



CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102



ROBERT LOUGY
Acting Attorney General

STEVE C. LEE
Acting Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

BOARD OF PHARMACY PUBLIC SESSION MINUTES MONMOUTH CONFERENCE ROOM, 7th FLOOR May 25, 2016

I. CALL TO ORDER

The Open Session of the New Jersey Board of Pharmacy was called to order by the Board President, Mr. Thomas Bender, at 124 Halsey Street, Monmouth Conference Room, 7th floor, on May 25, 2016 at 9:10 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 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, P.L.1975/C.10:4-8.

III. ROLL CALL

Thomas F.X. Bender, R.Ph.	President
Richard Palombo, R.Ph.	Excused Absence
Margherita Cardello, R.Ph.	Late Arrival- 9:45 a.m.
Stephen Lieberman, R.Ph.	
Edward G. McGinley, R.Ph.	
Mahesh Shah, R.Ph.	
Mitch Sobel, R.Ph.	Excused Absence
Linda Witzal, R.Ph.	

OTHERS IN ATTENDANCE

Anthony Rubinaccio, R.Ph.	Executive Director
Jodi Krugman	Deputy Attorney General
Rachel Glasgow	Regulatory Analyst
Jennifer Wasiewicz	Board Staff

IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of May \$35,650 was collected in fines and penalties. The following permits, licenses, and registrations were issued during the month:

- Pharmacy Technicians registered – 300
- Pharmacists licensed – 49 (31 by examination/score transfer and 18 by reciprocity)

- Out-of-State Pharmacies registered – 18
- In-State Pharmacies licensed – 3
- Pharmacists receiving immunization approval – 24
- Interns (foreign graduates) licensed – 7

V. OLD BUSINESS

1) Public Orders Filed

- a. Sanjay Patel, RPh, Final Consent Order, filed 4/19/16
- b. Nino Paradiso, RPh, Consent Order, filed 05/03/16
- c. Jason D'Amico, Interim Consent Order of Voluntary Surrender of License, filed 05/04/16
Edward McGinley moved, seconded by Thomas Bender to ratify the decision. Motion passed 5-0.
- d. Daniel Albizati, Consent Order, filed 05/05/16
- e. Burgess Chemist, Consent Order, filed 05/05/16

2) Community Health Pharmacy - request for reconsideration of the Board's mitigation decision

Thomas Bender moved, seconded by Stephen Lieberman to move into Executive Session for deliberation and advice of counsel. **Motion passed 5-0-1.** Mahesh Shah was recused due to his affiliation with Angelo Cifaldi.

Stephen Lieberman moved, seconded by Linda Witzal, after deliberation in Executive Session, to grant reconsideration and reduce N.J.A.C. 13:45(H)-5.7 to a warning for failing to provide CDS inventory to inspector with the stipulation that the report must be readily available. **Motion passed 5-0-1.** Mahesh Shah was recused due to an affiliation with Angelo Cifaldi.

VI. NEW BUSINESS

1) NABP Overview of Verified Pharmacy Program (VPP) and e-Profile Connect - Bill Cover, R.Ph. –

Bill Cover R.Ph., Director of Government Affairs for NABP, presented the Board with an overview of the various services and programs that NABP supplies to its member states. NABP's goal is to support boards in their missions to protect public health. There are many variations between states in the way that pharmacy inspections are carried out, producing a gap in the consistency of the inspection process. NABP is asking that all states agree to ensure that a consistent standard is met by utilizing a standardized inspection process. The NABP Verified Pharmacy Program (VPP) allows access to inspection results and any disciplinary action from another state all in one database. Forty two states participated in creating the VPP blueprint. VPP inspections are an unannounced visit by an inspector – inspectors are all pharmacists; physically looking at what is on site at facility and whether it is consistent with what is in the VPP application. All states would be able to view that inspection, any noted

deficiencies would be communicated, as would any corrective action. Virginia is changing its Regulations to ensure VPP inspection for out of state sterile compounding pharmacies. The inspection form must meet standards of the universal inspection blueprint. The inspector does not have to be a NABP surveyor to be a part of the inspection program/VPP program. Virginia and North Dakota require VPP, New Mexico is moving towards it. Its primary use is for out-of-state sterile compounding pharmacies. Utilizing the Universal Inspection blueprint and allowing resident inspectors to do the inspection as long as the inspection meets VPP standards/ forms meet the standards. It would reduce costs to states for the inspections, help with data and information sharing. NABP will be able to update RPIC changes in the future. Access to the eProfile database may be affected by state law as to what information may be shared; but access limited to regulatory agencies. There is no access by the general public. E-profile data exchange for individuals helps for quick interchange of data.

The Board took this as informational.

2) Senate Bills, S1073 and S2060

Permits pharmacists to dispense self-administered hormonal contraceptives pursuant to a standing order, in accordance with protocols established by Board of Pharmacy and Board of Medical Examiners; clarifies certain health insurance coverage for contraceptives.

Edward McGinley moved, seconded by Mahesh Shah to support this bill. **Motion passed 6-0.**

3) Senate Bill, S2156

This item was removed from the agenda.

4) Senate Bill, S2135

Prohibits sale of tobacco products and electronic smoking devices at pharmacies.

Thomas Bender moved, seconded by Margherita Cardello to oppose this bill. Although the Board recognizes the deleterious effects of tobacco products, the Board is concerned that the bill imposes an onerous restriction on trade, which is unfair and unbalanced for pharmacies. The Board objects to the targeting of pharmacies and believes the bill removes a potential intervention opportunity. **Motion passed 6-0.**

5) Senate Bill, S2188

Requires health care practitioners prescribing opioid medications on first-time basis, or to minor children, limit amount of prescribed medication to seven-day

supply, except in certain circumstances.

The Board believes that the bill should be amended such that the practice laws of each of the health care practitioners with prescribing authority (e.g., dentists, podiatrists) are amended to clarify that the prescribing of opioid medications must be done in compliance with the bill's new prescribing parameters and supply limitations. In addition, to avoid patients being denied access to medications when the prescribers exceed the 7 day limit, the Board believes that it's important to require practitioners to communicate to the dispensers the medical judgment that exceeding the 7 day supply is appropriate and that a non-opioid alternative was not appropriate to address the medical condition. The Board notes that without addressing this communication of medical judgment it could slow down patient care at the point of dispensing.

Edward McGinley moved, seconded by Linda Witzal to support this Bill with comments as discussed. **Motion passed 6-0.**

6) Senate Bill, S2134

Authorizes expedited partner therapy, under which sexual partners of patients with sexually transmitted disease are treated without prior clinical examination.

Edward McGinley moved, seconded by Thomas Bender to oppose this bill as presented. The Board supports the bill's intent to curb the transmission of sexually transmitted diseases but is concerned about improper patient care because of the lack of knowledge about the identity of the "expedited partner" or partners and, therefore, the medication history of these individual/s. **Motion passed 6-0.**

7) Karim Mansour - request to accept intern hours earned in Indiana

Mahesh Shah moved, seconded by Margherita Cardello to accept the intern hours. **Motion passed 5-0-1.** Thomas Bender was recused to due to his affiliation with Walgreens.

8) Amit Saxena - request to accept intern hours earned in New York

Stephen Lieberman moved, seconded by Mahesh Shah to accept the intern hours. **Motion passed 6-0.**

9) PharMEDium - request to allow renewal of Pharmacy Permit

PharMEDium is strictly a 503(b) organization and does not fit into the definition of a pharmacy in which the Board has jurisdictional authority. DAG Krugman advised this is a statutory, not a regulatory, issue, therefore the Board does not have authority to grant waivers.

After discussion the Board will allow PharMEDium to withdraw the request for a waiver to permit renewal of their permit. The Board has agreed to provide a written explanation as to why New Jersey statute does not recognize their business model as the practice of pharmacy, therefore the Board does not have the authority to issue a permit.

Edward McGinley moved, seconded by Linda Witzal to allow PharMEDium to withdraw the waiver request. **Motion passed 6-0.**

10) Out of State Pharmacy - New applications for sterile compounding

a. Burman's Community, Brookhaven, PA

Edward McGinley moved, seconded by Mahesh Shah to pend this application until a VPP inspection is performed. **Motion passed 6-0.**

b. V-Pharm dba Keystone Professional Pharmacy, Wilkes-Barre, PA

Edward McGinley moved, seconded by Linda Witzal to pend this application until a VPP inspection is performed. **Motion passed 6-0.**

c. Health First Infusion, West Palm Beach, FL

Thomas Bender motioned, seconded by Edward McGinley to approve pending the receipt of information clarifying the relationship between MedCare pharmacy and Home First Infusion. **Motion passed 5-0.** Linda Witzal was out of the room.

11) Out of State Pharmacy - New applications with discipline

a. Meijer Pharmacy #463, Fort Wayne, IN –

Stephen Lieberman moved, seconded by Edward McGinley to approve this application. **Motion passed 5-0.** Linda Witzal was out of the room.

b. Allcare Specialty Pharmacy, Little Rock, AR

Edward McGinley moved, seconded by Stephen Lieberman to approve this application. **Motion passed 5-0.** Linda Witzal was out of the room.

c. Mission Pharmacy, San Antonio, TX

Mahesh Shah moved, seconded by Margherita Cardello to approve this application. **Motion passed 6-0.**

VII. MITIGATION REQUEST

1) Yuk Ly, RPIC - Walgreens Pharmacy, Pennsville, NJ

Stephen Lieberman moved, seconded by Margherita Cardello to remove the \$250 fine for violation of N.J.A.C.13:39-6.2(d). **Motion passed 5-0-1.** Thomas Bender was recused due to his affiliation with Walgreens.

2) **David Miller, RPIC** - Millers of Wyckoff Pharmacy, Wyckoff, NJ

Thomas Bender moved, seconded by Edward McGinley to move into executive session for advice of counsel and deliberation. **Motion passed 6-0.**

The Board returned to public session and Stephen Lieberman moved, seconded by Margherita Cardello to mitigate N.J.A.C.13:39-11.16(a) and N.J.A.C.13:39-11.16(b) to a warning, to remove N.J.A.C.13:39-11.12(a), N.J.A.C.13:39-11.16(c) and N.J.A.C.13:39-11.16(d). **Motion passed 6-0.**

3) **Jacob Saeman, R.Ph** - Millers of Wyckoff Pharmacy, Wyckoff, NJ

Thomas Bender moved, seconded by Edward McGinley to move into executive session for advice of counsel and deliberation. **Motion passed 6-0.**

The Board returned to public session and Mahesh Shah moved, seconded by Margherita Cardello to withdraw the UPL based on the information presented. A subsequent UPL will be issued citing N.J.A.C.13:39-6.15(h) and N.J.A.C.13:39-7.6 fining \$2500 and 4 continuing education credits. **Motion passed 6-0.**

4) **Edward Okebiorun, RPIC** - OK Pharmacy, Orange, NJ

Edward McGinley moved, seconded by Mahesh Shah to vacate the default and impose a new UPL against the RPIC reducing N.J.A.C.13:39-7.12(a)12 to a warning. Administratively close the initial UPL. **Motion passed 6-0.**

5) **Samirkumar Patel, RPIC** - Passaic Community Pharmacy, Passaic, NJ

Stephen Lieberman moved, seconded Linda Witzal remove N.J.A.C.13:39-6.15(d)(e) . **Motion passed 6-0.**

6) **Joseph Low, RPIC** - Shop Rite Pharmacy, Vineland, NJ

Stephen Lieberman moved, seconded by Linda Witzal to remove N.J.A.C.13:39-4.15(b)1. **Motion passed 5-0-1.** Thomas Bender was recused due an affiliation with ownership.

7) **David Teichman, RPIC** - Parkview Pharmacy, Teaneck, NJ

Stephen Lieberman moved, seconded by Mahesh Shah to deny mitigation as all actions taken were corrective. **Motion passed 6-0.**

- 8) **Jennifer Factor, RPIC** – ReUnion Rx Pharmacy, Atlantic Highlands, NJ

Edward McGinley moved, seconded by Stephen Lieberman to remove N.J.A.C. 13:39 -4.15 (b)1. **Motion passed 5-0-1.** Linda Witzal was recused due to a prior work affiliation.

VIII. INFORMATIONAL

AMAG Pharmaceuticals

The Board accepted this as informational.

IX. COMMITTEE REPORTS

Mahesh Shah - NABP 12th Annual Meeting Committee Report in San Diego

Mahesh Shah provided an overview of the NABP 112th Annual Meeting. Important points discussion from representatives from various states on numerous topics, drug supply security act, Prescription Drug abuse, PMP, pharmacy robbery and burglary, pharmacy technicians, pharmacist's prescriptive authority. Mr. Shah expressed this meeting for new board members was very insightful becoming oriented to NABP services, also tabletop sessions sponsored by pharmacy schools, USP, etc.

Thomas Bender thanked Edward McGinley for his contributions to NABP as president over the past year. Mr. McGinley will now hold the position of Chairperson of NABP.

X. APPROVAL OF MINUTES

Public session minutes from April 27, 2016.

Linda Witzal moved, seconded by Stephen Lieberman to accept the April 27, 2016 Public Session minutes as amended. **Motion passed 6-0.**

XI. ADJOURNMENT

Edward McGinley moved, seconded by Mahesh Shah for the Board to move into the Executive Session for review of 2 Old Business Items, 17 New Business Items, the Secretary's Report and Recommendation for Inspection Reports, and the approval of the July 22, 2015 Executive Session Minutes. **Motion passed 6-0.**

At 1:00 p.m., Stephen Lieberman moved, seconded by Mahesh Shah, to adjourn the Public Session. **Motion passed 6-0.**

