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BOARD OF PHARMACY PUBLIC SESSION MINUTES HUDSON CONFERENCE ROOM, 6th FLOOR FEBRUARY 22, 2017

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, Hudson Conference Room, 6th floor, on February 22, 2017 at 9:13 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.	Late Arrival 10:16 AM
Stephen Lieberman, R.Ph.	
Edward G. McGinley, R.Ph.	Excused Absence
Mahesh Shah, R.Ph.	
Mitch Sobel, R.Ph.	
Linda Witzal, R.Ph.	

OTHERS IN ATTENDANCE

Anthony Rubinaccio	Executive Director
Megan Cordoma	Deputy Attorney General
Rachel Glasgow	Regulatory Analyst

IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of February, the following permits, licenses, and registrations were issued during the month:

- Pharmacy Technicians registered – 502
- Pharmacists licensed – 46 (37 by examination/score transfer and 9 by reciprocity)
- Out-of-State Pharmacies registered –18
- In-State Pharmacies licensed –4
- Pharmacists receiving immunization approval – 27
- Interns (foreign graduates) licensed –3

V. OLD BUSINESS

1) Public Orders Filed

- a) Mark Smith - Consent Order filed 1-27-17
- b) Devassykutty Vareed - Final Order of Discipline filed 2-1-17
- c) Bijal Sheth - Final Order of Discipline filed 2-2-17
- d) Roya Behbahani - Final Order of Discipline filed 2-2-17
- e) Laurie Magargal - Final Order of Discipline filed 2-2-17
- f) Jermaine Dunbar - Provisional Order of Discipline filed 2-14-17
- g) Rebecca Windle - Provisional Order of Discipline filed 2-14-17
- h) Kevin Jones - Provisional Order of Discipline filed 2-14-17
- i) Caroline Sedrak - Provisional Order of Discipline filed 2-14-17
- j) Isamar Lorenzo - Provisional Order of Discipline filed 2-14-17

2) Rocky Patel – failure to respond to FOD

DAG Cordoma informed the Board that she had prepared the order of reinstatement as directed by the Board, and she will send it out immediately.

3) Muhammad Hagra – request to accept intern hours earned out of state

Richard Palombo moved, seconded by Mitch Sobel, that in the absence of a preceptor evaluation and the age of some of the internship hours (as far back as 2010), Mr. Hagra must do all of the internship hours again. He has never been licensed in any state. If he took the NAPLEX more than 5 years ago, he will need to do an internship and take the NAPLEX and MPJE again or he can get licensed in California and reciprocate to New Jersey after a year and taking the New Jersey MPJE. **Motion passed 6-0.**

4) Pentec – Out of State Pharmacy, sterile compounding application

Richard Palombo moved, seconded by Stephen Lieberman, that the Pharmacy inspections are recent and are acceptable, and that this application be allowed to proceed. **Motion passed 6-0.**

5) **BioTek ReMEDys Pharmacy – Out of State Pharmacy –sterile compounding**

Thomas Bender moved, seconded by Mahesh Shah, to allow this application to proceed. **Motion passed 6-0.**

6) **Jong Pak - request to remove restrictions from pharmacist license**

Mr. Pak requested that the Board remove the restrictions on his Pharmacist license. He initially surrendered his license in 2004 and it was reinstated in 2006 with restrictions. He gave the explanation of why he moved from a senior hospital position to Director of Automations at an automotive manufacturing facility: he wanted to have the management experience and to help his brother in law's business. Now Mr. Pak has an opportunity to be Pharmacy Director for East Orange General Hospital.

Richard Palombo moved, seconded by Stephen Lieberman, to accept Mr. Pak's explanation and to remove all restrictions on his pharmacist license, effective immediately. The licensing system will reflect this change immediately, and the Consent Order will follow as soon as possible. **Motion passed 5-0-1.** Mahesh Shah was recused due to his affiliation with Angelo Cifaldi.

7) **Specialty Rx Pharmacy - change of location application; request for waiver for labeling**

Linda Witzal moved, seconded by Richard Palombo, to grant the request for the labeling waiver for pharmacies, who were engaged in this type of package labeling for long term care facilities if (1) software will print "use by" on the foil instead of "exp", then no need to put "use by" on the label; (2) if foil must say "exp." then "use by" must be on the label either handwritten or otherwise. The Board referred to Rules and Regulations Committee for further review and possible issuance of a guidance document and/or changes to the rules. **Motion passed 6-0.**

NEW BUSINESS

1) **Opioid Initiative Overview (S3/A3)**

Sharon Joyce, Assistant Attorney General, and Howard Pine, Deputy Director, Division of Consumer Affairs, spoke concerning the new opioid initiative. AAG Joyce explained that on January 18, 2017, pursuant to the Attorney General's rulemaking authority under N.J.S.A. 45:1-17(b), the Attorney General notified New Jersey's prescribing boards -- State Board of Medical Examiners, the New Jersey Board of Nursing, the New Jersey State Board of Dentistry, and the New Jersey State Board of Optometrists -- that amendments to the Board's regulations are necessary to codify rigorous standards for the prescribing of controlled

dangerous substances for acute pain not associated with cancer or end of life care. Specifically, the amendments would require that an initial prescription for an opioid drug for treatment of acute pain shall not exceed a five-day supply, as determined by the directed dosage and frequency of dosage.

AAG Joyce further explained that S3/A3 was signed into law on February 15, 2017. The new law, P.L. 2017, c.28, which becomes effective on May 16, 2017, imposes certain restrictions on how opioids and other Schedule II controlled dangerous substances may be prescribed, and establishing special requirements for the management of acute and chronic pain including, in cases of acute pain, prohibiting a practitioner from issuing an initial prescription for an opioid drug in a quantity exceeding a five-day supply, and requiring the prescription to be for the lowest effective dose of an immediate-releasing opioid drug. The law also sets forth continuing education requirements for various licensed professionals, including pharmacists.

The law and rules do not impose any additional requirements for pharmacists to confirm that a prescription must be limited to a five-day supply of medication. However, note that pharmacists are required to perform their corresponding responsibility to ensure that all prescriptions for controlled dangerous substances are being written for a valid medical purpose.

Insurance plans issued in New Jersey will charge co-payments, coinsurance or deductibles for an initial prescription of an opioid drug prescribed pursuant to the law that is either:

- proportional between the cost sharing for a 30-day supply and the amount of drugs the patient was prescribed; or
- equivalent to the cost sharing for a full 30-day supply of the opioid drug, provided that no additional cost sharing may be charged for any additional prescriptions for the remainder of the 30 day supply.

Pharmacists may need to contact their insurance plans with any questions regarding how this component will be implemented.

Based upon Regulatory Analyst Rachel Glasgow's suggestion, the Board approved a motion to amend its sunset proposal, consistent with P.L. 2017, c.28 to include a requirement that, beginning with the 2019 biennial renewal of pharmacist licenses, pharmacists must complete 1 continuing education credit in programs or topics concerning prescription opioid drugs, including alternatives to opioids for managing and treating pain and the risk and signs of opioid abuse, addiction and diversion.

Because S3/A3 was signed into law, the Board did not comment on the bill.

2) **Mark Gianforcaro** – Reciprocity applicant, review of work experience

Linda Witzal moved, seconded by Mahesh Shah, to allow to Mr. Gianforcaro's application to proceed. He will need to retake the MPJE examination as his score is from several years ago. **Motion passed 7-0.**

3) **Ashwin Patel** – request to accept intern hours earned out of state

Mahesh Shah moved, seconded by Stephen Lieberman to accept 1800 hours from 2016 earned during his internship in New York, if he wishes to perform a Score Transfer. If he wished to reciprocate, he must demonstrate 1500 hours of active practice within the last two years in order to satisfy the requirements for reciprocity from Delaware. **Motion passed 7-0.**

4) **Shraddha Patel** – request to take NAPLEX for the 6th time

Richard Palombo moved, seconded by Linda Witzal to allow Ms. Patel to retake the NAPLEX. **Motion passed 6-1.** Thomas Bender was opposed.

5) **Genoa, a QoL Healthcare Company, LLC** – waiver request

Genoa expressed that it had no need for class A prescription balances (and a complete set of metric weights or equivalent weighing device) in its listed facilities (below) because they do not engage in compounding, and requested waivers to not require those balances in to be place, and the requirement to have them inspected by the Bureau of Weights and Measures. They indicated they also did not utilize automatic counting devices.

- 28RS00747500: 93 West Palisade Ave, Room 128, Englewood, NJ 07631-2611
- 28RS00742700: 400 Market Street, Suite 200, Camden, NJ 08102-1526
- 28RS00665000: 270 State Route 35, Red Bank, NJ 07701-5920
- 28RS00689400: 700 Airport Rd, Lakewood, NJ 08701-5907
- 28RS00697100: 00 395 Main St., Hackensack, NJ 07601-5806
- 28RS00722200: 160 Route 9, Room 11, Bayville, NJ 08721-1229
- 28RS00725500: 128 Crest Haven Road, Suite I 00, Cape May Court House, NJ 08210-1651
- 28RS00749600: 1259 Route 46 E, Bldg 2, Ste I OOA, Parsippany, NJ 07054-4921
- 28RS00751900: 53 Haddonfield Road, Ste 316, Room 35, Cherry Hill, NJ 08002-4802

Richard Palombo moved, seconded by Linda Witzal to grant the waivers based on Genoa supplying an affidavit indicating that they will not perform (sterile or non-

sterile) compounding, without having the required equipment available. The waiver is only applicable to pharmacies listed on the waiver request letter, and is not valid for any electronic counting device that may be currently in use, or implemented in the future. If that situation changes for a specific facility, that facility's waiver would be automatically rescinded. **Motion passed 6-1.** Stephen Lieberman was opposed.

6) Fred's Pharmacy – 2 waiver requests

Fred's Pharmacy may be acquiring multiple pharmacies as a result of the Walgreens-RiteAid merger. Since they do not anticipate the changing of any personnel at the time of potential acquisition of certain pharmacies, they are seeking a waiver to obtain the signature of the RPIC for each store in order to facilitate the timely submission and processing of each required pharmacy change-of-ownership application. They are also requesting a waiver of the submission of Affidavit C, with certain questions regarding a physician's financial interest in the pharmacy. In light of the organizational structure of the pharmacy, whereby each location will be owned by a domestic LLC, that is owned entirely by a parent company, it is their position that this Affidavit would not be relevant to the particular pharmacies.

Stephen Lieberman moved, seconded by Linda Witzal to grant the waivers to allow Fred's Pharmacy to submit affidavit that no RPIC or personnel is changing in lieu of Affidavit B, and completion of Affidavit C. Fred's Pharmacy had to follow all rules regulating notification of the change in PIC subsequent to the initial processing of the change-of-ownership application(s). **Motion passed 5-0-2.** Thomas Bender and Margherita Cardello were recused due to their affiliations with Walgreens and RiteAid.

7) Meadowview Psychiatric Hospital – waiver request

Meadowview Psychiatric Hospital is requesting a waiver for regulation 13:39-7.18 OUTDATED DRUGS OR DRUGS MARKED "SAMPLES". Currently Otsuka America Pharmaceuticals, Inc. is offering an inpatient sample program for Ability Maintena, a once a month injectable medication for the treatment of schizophrenia.

Mitch Sobel moved, seconded by Stephen Lieberman to grant the waiver for inpatient use. The hospital is to supply to the Board a description of how they would segregate the sample medication from regular hospital stock medication, and who would be eligible to receive it, and they would not be charging or billing any person or entity for the medication. **Motion passed 7-0.**

8) Mandell's Pharmacy – Terry Malanda – question regarding faxing prescriptions

Terry Malanda, RPh, wrote the Board explaining that they receive many of their prescriptions via their own fax server and sometimes run into problems with the transmission which results in crimped faxes or partial faxes. Because of that they are investigating the use of a service called Sfax by a company named Scrypt and the possibility of using their secure web server instead of the pharmacy's fax server to alleviate this matter. However, before doing so, they want to verify with the Board that these faxes will still be considered a legal prescription according to New Jersey pharmacy law.

Chair Direct: The Board is to request a copy of the image of the fax that they would receive and print out after they accessed the system. Refer to Rules and Regulations.

9) On-body Injector for Neulasta and USP 797 - request for guidance

Chair Direct: The Board should contact the FDA regarding whether they considered preparation of the device to be a sterile manipulation that should comply with cGMP or USP 797.

10) Biomed PA Inc. dba Soleo Health – Out of State, name change - sterile compounding application

The Board received and reviewed a Sterile and Non Sterile Compounding change of location application, including New Jersey inspection report from February 18, 2016 and an NABP inspection from May 22, 2014.

Richard Palombo moved, seconded by Linda Witzal to approve the name change. **Motion passed 6-0.** Stephen Lieberman was out of the room.

11) PharmaScript Inc. - Out of State, sterile compounding application

Linda Witzal moved, seconded by Mahesh Shah that the applicant must comply with all requirements. The Illinois inspection was prior to opening (12/17/15). The application will remain pending until the Board receives an updated inspection report. **Motion passed 6-0.** Stephen Lieberman was out of the room.

12) Crescent Healthcare - Out of State, sterile compounding application

The Board received and reviewed a Sterile Compounding change of location application, including a New York inspection report from 2015 and 2016 that indicated a follow up inspection was required.

Chair Direct: The applicant should provide an explanation as for why the SOP's contain the name "Optioncare". The Board office will also request a copy of their current DEA registration. The application will pend until the Board receives the requested information.

- 13) Diplomat Specialty Infusion Group** – existing Out of State pharmacy - requesting to perform sterile compounding

Thomas Bender moved, seconded by Stephen Lieberman to approve and provide clarification if any central fill applications exist. **Motion passed 6-0.** Mitch Sobel was out of the room.

- 14) Fairview Specialty Services Pharmacy** - Out of State pharmacy with discipline, change of ownership application

Richard Palombo moved, seconded by Linda Witzal to accept the change of officer and notification of discipline as an FYI. **Motion passed 6-0.** Mitch Sobel was out of the room.

- 15) Continuing Education Verification 2013-2015** – responses

a. Leann Poole

Richard Palombo moved, seconded by Mahesh Shah to finalize the POD with modification, removing the \$1,000 fine for misrepresentation, imposing a fine of \$300 representing the 3 missing credits, and a suspension is no longer necessary. **Motion passed 6-0.** Mitch Sobel was out of the room.

b. Allyson Longo

Stephen Lieberman moved, seconded by Richard Palombo to finalize the POD with modification, removing the \$1,000 fine for misrepresentation, imposing a fine of \$200 representing the 2 missing credits, and a suspension is no longer necessary. **Motion passed 7-0.**

c. Tara Lee Fricke

Stephen Lieberman moved, seconded by Masheh Shah to finalize the POD with modification, removing the \$1,000 fine for misrepresentation, imposing a fine of \$200 representing the 2 missing credits, and a suspension is no longer necessary. **Motion passed 7-0.**

d. Shahid Chohan

Stephen Lieberman moved, seconded by Richard Palombo to finalize the POD

with modification, removing the \$1,000 fine for misrepresentation, imposing a fine of \$300 representing the 3 missing credits, and a suspension is no longer necessary. **Motion passed 7-0.**

e. Brian Dreitlein

Richard Palombo moved, seconded by Stephen Lieberman to finalize the POD without modification. **Motion passed 7-0.**

f. Tatyana Rabaev

Stephen Lieberman moved, seconded by Mahesh Shah to finalize the POD with modification, removing the \$1,000 fine for misrepresentation, imposing a fine of \$100 representing the 1 missing credit, and a suspension is no longer necessary. **Motion passed 7-0.**

g. Burton Cohen

Stephen Lieberman moved, seconded by Mahesh Shah to finalize the POD with modification, removing the \$1,000 fine for misrepresentation, and a suspension is no longer necessary. **Motion passed 7-0.**

h. Stephen Ulrich

Mitch Sobel moved, seconded by Thomas Bender to finalize the POD with modification, removing the \$1,000 fine for misrepresentation, imposing a fine of \$600 representing the 6 missing credits, and a suspension is no longer necessary. **Motion passed 7-0.**

i. Julie Plotnikov

Richard Palombo moved, seconded by Mahesh Shah to finalize FOD without modification, imposing \$150 fine and to place her license inactive upon payment of fine and completed credits. **Motion passed 7-0.**

j. Stephen Kaufman

Stephen Lieberman moved, seconded by Mitch Sobel to finalize the POD with modification, removing the \$1,000 fine for misrepresentation, imposing a fine of \$1300 representing the 13 missing credits, and a suspension is no longer necessary. **Motion passed 7-0.**

k. Soo Sun Hwang

Chair Direct: DAG Cordoma to review

l. Danielle Williams

Thomas Bender moved, seconded by Linda Witzal to finalize the POD with modification, removing the \$1,000 fine for misrepresentation, imposing a fine of \$200 representing the 2 missing credits, and a suspension is no longer necessary. **Motion passed 7-0.**

m. Maryam Javdan

Richard Palombo moved, seconded by Mitch Sobel to finalize the POD with modification, removing the \$1,000 fine for misrepresentation, and a suspension is no longer necessary. **Motion passed 7-0.**

n. William Brumbach

Stephen Lieberman moved, seconded by Mitch Sobel to finalize the POD with modification, removing the \$1,000 fine for misrepresentation, imposing a fine of \$300 representing the 3 missing credits, and a suspension is no longer necessary. **Motion passed 7-0.**

o. Suzanne Soliman

Mitch Sobel moved, seconded by Richard Palombo to finalize the POD with a reprimand and modification, removing the \$1,000 fine for misrepresentation, imposing a fine of \$200 representing the 2 missing credits, and a suspension is no longer necessary. **Motion passed 7-0.**

p. Aleksandra Srbljak

Mahesh Shah moved, seconded by Stephen Lieberman to finalize the POD with modification, removing the \$1,000 fine for misrepresentation, imposing a fine of \$200 representing the 2 missing credits, and a suspension is no longer necessary. **Motion passed 7-0.**

16) Carepak Pharmacy - request to "share" doctor's space

Wonkyu Shon, RPh, submitted an application for a Pharmacy to rent space from a Podiatrist in the Podiatrist's office. He responded to the Board's questions regarding pharmacy security, the business model for the pharmacy, etc.

Richard Palombo moved, seconded by Mahesh Shah to approve this request. **Motion passed 5-2.** Mitch Sobel and Stephen Lieberman were opposed.

VI. MITIGATION REQUEST

1. Siva Narayan Tallavajhala, RPIC – United Drugs Pharmacy, Newark, NJ

Steve Lieberman moved, seconded by Thomas Bender to deny the mitigation request for violation of N.J.A.C. 13:39-6.12, to approve the mitigation request for violation of N.J.A.C. 13:39 – 6.15 (d)(e) and to remove the \$500 fine. **Motion passed 6-0-1.** Mahesh Shah was recused due to his affiliation with Angelo Cifaldi.

2. Esther Lee, RPIC – Garfield Pharmacy, Garfield , NJ

Stephen Lieberman moved, seconded by Thomas Bender to deny all three mitigation requests. **Motion passed 6-0-1.** Mahesh Shah due to his affiliation with Angelo Cifaldi.

3. Basem Saad Mekhail, CVS, Bayonne, NJ

Stephen Lieberman moved, seconded by Mitch Sobel to mitigate the \$50 fine. **Motion passed 7-0.**

VII. INFORMATIONAL

Impax Laboratories – provided information regarding the availability of a low-cost Epinephrine Auto Injector (EAI)

The Board took this as informational.

VIII. COMMITTEE REPORTS

N/A

IX. APPROVAL OF MINUTES

Public Session minutes for February 22, 2017.

Richard Palombo moved, seconded by Stephen Lieberman to approve the February 22, 2017 public session minutes as amended. **Motion passed 7-0.**

X. ADJOURNMENT

At 2:47 p.m. Mitch Sobel moved, seconded by Mahesh Shah, to adjourn to the Public Session. **Motion passed 7-0.**

At 2:48 p.m. Mitch Sobel moved, seconded by Stephen Lieberman, to go into Executive Session. **Motion passed 7-0.**