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Governor

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# ***New Jersey Office of the Attorney General***

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## **BOARD OF PHARMACY PUBLIC SESSION MINUTES MONMOUTH CONFERENCE ROOM, 7th FLOOR May 27, 2015**

### **I. CALL TO ORDER**

The Open Session of the New Jersey Board of Pharmacy was called to order by the Board President, Mr. Thomas F.X. Bender, at 124 Halsey Street, Monmouth Conference Room, 7<sup>th</sup> floor, on May 27, 2015 at 9:07 a.m. All members were duly notified of the time, place and all pertinent materials were provided to the members.

### **II. SUNSHINE LAW ANNOUNCEMENT**

President Thomas F.X. Bender 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, PL1975/C.10:4-8.

### **III. ROLL CALL**

|                            |                |
|----------------------------|----------------|
| Thomas F.X. Bender, R.Ph.  | President      |
| Richard Palombo, R.Ph.     | Vice President |
| Margherita Cardello, R.Ph. |                |
| Edward G. McGinley, R.Ph.  |                |
| Mahesh Shah, R.Ph.         |                |
| Stephen Lieberman, R.Ph.   |                |
| Calliope Alexander         |                |
| Carol Jacobson, Esq.       |                |
| Linda Witzal, R.Ph.        |                |
| Mitch Sobel, R.Ph.         |                |

### **OTHERS IN ATTENDANCE**

|                           |                         |
|---------------------------|-------------------------|
| Anthony Rubinaccio, R.Ph. | Executive Director      |
| Matthew Wetzel            | CDS Executive Director  |
| Jodi Krugman              | Deputy Attorney General |
| Rachel Glasgow            | Regulatory Analyst      |
| Jessica Kelley            | Board Staff             |

#### IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of April, \$32,275 was collected in fines and penalties. The following permits, licenses, and registrations were issued during the month:

- Pharmacy Technicians registered – 295
- Pharmacists licensed – 47 (31 by examination/score transfer and 16 by reciprocity)
- Out-of-State Pharmacies registered – 8
- In-State Pharmacies licensed – 6
- Pharmacists receiving immunization approval – 27
- Interns (foreign graduates) licensed – 8

The 111<sup>th</sup> Annual NABP meeting was held in New Orleans, LA May 16-19, 2015. The event was well attended by over 50 states and territories. Many topics were covered and included:

- *Combating Prescription Drug Abuse – Together We Are Making a Difference*
- *DQSA – Are We There Yet?*
- *Drug Supply Chain Integrity – What Will the Future Hold?*
- *Inspection Tools – Update on the Uniform Inspection Blueprint*
- *Team-Based Care – Where Do We Start?*
- *FDA MOU*

Congratulations to Edward McGinley, MBA, RPh who was inaugurated as the President of NABP at the 111<sup>th</sup> annual meeting. Mr. McGinley will focus on building team based care and collaboration with other regulators as well as prescription drug abuse as his presidential initiatives.

The Board thanks Carol Jacobson for her contributions as a public member during her tenure. We wish Carol the best in her retirement!

#### V. OLD BUSINESS

##### 1) Memorandum of Understanding between FDA & States – Board Comments

The Board reviewed the draft MOU, comments presented from Board members, and the NABP review of the MOU.

- *Any report about compounded products for human use shipped out of NJ MUST be investigated to determine the root cause of the problem. Although we would, of course, investigate NJ-based pharmacy contamination, the MOU would make it mandatory even if none of the product was utilized in NJ and regardless of our resources and priorities.*

- *Reports of complaints about NJ based compounding pharmacies MUST be reported to the FDA within 72 hours, although no procedure or standards are proposed.*
- *Ongoing monitoring of pharmacies would be mandatory to determine the amount of product shipped out of state, relative to the total amount of compounded product, as would reporting to the FDA whenever the ratio exceeded 30%. These requirements would place a new regulatory and monitoring burden on NJ. The requirement lacks specificity regarding the defining the number of units to determine volume; the mechanism to determine the ratio during an inspection or through submissions from the compounding pharmacy; whether veterinary products are included or the requirements only pertain to compounded drugs for human use; the course of action when the pharmacy exceeds the 30% limit; and any distinctions on monitoring physician (as opposed to pharmacy/pharmacist prepared) compounding.*

Board Comments:

1. *Investigation of Complaints:*

- A. Not feasible as stated by FDA for time constraints for states to report. The New Jersey Board of Pharmacy ("BOP") already investigates and handles in the most efficient way- via inspection process and via license for out of state pharmacy and scrutiny of operations to ensure that the consumer is protected.*
- B. Any Adverse Events - this is not feasible to burden the state to be responsible for ANY adverse EVENT- Not enough man hours to comply. Who is identifying adverse event?*
- C. Method and or the process for investigations not being identified as a standard for a standard. MOU appears to just be removing any responsibility from the FDA and then the State could be left with huge liability and due to the interpretation of the FDA's opinion of how the state handled the issue.*

2. *Inordinate Amounts:*

*The ability to gather, maintain accountability, and keep track of a number that has not been identified as to how the state would calculate the number is HUGE BURDEN due to the lack of understanding from Congress regarding Prescription Dispensing and Distributed the ability to accurately calculate the number of units or percentage correctly is not attainable.*

3. *Exemptions from Interstate Distribution Provisions:*

*The current Outsourcing licensing registration identifies the manner in which a facility that is producing and distributing to ensure safe and properly prepared product. Due to Congress not exempting certain products or therapies that would be counted in the percentage would again be a huge burden on providers such as Home infusion and could cause a negative outcome to the end user, the patient, who we are trying to protect.*

4. *Information Sharing between states:*

*The language of this draft does not identify how or who and the cost associated with reporting any adverse event to communicate this information. Currently the BOP identifies any issues or problems reported by NJ residents from out-of-state pharmacy and information is sent to that originating state.*

5. *Enforcement of 5 % volume:*

*Extremely burdensome and not realistic to maintain and monitor and without additional funding and resources this is not attainable.*

6. *The estimates of how many complaints, the time required to handle the complaint and the burden for this MOU to be executed appears to be under estimated.*

Edward McGinley explained that the NABP's alterations to the draft MOU addressed the major issues which have been brought to the attention of the NABP by the states. The Board's support of the NABP alterations would support a level of consistency between the states when presenting the comments to the FDA.

Richard Palombo moved, seconded by Mitch Sobel, to support NABP's modifications along with Mr. McGinley's observations and the set of comments on today's agenda. **Motion passed 10-0.**

2) **Total Vein Pharmacy – Out-of-State Pharmacy, Sterile Compounding – Updated NABP VPP inspection Report**

The Board previously considered the non-resident application at the February 20, 2015 meeting.

*Edward McGinley moved, seconded by Carol Jacobson, that the pre-opening inspection report was completed in June 2014 and that the pharmacy has been operational for 7 months. The Board requests a third party (such as NABP) or the Texas Board of Pharmacy complete an inspection as to determine operations now so their dynamic conditions can be measured. The application will be reconsidered after the results from a new inspection are received. Motion passed 8-0.*

While reviewing the inspection report, the Board noted deficiencies associated with Texas regulation related to labeling and alarm codes. The Board determined to focus on New Jersey regulations.

Edward McGinley moved, seconded by Mahesh Shah, to approve the out-of-state pharmacy application based upon the VPP inspection report of 04/01/15. The pharmacy is to send the Board its response to the VPP report. **Motion passed 9-1. Mitch Sobel was opposed.**

**3) Direct Success Pharmacy – Updated Pharmacy Technician Training Manual**

The Board previously considered the pharmacy technician training manual and program at the February 4, 2015 meeting. The training program would allow the pharmacy to exceed the 2:1 pharmacy technician to pharmacist ratio.

*Stephen Lieberman reviewed the documentation provided and presented his recommendation to the Board. He suggested that if Direct Success updated the training manual to include information regarding filing requirements for CDS, and corrected an error on page 40 which indicates that pharmacy technicians '... may accept authorization from patient for a refill', that the Board should approve this Pharmacy Technician Training program. Thomas Bender moved, seconded by Richard Palombo to support Mr. Lieberman's recommendation. Motion passed 9-0.*

Direct Success Pharmacy provided the Board with an updated training manual, addressing the above requirements.

Margherita Cardello moved, seconded by Stephen Lieberman, to approve the updated training manual. **Motion passed 10-0.**

**4) Public Orders Filed**

- a. Noha Amar, Pharmacy Technician – FOD – Suspension of Registration (4/22/15)
- b. Samir Kumar Patel, R.Ph. – Consent Order – Administrative Action (4/22/15)
- c. Alton Chatmon, R.Ph. – Interim Consent Order – Suspension of License (4/23/15)
- d. Light Pharmacy, Inc., Bridgeton, NJ – Interim Consent Order – Suspension of Registration (4/23/15)
- e. Morning Star Pharmacy, Millville, NJ – Interim Consent Order – Suspension of Registration (4/23/15)

**VI. NEW BUSINESS**

**1) Automated Delivery Device Regulations** – a summation from Regulatory Analyst Rachel Glasgow

Ms. Glasgow provide the Board with a summary of 13:39-7.22, Use of automated delivery devices.

Thomas Bender moved, seconded by Edward McGinley, to approve the regulation for proposal. **Motion passed 10-0.**

2) **Focus Rx, Holbrook, NY** – Sterile Compounding Pharmacy applicant.

Mahesh Shah moved, seconded by Linda Witzal, to approve this non-resident application. **Motion passed 10-0.**

3) **Natalie Homan, R.Ph.** – Reciprocity Candidate, NY licensure

Ms. Homan is licensed as a pharmacist through the New York State Board of Pharmacy, but has not practiced since 2003 to raise her children.

Richard Palombo moved, seconded by Mahesh Shah, that Ms. Homan does not satisfy the requirements of N.J.S.A. 45:1-7.5 for licensure via reciprocity. Ms. Homan should be allowed to withdraw her application. **Motion passed 10-0.**

4) **Pharmacy Self-Assessment Checklist**

The Board reviewed a self-assessment checklist composed by Michael Westenberger and Anthony Rubinaccio. The checklist will be posted on the Board's website, available to retail pharmacies as a reference tool. It is subject to change and is to be used as a reference tool, not an official inspection tool

Margherita Cardello moved, seconded by Mahesh Shah, to approve the amended checklist as a reference document available for retail pharmacy use. **Motion passed 10-0.**

5) **Ocean Health Initiatives** – closed door pharmacy requesting waiver of signage requirements.

The Board received and reviewed the request to waive signage requirements as the pharmacy is a closed door, 340b pharmacy.

Linda Witzal moved, seconded by Stephen Lieberman, to approve the waiver of N.J.A.C. 13:39-5.3. **Motion passed 10-0.**

## VII. MITIGATION/HEARING REQUEST

1) **Mitigation Request – Arienne Carrington, RPIC-** Pathmark Pharmacy, South Orange, NJ

Following an inspection revealing a violation related to the security system, a UPL was issued seeking a fine for this, other violations, and a letter of corrective action.

Martin Dunleavy, Esq., provided an explanation on behalf of Pathmark Pharmacy, stating that the citation was the result of a miscommunication with the Board's

inspector and that the pharmacy was and is equipped with a back-up security system. Margherita Cardello moved, seconded by Stephen Lieberman, to remove the citation for violation of N.J.A.C. 13:39-4.5(b)1. **Motion passed 10-0.**

2) **Mitigation Request – Sanjita Mavinkurve, RPIC-** Shop Rite Pharmacy, Bernardsville, NJ

Following an inspection revealing a violation related to the back-up security system and posted pharmacy hours, a UPL was issued seeking a fine for this, other violations, and a letter of corrective action.

David Lee, the Director of Pharmacy provided an explanation that he was unaware of back-up security system requirements, but it has since surveyed his stores and has begun installation in the deficient pharmacies.

Margherita Cardello moved, seconded by Carol Jacobson, to deny mitigation as the response was remedial. **Motion passed 9-0. Thomas Bender was recused as his brother-in-law is the owner of this pharmacy.**

3) **Mitigation Request – Shereef Mabrouk, RPIC,** CVS Pharmacy, Flemington, NJ

Following an inspection revealing a violation related to CDS inventory, a UPL was issued seeking a fine for this, other violations, and a letter of corrective action.

Shereef Mabrouk, RPIC provided an explanation that the pharmacist working during the inspection was not the regular pharmacist and could not find the biennial CDS inventory. On the following day, the biennial CDS inventory was retrieved and provided to the inspector.

Edward McGinley moved, seconded by Richard Palombo, to request an explanation of the discrepancies between the cover page and what appears in the inventory on the following pages. If the discrepancies can be explained to the satisfaction of the Executive Director, the citations will be removed. **Motion passed 10-0.**

4) **Mitigation Request – Sreedhar Vajinepalli, RPIC,** Health Care Pharmacy, Passaic, NJ

Following an inspection revealing a violation related to CDS inventory, a UPL was issued seeking a fine for this, other violations, and a letter of corrective action.

Angelo Cifaldi, Esq. provided an explanation on behalf of Health Care Pharmacy that the pharmacy, while unable to readily retrieve a copy of its biennial inventory for the inspector, the pharmacy does maintain proper biennial inventory and has attached it for the Board's review.

Edward McGinley moved, seconded by Thomas Bender, to remove the citation for violation of N.J.A.C.13:45H-5.7. **Motion passed 9-0. Mahesh Shah was recused due to a previous affiliation with Angelo Cifaldi.**

**5) Mitigation Request – Hiten Patodiya, RPIC, BMC Pharmacy, Bayonne, NJ**

Following an inspection revealing a violation related to CDS inventory, a UPL was issued seeking a fine for this, other violations, and a letter of corrective action.

Hiten Patodiya, RPIC provided an explanation, that while the CDS inventory was in the CII cabinet and was not easily retrievable at the time of inspection, they faxed the CDS inventory to the Enforcement Bureau.

Mahesh Shah moved, seconded by Richard Palombo, to remove the citation for violation of N.J.A.C.13:45H-5.6(b) and N.J.A.C. 13:39-6.2(d). **Motion passed 10-0.**

**VIII. INFORMATIONAL**

N/A

**IX. COMMITTEE REPORTS**

N/A

**X. APPROVAL OF MINUTES**

Mitch Sobel moved, seconded by Richard Palombo to approve the May 6, 2015 Public Session Minutes as amended. **Motion passed 9-0. Stephen Lieberman was out of the room.**

**XI. ADJOURNMENT**

Margherita Cardello moved, seconded by Linda Witzal, to move into the Executive Session for review of 10 Complaints, 2 Old Business Items, 6 New Business Items, the Secretary's Report and Recommendation on Inspection Reports from, and the approval of the Executive Session Minutes. The Public Session was adjourned at 11:41 a.m. **Motion passed 10-0.**