 a.m. Richard Palombo moved, seconded Mahesh Shah, to Adjourn Public Session and move into Executive Session for review of 13 Complaints, 4 Old Business Items, 11 New Business Items, the Secretary's Report and Recommendation on Retail and institutional Permits, the Secretary's Report and Recommendation on Inspection Reports and approval of April 24, 2013 Executive Session Minutes.