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BOARD OF PHARMACY PUBLIC SESSION MINUTES MONMOUTH CONFERENCE ROOM, 7th FLOOR JULY 22, 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, 7th floor, on July 22, 2015 at 9:06 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, P.L.1975/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.	Absent
Stephen Lieberman, R.Ph.	
Calliope Alexander	
Linda Witzal, R.Ph.	
Mitch Sobel, R.Ph.	

OTHERS IN ATTENDANCE

Anthony Rubinaccio, R.Ph.	Executive Director
Matthew Wetzel	DCU Executive Director
Jodi Krugman	Deputy Attorney General
Rachel Glasgow	Regulatory Analyst

IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of June, \$66,132, was collected in fines and penalties. The following permits, licenses, and registrations were issued during the month:

- Pharmacy Technicians registered – 303
- Pharmacists licensed – 42 (17 by examination/score transfer and 25 by reciprocity)
- Out-of-State Pharmacies registered – 35
- In-State Pharmacies licensed – 10
- Pharmacists receiving immunization approval – 30
- Interns (foreign graduates) licensed – 6

The August 26th Board meeting will be moved to September 2nd.

The Drug Enforcement Administration (DEA) will be holding their 10th Annual Drug Take Back Day on September 26th. Details on the participating locations will be forthcoming.

V. OLD BUSINESS

1) Temperature Control Regulations – Update

The agenda item was tabled and referred back to Rules and Regulations Committee for additional review and revision.

2) Mark Cardis, R.Ph. – PAP support for unrestricted license request

Mark Cardis re-submitted a request to the Board for an unrestricted license to practice pharmacy in the State of New Jersey.

At the May 6, 2015 Public Session Board meeting, the Board received and reviewed Mr. Cardis' request to modify his Consent Order filed on July 14, 2011, following diversion of CDS by creating fictitious pharmacy records. Mr. Cardis has complied with the stipulations of his Consent Order, remains in progressive recovery with PAP, and is currently working as a pharmacist.

*Mitch Sobel moved, seconded by Linda Witzal, to deny the request for modification of the Consent Order. **Motion did not carry 4-3.***

*Upon further discussion, Carol Jacobson moved, seconded by Richard Palombo, to inquire if PAP can unconditionally support Mr. Cardi's return as a pharmacist and specifically address if he can practice as a RPIC, a preceptor, an owner, and engage in unrestricted practice. **Motion carried 7-0.***

Thomas Bender moved, seconded by Stephen Lieberman to deny the request by Mark Cardis, based upon his past egregious behavior and the Board's belief that Mr. Cardis should continue to be monitored by the New Jersey Professional Assistance

Program (PAP). The Board does not believe Mr. Cardis should be a pharmacist-in-charge while he remains under continued monitoring by the PAP. **Motion fails 4-3.** Margherita Cardello was recused to Mr. Cardis' prior affiliation with Rite Aid.

Richard Palombo moved, seconded by Linda Witzal, for the Board to accept the request by Mark Cardis for an unrestricted license to practice pharmacy in the State of New Jersey, based upon the June 19, 2015 report from PAP, which "unconditionally supports his continuing work as a pharmacist, without any restrictions."

During the Board's discussion of the motion, Mitch Sobel moved, seconded by Stephen Lieberman for the Board to go into Executive Session for deliberation and advice of counsel. **Motion carried 7-0.** Margherita Cardello was recused to Mr. Cardis' prior affiliation with Rite Aid. The Board entered Executive Session at 9:25 a.m.

Mitch Sobel moved, seconded by Stephen Lieberman for the Board to go into Public Session. **Motion carried 7-0.** Margherita Cardello was recused to Mr. Cardis' prior affiliation with Rite Aid. The Board entered Public Session at 9:49 a.m.

Richard Palombo moved, seconded by Linda Witzal, to withdraw the motion on the floor.

Richard Palombo moved, seconded by Linda Witzal for the Board to grant Mark Cardis an unrestricted license to practice pharmacy in the State of New Jersey, contingent upon the Board receiving a letter from the PAP, which specifically supports Mr. Cardis' potential return to practice as a pharmacist-in-charge, pharmacy owner, and/or pharmacist preceptor. **Motion carried 7-0.** Margherita Cardello was recused to Mr. Cardis' prior affiliation with Rite Aid.

3) Pharmalabs, St. Petersburg, FL – Out-of-state pharmacy application – Response to Board's request for additional information

The Board received and reviewed Pharmalabs' attestation that the pharmacy's responses to the Sterile Compounding Questionnaire that was submitted to the Board on or about June 2014 are still accurate and valid, with no updates or changes. Copies of documentation of the successful completion of training reports for employees participating in sterile compounding and a copy of the policy and procedures manual regarding the shipping of products to patients, was also reviewed by the Board.

Edward McGinley moved, seconded by Linda Witzal for the Board to approve the out-of-state registration application for Pharmalabs, LLC d/b/a PharmaLabs. **Motion carried 7-1.** Thomas Bender voted in opposition.

4) Angelo Cifaldi, Esq. on behalf of his client, Nick Stamatiadis, R.Ph., – Request for termination of probation

Chair Direct: The Board requests information about Nick Stamatiadis' recent employment history in the practice of pharmacy to determine if Mr. Stamatiadis has met his requirement to be screened for two-years of employment in the practice of pharmacy. The Board will ask the NJ Professional Assistance Program (PAP) about three (3) of Mr. Stamatiadis' test results that were classified as disqualified.

VI. NEW BUSINESS

1) **Fanny A Musto, R.Ph.** – Collaborative Practice Pre-Approval application

Richard Palombo moved, seconded by Stephen Lieberman, for the Board to approve Fanny Musto's Collaborative Practice Pre-Approval application for Medication Therapy Management and immunizations. **Motion carried 7-0.** Edward McGinley was recused due to his past affiliation with Ms. Musto at Pathmark and that he remains in periodic contact with her.

2) **Ethan V. Nhan, R.Ph.** – Collaborative Practice Pre-Approval application

Chair Direct: The Board requests clarification from Ethan Nhan, that the anticoagulation program he completed meets the requirements in N.J.A.C. 13:39-13.3; the program must be 1) offered by an American Council of Pharmaceutical Education-approved provider, 2) be a post-graduate residency program accredited by the American Society of Health-System Pharmacists, or 3) be a certification program from the Board of Pharmacy Specialties.

3) **Kristen Winters, R.P.** – Request for Reinstatement of Pharmacist License

Stephen Lieberman moved, seconded by Margherita Cardello, that the Board reviewed Kristen Winters' job history summary and determined that Ms. Winters has not been engaged in the practice of pharmacy for over fifteen (15) years. Prior to considering Ms. Winters application for reinstatement of her license to practice pharmacy, the Board needs proof of her competency in the practice of pharmacy. The Board requests that Ms. Winters first register for and take the NABP Pharmacist Assessment for Remediation Evaluation (PARE) Exam. Upon completion and review of Ms. Winters' PARE Exam results, the Board may require additional training or supervised experience in order to address any deficiencies identified by the PARE Exam. The Board also requests that Ms. Winters submit proof of her successful completion of Continuing Education (CE) for license to practice pharmacy in New Jersey or any other state where Ms. Winters may be licensed. **Motion carried 8-0.**

4) Pamela Mandel, Esq. on behalf of her client, **Bergen Point Pharmacy** – Penalty reconsideration request

The Board reviewed the June 15, 2015 letter from Pamela Mandel, Esq. on behalf of

her client Bergen Point Pharmacy, requesting mitigation of the fines assessed by the Board to the pharmacy in conjunction with a September 26, 2011 inspection.

Edward McGinley moved, seconded by Richard Palombo that the Board acknowledges the clerical error made by the Board office, but that error does not change the Board's initial uniform penalty letter and subsequent decision to deny all mitigation requests. The Board denies Ms. Mandel's new request to remove or stay the fines assessed to her client. The Board's inspection documents, signed by Luis Melendez, R.Ph., on the date of the Board inspection, indicate that the pharmacist-in-charge, Teresa Mars, R.Ph., was working less than thirty-five (35) hours per week as required by N.J.A.C. 13:39-6.2(f). **Motion carried 8-0.**

- 5) Pamela Mandel, Esq., on behalf of her client, **Vencer Vital Care** – Pharmacy waiver requests only

Chair Direct: The Board tabled its consideration of Pamela Mendel's, Esq., request on behalf of her client, Vencer Vital Care, until the Board receives the official inspection report from the Enforcement Bureau. In advance of the Board's future consideration of this request, the following information should be submitted by Vencer Vital Care; the pharmacist-in-charge for each of the three (3) pharmacies, centralized prescription handling agreements which were approved prior to the July 22, 2015 Board meeting, and a clarification of the hours that Vencer Vital Care is requesting in their waiver.

- 6) **Richard Tomasulo, R.Ph.** – Reciprocity applicant with disciplinary history

Stephen Lieberman moved, seconded by Margherita Cardello for the Board to go into Executive Session for the advice of counsel based on Richard Tomasulo's reported disciplinary history. **Motion carried 8-0.** The Board entered Executive Session at 1:17 p.m.

Mitch Sobel moved, seconded by Stephen Lieberman for the Board to go into Public Session. **Motion carried 8-0.** The Board entered Public Session at 1:34 p.m.

Thomas Bender moved, seconded by Calliope Alexander that the Board will allow Richard Tomasulo to proceed with the reciprocity application process. The Board will also send Mr. Tomasulo a Letter of Concern for the misrepresentation of his past disciplinary history on his reciprocity application. **Motion carried 8-0.**

- 7) **Amir Tadros, R.Ph.** – Request for unrestricted license

Amir Tadros requested relief from the terms of the Final Order filed on August 22, 2012.

Edward McGinley moved, seconded by Stephen Lieberman for the Board to relieve Amir Tadros, R.Ph., from item #1 and #2 in the Final Order and for the Deputy

Attorney General to draft and issue an amended order reflecting the relief. If Mr. Tadros can prove that he is no longer on the Office of Inspector General (OIG) debarment/exclusion list, then the Board will relieve Mr. Tadros from item #3 in the Final Order. If Mr. Tadros cannot prove he is off the OIG debarment list, then item #3 will remain in effect in the new order. **Motion carried 8-0.**

8) Pharmacy Creations, Mark Boesen, Esq. – Request for modification of Consent Orders

Pharmacy Creations submitted a request to the Board for relief from the terms of the two Interim Consent Orders that Pharmacy Creations and the Board entered into on May 14, 2014 and July 21, 2014 respectively.

Thomas Bender moved, seconded by Linda Witzal for the Board to grant Pharmacy Creations, an unrestricted pharmacy permit. The pharmacy has complied with all the terms of the Interim Consent Orders. **Motion carried 8-0.**

9) Partners Pharmacy – Request to utilize “AP Passport” Automated Dispensing System at Care One nursing facility in Teaneck, NJ

Jim Montree and John Walker appeared before the Board to discuss the installation and implementation of the AP Passport automated dispensing system at a Care One facility in Teaneck, NJ. The machine is not only used for a patients’ first dose, but also for a patients’ daily medication regimen. The machine does not store patient information, but accesses the patient profile in the pharmacy software to dispense the correct medication and dose for each individual patient. Pharmacy personnel will not be on-site daily, but the pharmacy technicians who will fill or refill the machine will be employed by the pharmacy.

Partners Pharmacy will install the machine on-site in Teaneck, NJ and run validation tests for the Board to review. All training materials, policy and procedures, and standard operating procedures (SOP) will be submitted to the Board for review too. The Board will review the validation testing and upon a satisfactory review, a Board inspector will need to inspect the machine on-site.

Linda Witzal was recused because she was formerly employed by Partners Pharmacy.

10) Clinical Intervention Center – Des Plaines, IL - Omnicare of Northern Illinois – Out of State Pharmacy Application

Richard Palombo moved, seconded by Linda Witzal for the Board to approve Clinical Intervention Center’s application for registration as an out-of-state pharmacy and to require the pharmacy to file a central prescription handling agreement with the Board for review and approval. **Motion carried 8-0.**

11) Trilogy Pharmacy – Dallas, TX – Out-of-state pharmacy with PIC discipline

Edward McGinley moved, seconded by Thomas Bender for the Board to go into Executive Session for the advice of counsel and discussion of a potential violation of law. **Motion carried 8-0.** The Board entered Executive Session at 1:17 p.m.

Mitch Sobel moved, seconded by Stephen Lieberman for the Board to go into Public Session. **Motion carried 8-0.** The Board entered Public Session at 1:34 p.m.

Chair Direct: The Board will hold Trilogy Pharmacy's application for registration as an out-of-state pharmacy pending. The pharmacy needs to submit an updated application that addresses the following issues: 1) conflicting hours of operation; 2) does Trilogy compound for office use?; 3) has Trilogy shipped medication to patients in New Jersey in the past?; 4) submit an attestation that Trilogy will not ship to New Jersey patients until an amended application is approved by the Board; and 5) is Trilogy compounding sterile products?, if so, then Trilogy must complete the Board sterile compounding survey. The Board will also send Trilogy a Letter of Concern for Trilogy's failure to disclose prior disciplinary actions against the pharmacy in other states.

12) BioRx, Cincinnati, OH – Out-of-state pharmacy – Sterile Compounding

The Board received and reviewed BioRx's Verified Pharmacy Program (VPP) inspection report.

Chair Direct: The VPP inspection report was missing page 45 which lists the areas needing corrective action. The Board requests this page along with BioRx's corrective action plan for each item listed on the VPP report.

13) Pharmatek Pharmacy, Peoria, AZ – Out-of-state pharmacy – PIC discipline

The Board received and reviewed Jeffrey Hannibal, R.Ph., pharmacist-in-charge's disciplinary history.

Edward McGinley moved, seconded by Thomas Bender for the Board to approve Pharmatek Pharmacy's application for registration as an out-of-state pharmacy, pending receipt by the Board office of proof that Jeffrey Hannibal's license to practice pharmacy is current. **Motion carried 8-0.**

14) Innoveix Pharmaceuticals, Inc, Addison, TX – Out-of-state pharmacy – Sterile Compounding

The Board received and reviewed Innoveix Pharmaceuticals, Inc.'s response to the Board's sterile compounding survey.

Chair Direct: The Board requests the following documentation from Innoveix

Pharmaceuticals: 1) testing logs for the pharmacist-in-charge and other sterile compounding personnel; 2) documentation for a Beyond Use Date of six (6) months for Gonadotropin; and 3) the strength of and compounding log sheets for Sildenafil.

15) Leiter's Compounding, San Jose, CA – Out-of-state pharmacy change of ownership – Sterile Compounding

The Board received and reviewed Leiter's Compounding's response to the Board's sterile compounding survey.

Edward McGinley moved, seconded by Richard Palombo to approve Leiter's Compounding's application for registration as an out-of-state pharmacy. **Motion carried 8-0.**

16) Vidascript, Miami, FL – Out-of-state pharmacy Application

The Board received and reviewed Vidascript's application for registration as an out-of-state pharmacy.

Edward McGinley moved, seconded by Richard Palombo to approve Vidascript's application for registration as an out-of-state pharmacy, pending receipt by the Board office receipt of a signed affidavit that Vidascript does not perform sterile compounding. **Motion carried 8-0.**

17) Board Elections – President and Vice-President

Stephen Lieberman moved, seconded by Margherita Cardello to nominate Thomas F.X. Bender to serve a one-year term as President of the Board of Pharmacy.

Richard Palombo moved, seconded by Mitch Sobel to close the nominations.

By a vote of 8-0, Thomas F.X. Bender was elected President of the Board of Pharmacy for another one-year term.

Mitch Sobel moved, seconded by Margherita Cardello to nominate Richard Palombo to serve a one-year term as Vice-President of the Board of Pharmacy.

Stephen Lieberman moved, seconded by Linda Witzal to close the nominations.

By a vote of 8-0, Richard Palombo was elected Vice-President of the Board of Pharmacy for another one-year term.

VII. MITIGATION REQUEST

1) **Virtua Hospital, Greg Bauer, Director Pharmacy Services, Voorhees, NJ**

Virtua Hospital requested mitigation of the following citations: 1) N.J.A.C. 13:39-11.14(4); 2) N.J.A.C. 13:39-11.14(b); 3) N.J.A.C. 13:39-11.9(f); 4) N.J.A.C. 13:39-11.14(b); and 5) N.J.A.C. 13:39-11.21(a)7.

Thomas Bender moved, seconded by Richard Palombo for the Board to remove all the above cited violations based on the pharmacy's letter and corrective actions taken during the inspection. Additionally, the Board notes that the IV robot was not operational and compounding medications for patients at the time of inspection. **Motion carried 8-0.**

2) **Innovo Specialty Compounding Pharmacy, Erin Magennis, Esq., East Brunswick, NJ**

Innovo Specialty Compounding Pharmacy requested mitigation of the following citations: 1) N.J.A.C. 13:39-11A.9(g); 2) N.J.A.C. 13:39-7.17 and 13:39-11A.9(g); 3) N.J.A.C. 13:39-6.2(f)1 and N.J.A.C. 13:39-6.2(f)9; and 4) N.J.A.C. 13:39-11A.11(b).

Mitch Sobel moved, seconded by Richard Palombo for the Board to table the mitigation request, pending review by the Board of the original inspection report. **Motion carried 8-0.**

3) **Future Pharmacy, Edward Bakman, PIC, Old Bridge, NJ**

Future Pharmacy requested mitigation of the following citations: 1) 16 C.F.R. 1700.14 and 16 C.F.R. 1700.15; and 2) N.J.A.C. 13:39-7.19(b)9 and 13:39-7.19(b)9.i.

Stephen Lieberman moved, seconded by Thomas Bender to deny the mitigation request for the above cited violations. Information on allergies could have been entered manually, even if there was a software problem. **Motion carried 7-1.** Edward McGinley voted in opposition.

4) **Rite Aid Pharmacy #3974, Deborah Hurley, Administrator, Brick, NJ**

Rite Aid Pharmacy #3974 requested mitigation of the following citations: 1) N.J.A.C. 13:39-4.15(c)3; and 2) 21 C.F.R. 1301.11-1301.12

Edward McGinley moved, seconded by Thomas Bender for the Board to remove N.J.A.C. 13:39-4.15(c)3 and the associated fine. The Board also mitigated the citation, 21 C.F.R. 1301.11-1301.12, to a Warning. **Motion carried 7-0.**

Margherita Cardello was recused due to her affiliation with Rite Aid.

5) Rite Aid Pharmacy, Deborah Hurley, Administrator, South River, NJ

Rite Aid Pharmacy #10528 requested mitigation of the following citation: N.J.A.C. 13:39-6.6(h)(c)(d).

Stephen Lieberman moved, seconded by Mitch Sobel to deny the mitigation request for N.J.A.C. 13:39-6.6(h)(c)(d). Information needed by the Board to complete pharmacy technician applications was not provided until after the inspection. **Motion carried 7-0.** Margherita Cardello was recused due to her affiliation with Rite Aid.

6) Walgreens Pharmacy, Shridevi K. Patel, PIC, Newark, NJ

Walgreens Pharmacy #10438 requested mitigation of the following citation: N.J.A.C. 13:39-6.12.

Stephen Lieberman moved, seconded by Mitch Sobel to deny the mitigation request for N.J.A.C. 13:39-6.12. **Motion carried 7-0.** Thomas Bender was recused due to his affiliation with Walgreens.

7) New Aces Pharmacy, Jessica Tsai, PIC, Denville, NJ

New Aces Pharmacy requested mitigation of the following citation: N.J.A.C. 13:39-5.3(a).

Mitch Sobel moved, seconded by Calliope Alexander to remove N.J.A.C. 13:39-5.3(a) and the associated fine. **Motion carried 8-0.**

VIII. INFORMATIONAL

1) Bill A-709 – Prescription Drug Disposal Bill

Effective January 1, 2016, Assembly Bill 709, which was signed into law by Governor Chris Christie, P.L.2015,c.66., on June 26, 2015, requires prescribers and pharmacies, that dispense a controlled substance to an individual/patient, to furnish the individual/patient with a copy of a notice of how to properly dispose of unused prescription drugs. The Division of Consumer Affairs in the Department of Law and Public Safety shall prepare and post on its website the notice that prescribers and pharmacies shall use.

2) **District I/II Meeting**

The National Associations of Boards of Pharmacy (NABP) District I and II meeting will be held on September 24, 2015 through September 26, 2015 in Portsmouth, NH.

3) **Bill S-2578 – Optometrist Prescribing Authority regarding Hydrocodone containing products**

Effective June 26, 2015, Senate Bill 2578 which was signed into law by Governor Chris Christie, P.L.2015,c65., authorizing optometrists with the proper certification, to prescribe hydrocodone containing products (HCP) regardless of schedule. HCPs are the only Schedule II controlled substance that optometrist can prescribe.

IX. COMMITTEE REPORTS

N/A

X. APPROVAL OF MINUTES

Public Session Minutes of June 24, 2015

Margherita Cardello moved, seconded by Mitch Sobel for the Board to approve the June 24, 2015 Public Session Minutes as amended. **Motion carried 8-0.**

XI. ADJOURNMENT

Margherita Cardello moved, seconded by Mitch Sobel for the Board to move into Executive Session to consider the Richard Tomasulo, R.Ph. and Trilogy Pharmacy matters which were moved to Executive Session for advice of counsel.

Motion carried 8-0.

Mitch Sobel moved, seconded by Stephen Lieberman for the Board to go into Public Session. **Motion carried 8-0.** The Board entered Public Session at 1:34 p.m.

Stephen Lieberman moved, seconded by Margherita Cardello for the Board to move into the Executive Session for review of 4 Complaints, 1 Old Business Item, 8 New Business Items, the Secretary's Report and Recommendation for Inspection Reports, and the approval of the June 24, 2015 Executive Session Minutes.

Motion carried 8-0.

At 1:35 p.m., the Board adjourned the Public Session.