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BOARD OF PHARMACY PUBLIC SESSION MINUTES MONMOUTH CONFERENCE ROOM, 7th FLOOR September 2, 2015

I. CALL TO ORDER

The Open Session of the New Jersey Board of Pharmacy was called to order by the Board Vice President, Mr. Richard Palombo, at 124 Halsey Street, Monmouth Conference Room, 7th floor, on September 2, 2015 at 9:00 a.m. All members were duly notified of the time, place and all pertinent materials were provided to the members.

II. SUNSHINE LAW ANNOUNCEMENT

Vice President Richard Palombo 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.	Excused Absence
Richard Palombo, R.Ph.	Vice-President
Margherita Cardello, R.Ph.	Late Arrival- 9:16 a.m.
Edward G. McGinley, R.Ph.	
Mahesh Shah, R.Ph.	
Stephen Lieberman, R.Ph.	
Calliope Alexander	
Linda Witzal, R.Ph.	
Mitch Sobel, R.Ph.	Excused Absence

OTHERS IN ATTENDANCE

Anthony Rubinaccio, R.Ph.	Executive Director
Megan Cordoma	Deputy Attorney General
Rachel Glasgow	Regulatory Analyst
Jessica Kelley	Board Staff

IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of July, \$21,913 was collected in fines and penalties. The following permits, licenses, and registrations were issued during the month:

- Pharmacy Technicians registered – 101
- Pharmacists licensed – 90 (75 by examination/score transfer and 15 by reciprocity)
- Out-of-State Pharmacies registered – 5
- In-State Pharmacies licensed – 9
- Pharmacists receiving immunization approval – 62
- Interns (foreign graduates) licensed – 8

V. OLD BUSINESS

1) **Mark Cardis, R.Ph** – Request for modification of Consent Order

During the July 22, 2015 public meeting, Richard Palombo moved, seconded by Linda Witzal to grant an unrestricted license as long as PAP specifically supported removing the restrictions on acting as a RPIC, owner and preceptor.

Dr. Louis Baxter of NJPAP addressed the Board's request and unconditionally supports Mr. Cardis' return as a pharmacist and his ability to act as a RPIC, owner and preceptor.

Linda Witzal moved, seconded by Mahesh Shah, to grant Mr. Cardis an unrestricted license. **Motion carried 6-0.**

2) **John Abraham, RPIC** – Rite Aid Pharmacy, Somerset, NJ – Mitigation Request

The Board received and reviewed the CDS inventory, which was required for the consideration of this mitigation request.

Edward McGinley moved, seconded by Stephen Lieberman to remove N.J.A.C. 13:45H-5.5(b) and the \$1000 fine associated with it. **Motion carried 6-0.**

3) **Public Orders Filed**

- a. Liberty Drug and Surgical – Interim Consent Order (7/14/15)
- b. Marvin Davis, Pharmacy Technician – POD – Suspension of Registration (7/27/15)
- c. Howard Dukes, Pharmacy Technician – POD – Suspension of Registration (7/27/15)

VI. NEW BUSINESS

- 1) **Bill A4672, FYI** – Repeals law suspending certain licensee, registration and certifications for failure to repay student loans.

This bill repeals sections 1 and 2 of P.L.1999, c.54, which stipulates that persons who are licensed by the Director of the Division of Consumer Affairs or by the various professional and occupational boards located within the Division of Consumer Affairs shall have their licenses suspended by the director or the board by which they are regulated when the director or board is notified by a lender or guarantor of nonpayment or default of a State or federal direct or guaranteed educational loan by those persons. P.L.1999, c.54 also provides that the Supreme Court of the State of New Jersey may suspend the licenses of attorneys who fail to repay student loans.

Calliope Alexander moved, seconded by Mahesh Shah, to support the bill as presented. **Motion carried 6-0.**

- 2) **Bill A4497, FYI** – Prohibits courts and professional boards from denying a professional license to child support obligors under certain circumstances.

This bill prohibits courts and professional boards from denying professional licenses to individuals because they are delinquent in paying child support. Under current law, an individual may be denied a professional license because that individual has a child support arrearage that equals or exceeds the amount of child support payable for six months. This provision may make it more difficult for a child support obligor to make child support payments, because the obligor may be denied employment or advancement opportunities which would enable the obligor to make payments. Under this bill, courts and State agencies, including professional and occupational boards, may not deny a child support obligor a professional license due to child support arrearages. When a professional license is issued to an obligor, the obligor is sent a written notice following the issuance of the license, by certified and regular mail, return receipt requested, at the obligor's last-known address or place of business or employment, advising the obligor that the obligor's license may be revoked or suspended unless, within 30 days of the postmark date of the notice, the obligor makes a written request for a court hearing to establish a payment schedule to satisfy the remainder of the arrearages, or take any other action the Probation Division determines necessary. Following this notice, the obligor's license may be suspended or revoked if the obligor fails to make the written request.

Edward McGinley moved, seconded by Richard Palombo to support the bill as presented. Stephen Lieberman opposed the bill and Calliope Alexander abstained. **Motion carried 5-1-1.**

- 3) **Garden State Pharmacy Owners, Inc.** – Request for clarification of FDA guidance paper for dispensing growth hormone

The FDA has issued a guidance paper for the dispensing of growth hormone (GH) that identifies five (5) specific diagnoses for the use of growth hormone, which does not include infertility. While physicians feel strongly that GH will positively affect the outcome for their patients facing infertility, pharmacists are concerned that the existence of the FDA guidance paper could pose a legal issue for dispensing GH.

Following a general discussion of the topic at hand, the Board cannot offer any clarification or recommendations on the federal guidance.

- 4) **So-Young Chang, R.Ph.** – Collaborative Practice Pre-Approval Application

Linda Witzal moved, seconded by Mahesh Shah to approve this application. **Motion carried 6-0-1.** Edward McGinley was recused as Ms. Chang had previously worked for him.

- 5) **Jersey City Medical Center** – Request for waiver of N.J.A.C. 13:39-7.18

The Board received and reviewed the waiver request, allowing the medical center to provide samples of Abilify Maintena, a long acting injection for schizophrenia, to inpatients prior to discharge in an effort to continue the patient's therapy, which may be hindered by impaired cognitive function or economic hardship.

Edward McGinley moved, seconded by Stephen Lieberman to approve the waiver with the caveats that the waiver applies only to the Abilify Maintena sample product, the product will remain segregated, policy and procedure and a copy of the Board's approval letter must be readily available to inspectors at the time of the inspection, and the waiver will be terminated once they stop receiving the product for free. Jersey City Medical Center is to report to the Board any issues they encounter and any changes to the representation in their waiver request letter. **Motion carried 7-0.**

- 6) **Trinitas Regional Medical Center** – Request for waiver of N.J.A.C. 13:39-7.18

The Board received and reviewed the waiver request, allowing the medical center to provide samples of Abilify Maintena, a long acting injection for schizophrenia, to inpatients prior to discharge in an effort to continue the patient's therapy, and Invega Sustenna, a once monthly injectable medication for the treatment of schizophrenia and schizoaffective disorder. The ability to otherwise receive these medications may be hindered by impaired cognitive function or economic hardship.

Stephen Lieberman moved, seconded by Linda Witzal to approve the waiver with the caveats that the waiver applies only to the Abilify Maintena and Invega Sustenna sample products, the products will remain segregated, policy and

procedure and a copy of the Board's approval letter must be readily available to inspectors at the time of the inspection, and the waiver will be terminated once they stop receiving the product for free. Trinitas Regional Medical Center is to report to the Board any issues they encounter and any changes to the representation in their waiver request letter. **Motion carried 7-0.**

7) **Randall Higgins, R.Ph.** – Request for unrestricted license

Item tabled until Mr. Higgins provides the Board with a detailed description of his work history and proof that he's shown his order to his employers.

8) **Conversio Health, San Luis Obispo, CA** – Out-of-State Pharmacy Applicant, Sterile Compounding

Edward McGinley moved, seconded by Stephen Lieberman to approve this application once the Board office receives proof their California license was renewed, as the application indicates that it expired on September 1, 2015. **Motion carried 7-0.**

9) **Reciprocity and Scope of Practice Questions**

The Board received and reviewed an inquiry, requesting clarification on licensure requirements for pharmacists working from Puerto Rico.

The Board briefly discussed a pending reciprocity statute change, which was tabled.

Margherita Cardello moved, seconded by Mahesh Shah, that if the individual took the NAPLEX, they may reciprocate to their license to New Jersey. If the pharmacist works out of the actual pharmacy in Puerto Rico, the pharmacy would need to obtain a non-resident permit. **Motion carried 7-0.**

10) **Danielle D. Carter** – Active Pharmacy Technician, Finalization of POD

Edward McGinley moved, seconded by Stephen Lieberman to finalize the POD for failure to comply with the Board's request for additional documentation. **Motion carried 7-0.**

11) **Marwa Samaha** – Request to accept intern hours earned out of state

The Board reviewed Ms. Samaha's request to accept 840 hours completed under Mohamad Kourani at Caremore Rx Pharmacy in Bronx, NY.

Edward McGinley moved, seconded by Mahesh Shah to approve the hours requested. **Motion carried 7-0.**

12) NABP, Internet Drug Outlet Identification Program – FYI

The Board reviewed the April 2015 progress report of the Internet Drug Outlet Identification Program. The report outlines the necessity to protect consumers from illegal online drug sellers and the potential health and safety risks posed by fake online pharmacies. NABP has found that 96% of nearly 11,000 websites selling prescriptions were found to be out of compliance with pharmacy laws and patient safety standards. NABP continues to educate through the AWA_Rx_E program and recommend the use of Internet pharmacies accredited through the VIPPS and Vet-VIPPS programs. To help raise public awareness of the danger posted by internet drug outlets, and to provide an online domain where consumers can be sure the websites are legitimate, NABP continues to publicize the launch of its .Pharmacy TLD. The .Pharmacy domain is given only to legitimate website operators who adhere to pharmacy laws in their jurisdictions, helping consumers identify safe pharmacy websites.

VII. MITIGATION REQUEST

- 1) Mitigation Request – Christy Kim, Pharmacy Manager, Baxter Healthcare Corporation, Logan Township, NJ – Reconsideration**

Item tabled.

- 2) Mitigation Request – Ami Patel, RPIC, Innovo Specialty Compounding Solutions, East Brunswick, NJ 08816**

With the advice of counsel, this request was moved to the executive agenda.

- 3) Mitigation Request – Chiselo Achebe, RPIC, Walgreens Pharmacy, Livingston, NJ**

Walgreens Pharmacy requested mitigation of the following citations: 1) N.J.A.C. 13:39-7.18; and 2) N.J.A.C. 13:39-6.2(f)7.

Edward McGinley moved, seconded by Stephen Lieberman to remove N.J.A.C. 13:39-7.18, N.J.A.C. 13:39-6.2(f)7 and the associated fines. **Motion carried 7-0.**

- 4) Mitigation Request – Nahed Ahmed, R.Ph., Organix Pharmacy, Pompton Lakes, NJ**

Organix Pharmacy requested mitigation of N.J.A.C. 13:39-4.15(a)1.

Margherita Cardello moved, seconded by Linda Witzal to deny the request. **Motion carried 6-1.** Stephen Lieberman was opposed.

- 5) **Mitigation Request – Frank Falcone, RPIC**, Montgomery Pharmacy, Inc., Jersey City, NJ

Montgomery Pharmacy, Inc. requested mitigation of N.J.A.C. 13:39-7.20(a).

Edward McGinley moved, seconded by Margherita Cardello to deny the request. **Motion carried 7-0.**

- 6) **Mitigation Request – Florance Ndubizu, RPIC**, Healthcare Pharmacy, Trenton, NJ

Ms. Nubizu submitted a letter of corrective action, addressing all of the citations.

Stephen Lieberman moved, seconded by Edward McGinley to deny mitigation. **Motion carried 7-0.**

- 7) **Mitigation Request – Guiseppi Cucaro, RPIC**, Community Pharmacy & Surgicals, Inc., Jersey City, NJ

Angelo Cifaldi, Esq., on behalf of Community Pharmacy and Surgicals, requested mitigation of the following citations: 1) N.J.S.A. 45:14-69(d); 2) N.J.S.A. 45:14-70(c); 3) N.J.S.A. 45:14-71; 4) N.J.A.C. 13:39-4.15(a)1; 5) N.J.A.C. 13:39-4.15(b)3; and 6) N.J.A.C. 13:39-5.8(a)1.

Edward McGinley moved, seconded by Stephen Lieberman to remove N.J.A.C. 13:39-4.15(b)3 and the associated fines, mitigate N.J.A.C. 13:39-5.8(a)1 to a warning, and combine N.J.S.A. 45:14-69(d), N.J.S.A. 45:14-70(c), N.J.S.A. 45:14-71, and N.J.A.C. 13:39-4.15(a)1, for one (1) \$1,000 fine. **Motion carried 6-0.** Mahesh Shah was recused due to his affiliation with Angelo Cifaldi and DAG Cordoma was recused as she is related to the RPIC.

- 8) **Mitigation Request – Robert Palmisano, RPIC**, Meridian At Home Infusion Pharmacy, Eatontown, NJ

Meridian At Home Infusion Pharmacy requested mitigation of N.J.A.C. 13:45H-5.7.

Edward McGinley moved, seconded by Stephen Lieberman to remove N.J.A.C. 13:45H-5 and to notify the licensee that the biennial CDS inventory must be printed and kept separately. **Motion carried 7-0.**

- 9) **Mitigation Request – Brijendera Singh, RPIC**, Long Valley Pharmacy, Long Valley, NJ

Long Valley Pharmacy requested mitigation of 1) N.J.A.C. 13:39-7.18; and 2)

N.J.A.C. 13:39-6.2(f)7; 3) N.J.A.C. 13:39-12(a)3; 4) N.J.A.C. 13:39-7.12(a)9; 5) N.J.A.C. 13:39-7.12(b)6; and 6) N.J.A.C. 13:39-7.19(b)9 & 9i.

Edward McGinley moved, seconded by Stephen Lieberman to deny the mitigation request. **Motion carried 7-0.**

VIII. INFORMATIONAL

1) NABP, .Pharmacy Domain Names

On June 3 2015, NABP began accepting applications for pharmacy names from all eligible pharmacy-related entities, following a previous registration period for boards of pharmacy, trademark holders, VIPPS and Vet-VIPPS pharmacies, and dispensing pharmacies. Entities seeking a .pharmacy domain name should submit an application and supporting documentation to NABP.

2) Electronic Prescribing of Controlled Substances (EPCS) for a Pharmacy

Matthew Wetzel, Executive Director of the Drug Control Unit reviewed EPCS with the Board, highlighting that New Jersey practitioners and pharmacies may utilize EPCS for all patient prescriptions. Benefits of using EPCS include a streamlined workflow, improved legibility, reduced prescription fraud, decrease adverse drug events, and condensed record keeping. In order to use EPCS, both the prescriber and the pharmacy must be EPCS certified. Pharmacies may reach out to their software vendor to see if they're certified for EPCS. If the vendor is not certified for EPCS, they will have to undergo a third-party audit or certification as defined by the DEA rules.

3) Guidance Regarding the Issuance of Multiple Schedule II CDS Prescriptions to a Patient

Matthew Wetzel, Executive Director of the Drug Control Unit reviewed the re-issuance of guidance regarding multiple schedule II CDS prescriptions. *Since March 1, 2010, pursuant to N.J.S.A. 45:9-22.19, only physicians, licensed by the New Jersey Board of Medical Examiners, are permitted to issue multiple prescriptions, authorizing a patient to receive a total of up to a 90-day supply of a schedule II controlled dangerous substance. Under the law and corresponding Board regulation, N.J.A.C. 13:35-7.6(c)*

Under the law and corresponding Board regulation, N.J.A.C. 13:35-7.6(c)3, a physician may issue multiple prescriptions to a patient so that the patient may receive a total of up to a 90-day supply of a Schedule II controlled dangerous substance provided that:

i. Each separate prescription is issued for a legitimate medical purpose by the physician acting in the usual course of professional practice;

- ii. The physician provides written instructions on each prescription, other than the first prescription if it is to be filled immediately, indicating the earliest date on which a pharmacy may fill each prescription;*
- iii. The physician determines that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse; and*
- iv. The physician complies with all other applicable State and Federal laws and regulations.*

Similarly, the New Jersey Controlled Dangerous Substance regulation, N.J.A.C. 13:45H-7.5(a) provides that, when up to three separate prescriptions for a total of up to a 90-day supply of a Schedule II controlled substance are issued to a patient by a physician pursuant to N.J.S.A. 45:9-22.19 (P.L. 2009, c. 165), a pharmacist shall fill such prescriptions and the prescriptions may not be filled until the date indicated on the prescription by the physician as the earliest date for filling.

The exception provided by N.J.S.A. 45:9-22.19 (P.L. 2009, c.165) does not apply to any other licensed prescriber/practitioner, including: dentists, optometrists, veterinarians, advanced practice nurses, certified nurse midwives, and physician assistants.

Pharmacists are encouraged to check the Division of Consumer Affairs website, the Board of Pharmacy's website, and trade newsletters regarding the guidance.

4) Implementation of law(P.L.2015, c.74), Effective November 1, 2015- NJPMP

In July 2015, Governor Chris Christie signed Senate Bill 1998 into law (P.L.2015, c.74), which substantially revises the scope and expands the capabilities of the New Jersey Prescription Monitoring Program. While some requirements with the law may be differed while technology enhancements are made with the NJPMP and regulations are clarified, pharmacists can take action to be ready to comply with the new law. As of November 1, 2015, certain restrictions limiting interstate data sharing will be eliminated. All pharmacists should register to access the NJPMP. The mobile app for iOS, Android and Windows phones and devices is up and running. Pharmacists are encouraged to check the Division of Consumer Affairs website, the Board of Pharmacy's website, and trade newsletters regarding the implementation of the new law.

IX. COMMITTEE REPORTS

N/A

X. APPROVAL OF MINUTES

Calliope Alexander moved, seconded by Margherita Cardello to approve the July 22, 2015 Public Session Minutes as amended. **Motion carried 7-0.**

XI. ADJOURNMENT

Margherita Cardello moved, seconded by Stephen Lieberman for the Board to move into the Executive Session for review of 3 Complaints, 2 Old Business Item, 16 New Business Items, the Secretary's Report and Recommendation for Inspection Reports, and the approval of the July 22, 2015 Executive Session Minutes.

Motion carried 7-0.

At 10:51 a.m., the Board adjourned the Public Session.