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BOARD OF PHARMACY PUBLIC SESSION MEETING MINUTES MONMOUTH CONFERENCE ROOM, 7th FLOOR February 26, 2014

I. CALL TO ORDER

The Open Session Meeting of the New Jersey Board of Pharmacy was called to order by the Board President Thomas Bender in the Monmouth Conference Room at 124 Halsey Street, Newark, New Jersey on February 26, 2014, at 9:10 a.m. All members were duly notified of the time and place and all pertinent materials were provided to the Board Members.

II. SUNSHINE LAW ANNOUNCEMENT

President Thomas Bender read a statement that the newspapers and appropriate elected officials have 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 Bender, R.Ph.	President
Richard Palombo, R.Ph.	Vice President
Margherita Cardello, R.Ph.	Late Arrival 10:22 AM
Marc Sturgill, PharmD	
Mahesh Shah, R.Ph.	
Stephen Lieberman, R.Ph.	
Edward McGinley, R.Ph.	Excused Absence

OTHERS IN ATTENDANCE

Anthony Rubinaccio, R.Ph.	Executive Director
Rachel Glasgow	Regulatory Analyst
Matthew Wetzel	Government Representative
Linda Brodie	Board Staff
Megan Cordoma	Deputy Attorney General

IV. UPDATES BY EXECUTIVE DIRECTOR

Director Rubinaccio reported for the month of January \$ 19,875 in fines and penalties were collected. The following permits, licenses, and registrations were issued during the month of January:

- Technicians - 211
- Pharmacist - 41 (30 by examination/score transfer and 11 by reciprocity)
- Out-of-state pharmacies – 11
- In-state pharmacies - 9
- Pharmacists receiving immunization approval - 27
- Interns - 7

FDA inter-governmental working meeting:

On March 20-21, 2014, the FDA will be hosting an inter-governmental working meeting with state officials and their representatives at their headquarters in Silver Springs Maryland. The purpose is to discuss the oversight of compounding pharmacies, and the relationship between the activities of the FDA and the states under the new Drug Quality and Security Act, signed into law on November 27, 2013.

Topics of discussion will include:

- Providing an overview of the new federal law and FDA's plans for implementation
- Conducting inspections of sterile compounding facilities
- Improving communication between the FDA and the states with regard to compounding, including issues related to sharing confidential information
- Recent state legislative and regulatory changes related to sterile compounding and state plans with regard to licensing outsourcing facilities
- What the FDA should include in the standard Memorandum of Understanding that the FDA is required to develop under section 503A of the Federal Food, Drug, and Cosmetic Act (FFDCA), addressing the interstate shipment of compounded products.

The Goal of this meeting is to identify opportunities to better protect the public health by strengthening oversight of compounding pharmacies, including through improved federal-state collaboration.

Director Rubinaccio will be attending to represent New Jersey, and he asked the Board members to individually send him any questions they may have about the new law, etc.

V. OLD BUSINESS

1) Public Orders Filed

- a. Alfredo Balleras, R.Ph.- Amended Order of Reinstatement (1/9/14)
- b. MaryAnn Solomon, Pharm. Tech. - Final Order (1/9/14)
- c. Joseph Chiodo, R.Ph. - Consent Order (1/9/14)
- d. Shayona Pharmacy - Vol. Interim Consent Order (1/7/14)
- e. Jacobs Pharmacy - Interim Order and Report of Hearing (1/21/14)
- f. Shayona Pharmacy - 2nd Vol. Interim Consent Order (1/13/14)
- g. Jennifer Kim, R.Ph. - Consent Order (1/29/14)
- h. Liberty Drug & Surgical-Interim Consent Order (1/31/14)
- i. Thomas Gates - Consent Order (1/29/14)

2) Mark Cardis, R.Ph. - Request Modification of his Consent Order

Mr. Cardis wrote to the Board requesting removal of restrictions in his Consent Order, specifically item #6, which was filed in July of 2011. Mr. Cardis cited five years of documented recovery time with PAP, as well as a recommendation from Mr. Clark Boyd III, and from PAP as well.

Stephen Lieberman moved, seconded by Thomas Bender, to deny this request. Mahesh Shah, Marc Sturgill and Richard Palombo opposed. Margherita Cardello was recused due to her affiliation with Rite Aid. **Motion did not pass 2-3. This item is tabled until a quorum can be reached.**

3) Angelo Cifaldi, on behalf of his client Neelam Chand, R.Ph. – Request for removal of license restrictions

Ms. Chand entered into a consent Order with the Board on November 30, 2011 for submitting 51 prescriptions to Medco Health Solutions without a valid prescription. She entered into a consent order with the Department of Banking and Insurance, paid a \$5000 civil administrative penalty, in addition to a 5% surcharge of the settlement amount. Ms. Chand has supplied documentation of successfully completing the ProBE course, as required by her consent order.

Richard Palombo was recused due to his affiliation with Express Scripts (formerly Medco), and Mahesh Shah was recused due to his affiliation with Mr. Cifaldi.

Chair Direct: The Board office is to ask Ms. Chand to supply the Board with a narrative of what she has been doing for last two years (ie. where she is employed, etc.) as well as supplying a copy of the Continuing Education credits she has completed. If Ms. Chand is not working, the Board would like a narrative of what her future plans include.

VI. NEW BUSINESS

1) **Monmouth Medical Center/ Vantage Point Infusion Remodeling Application**

Mr. Gorell, esq. and Mr. Mathis RPIC attended the meeting to explain their application. They are opening a Monmouth Medical Center infusion center at a location called Vantage Point (100 Highway 36, West Long Branch), which will service Monmouth Medical Center patients, who are registered outpatients to Monmouth Medical Center. This will be a second infusion center for them, the first being on site and taken care of by the inpatient pharmacy of Monmouth Medical Center. The Vantage Point site is licensed as a hospital-based service. It is less than 3 miles from the Medical Center and is managed by Monmouth Medical Center employees. They will not be servicing off-the-street patients, and will not be providing retail services. There will be no controlled substances at the Vantage Point location, and only infusions/injections and pre-medications will be provided to patients on-site; no medication will be sent home with the patient. Patients who require narcotics or infusion services requiring blood products will be treated only at the hospital location.

The pharmacy service consists of a pharmacist and a pharmacy technician during regular business hours (8-4:30 Monday through Friday) with a chemotherapy compounding clean room and an ante-room with a containment isolator for compounding pre-meds. The pharmacy is physically separated from the infusion area, and the pharmacy (ante-room) has a keypunch lock and the clean room has a keyed access that only the pharmacy staff has access. Inside the pharmacy, medications are stored in Pyxis or a locked refrigerator (with key accessed through Pyxis). Mr. Mathis will be the pharmacist in charge, as the intent of the application for this pharmacy to be part of the Monmouth Medical Center Pharmacy. The same policies and procedures apply to both locations.

Richard Palombo moved, seconded by Mahesh Shah, to approve this application as a satellite pharmacy of the main pharmacy at the hospital. Director Rubinaccio is to notify the Department of Health of the Board's decision.

Motion passed 4-0. Marc Sturgill was recused due to a previous professional and current personal affiliation with Scott Mathis.

Richard Palombo moved, seconded by Marc Sturgill, to send the question of satellite pharmacies, and what constitutes a healthcare system 'campus', to the Rules and Regulations Committee for further discussion and clarification.

Motion passed 5-0.

2) **Vince Deluca, RPh. - Request for Reinstatement**

Mr. Deluca was arrested on two different occasions - August 21, 2009 and

September 8, 2009 - for allegedly stealing stock bottles of hydrocodone from two different Kinney Drug Store locations. His consent order states that his license to practice pharmacy in the State of New Jersey was suspended for a minimum period of three years, effective June 10, 2010, the date of the entry of his first criminal plea, at which time he had voluntarily refrained from practice. No application for reinstatement of license shall be considered by the Board until the later of three years or the completion of the requirements of any criminal judgment of conviction or diversionary program, similar to PTI. In addition, Mr. Deluca must demonstrate a minimum of six (6) months of sobriety prior to making any application for reinstatement, along with other terms as outlined in this consent order.

Mr. Deluca presented documentation indicating that that he has complied with the terms of his consent order (ie. completed his PTI, provided reports from treating physicians, etc.), and respectfully requested that the Board reinstate his license to practice pharmacy in New Jersey.

Stephen Lieberman moved, seconded by Marc Sturgill, for Mr. Deluca to take the PARE exam, and to provide the Board with all completed Continuing Education credits to date. After these two items have been completed, Mr. Deluca will be scheduled for an Investigative Inquiry. **Motion passed 5-0.**

3) **Janjikhel Rajiv- Pharmacist Candidate**

Janjikehl Rajiv is a foreign pharmacy graduate and has successfully completed his FPGEE, TOEFL and MPJE. In addition, as per the guidelines in effect at the time, he completed the required 1000 hours of internship. He appeared for the NAPLEX on 01/07/09 but did not pass the examination. He states that he has been unable to take the NAPLEX due to work and family constraints related to the need to spend a significant amount of time caring for his 2 children while his wife started, established and grew a small business of her own. He would like to take the NAPLEX in the near future. He stated that he enjoyed his time working at the pharmacy during his (previous) internship and even after its completion since it gave him an opportunity to interact directly with the consumer, something that he lacks in his current job in the pharmaceutical industry. He is presently employed at Forest Laboratories, Inc. and supports its R&D efforts in new drug development. In addition, he holds a Ph.D. in Pharmaceutics. Based on his education, the exams that he has passed to date and nature of his work in the pharmaceutical industry, he is requesting that a waiver be granted for re-doing the entire required amount of internship hours. He states that he realizes that he does not meet the current 1,440 hour internship requirement, but is willing to complete the extra hours (440 hours) required to bring the total up to the current requirement, in the event a complete waiver cannot be granted.

Richard Palombo moved, seconded by Stephen Lieberman, to deny the request to waive the amount of internship hour requirements. The Board reviewed all the information presented, and determined that his work experience does not meet the

qualifications to be applied as credit toward his internship hours requirement. Also, the Board noted that no hardship was presented. **Motion passed 5-0.**

4) Empower Pharmacy, Houston, TX - Application for Out-Of-State Pharmacy Registration Performing Sterile Compounding

Marc Sturgill moved, seconded by Stephen Lieberman, to approve the application as presented. Thomas Bender was opposed. **Motion passed 4-1.**

5) Johnson Compounding Pharmacy, Waltham, MA - Application for Out-of- State Pharmacy Registration Performing Sterile Compounding

Richard Palombo moved, seconded by Stephen Lieberman, to approve the application as presented. **Motion passed 5-0.**

6) Partners Pharmacy – Pharmacy Technician Training Program

James Matthews, R.Ph., regional vice president of Partners Pharmacy, submitted their Pharmacy Technician Training Program to the Board for approval in compliance with N.J.A.C.13:39 6.15-(e) 2 iii.

Partners Pharmacy owns and operates the three pharmacies listed below. They requested consideration and approval for each of these pharmacies:

Partners Pharmacy
70 Jackson Drive
Cranford, NJ 07016
Permit # 28RS00633600

Partners Pharmacy IV
70 Jackson Drive
Cranford, NJ 07016
Permit # 28RS00633500

Partners Pharmacy d/b/a Discover Rx
615 Montrose Ave
South Plainfield, NJ 07080
Permit # 28RS00603500

Marc Sturgill moved, seconded by Richard Palombo, to approve the Pharmacy Technician training program as presented. **Motion passed 5-0.**

7) Wedgewood Pharmacy - Pharmacy Technician Training Manual

Wedgewood Pharmacy submitted their Pharmacy Technician Training Manual to the Board for approval in compliance with N.J.A.C.13:39 6.15-(e) 2 iii.

Marc Sturgill moved, seconded by Richard Palombo, to approve the Pharmacy Technician training program as presented. **Motion passed 5-0.**

8) Angelo Cifaldi, Esq. - Request for an Advisory Opinion on Servicing Group Homes

Mr. Cifaldi sent the memo to the Board requesting an advisory opinion on the issue of long term care facilities requesting retail pharmacies to provide outpatient care for their residents. These medications are often dispensed in unit-doses, and are labeled as required by current regulations. Institutions will occasionally request that pharmacies re-label the medication due to an unanticipated change of directions. Mr. Cifaldi is requesting guidance from the Board on how to handle these types of requests.

Chair Direct: The Board does not issue advisory opinions, however, the Board does understand the challenges posed as outlined by Mr. Cifaldi. The Board instructs Mr. Cifaldi to refer to N.J.A.C. 13:39-9.2 for definitions of a health care facility, and that chapter in general, for regulations regarding institutional pharmacies. If the facility does not meet the institutional criteria, it must abide by the regulations that pertain to retail facilities.

9) Morgan Lewis Counselors at Law - Inquiry Concerning Certain Billing Arrangements

This item was moved to Executive session.

10) Assembly Bill, No. 3251 (Asm. Ramos) - Permits Pharmacist to administer influenza vaccines to children ages seven or older

a) NJPhA - Would like to discuss changes to New Immunization Law
Lori Clark, legislative counsel for NJPhA, and Elise Barry, Chief Executive Officer for NJPhA addressed the Board to offer assistance to the Rules & Regulations Committee members to get information out regarding the urgency of having the updated Immunization Regulations approved in time for this year's influenza season. Thomas Bender explained that since the Immunization Regulations were jointly promulgated by the Board of Pharmacy and the Board of Medical Examiners, any changes to them will also need to be approved by both Boards. The Board understands the challenges of pharmacies being able to order vaccines in time for the influenza season, while waiting for approval of the updated regulations. President Bender indicated that the Board will work as

quickly as possible to have the regulations adopted before the start of the influenza season.

The Board took this item as informational.

b) Prescription Blank Security Measures:

Rachel Glasgow provided an overview of the security and design for new New Jersey Prescription Blanks. Security features include: thermochromic ink, microprint, barcode/and numbers (which replaces the serial number and batch number and will be used to send information to the New Jersey PMP), hollow void on copying. A list of the print based security measures are printed on the back of each prescription blank. Also, the new blanks will reverse the existing color scheme (the front of the blank will be green, and the back will be blue). The current blanks cannot be sold after May 19, 2014. However, physicians may continue to write prescriptions using the old blanks until August 18, 2014. This information will be made available through the New Jersey State Board of Pharmacy Newsletter, by direct communication to chains and pharmacy organizations, and a communication via the PMP system to all pharmacies.

11) Pharmacists administration of Enoxaparin.

Director Rubinaccio received the following inquiry from Richard J. Artymowicz, Pharm.D., Director, Pharmacy Services, Cape Regional Medical Center, Cape May Court House, NJ:

From: Artymowicz, Rich

Sent: Friday, February 14, 2014 1:48 PM

To: 'anthony.rubinaccio@ips.state.nj.us'

Subject: Pharmacist Administration of enoxaparin or fondaparinux

Hello Anthony:

Sorry I missed your call this afternoon, thank you for getting back to me so quickly.

My hospital has an outpatient antithrombosis service that is staffed by pharmacists. Some of the patients seen there are being bridged with injectable anticoagulants. Currently, we have the patients self-administer their sq injections at home, but some cannot manage this well. We would like for the pharmacist to be able to administer these sq injections while the patient is having their INR checked. I wasn't sure how to interpret the collaborative practice act to accomplish this and was looking for some guidance.

Any help you can provide would be greatly appreciated.

This item was tabled to allow Board members additional time to review this issue. It will be placed on the agenda for March.

12) **Waiver request from Rita O'Connor, BSN, RN - Coordinator of the Sexual Assault Response Team (SART) / Forensic Nurse Examiner (FNE) Programs for the Ocean County Prosecutor's Office**

Ms. O'Connor provided background for her request by sending the following letter to the Board office:

“Currently, we conduct forensic medical examinations (FME) to victims of sexual assault throughout Ocean County in all acute care facilities (Community Medical Center, Kimball Medical Center, Ocean Medical Center, and Southern Ocean Medical Center) within 5 days of a sexual assault. As part of that FME, the victim is given prophylaxis medications for sexually transmitted diseases (STD) and emergency contraception. Our protocols are based on the Center for Disease Control (CDC) guidelines.

ANTIBIOTICS (to prevent STD's)

Azithromycin 2gms

OR

Cefixime 400 mg PO single dose

PLUS

Azithromycin 1 g PO –in a single dose

OR

Doxycycline 100 mg PO BID X 7 Days

PLUS

Metronidazole 2g orally –in a single dose

EMERGENCY CONTRACEPTIVE (to prevent pregnancy)

Plan B, Plan B One Step, Next Choice (Levonorgestrel)

We now have an examination room in the Prosecutor's Office in addition to the hospitals. The Attorney General's Guidelines for Providing Care to Victim's of Sexual Assault requires us to medicate the victim immediately following the FME.

We plan to have Dr. Dawn Kennedy-Little, who is our Medical Director; give the nurse a telephone order to administer the medications to victim's who are 13 years or older. Our plan is to have Dr. Kennedy-Little write or call in the prescriptions for two (2) patient doses of the medications. When one patient supply is used, I will return to the pharmacy to refill the supply. If necessary, I can provide the victim's name who received the medications. The medications can be picked up or delivered.

We would like to fill the prescriptions at a local pharmacy so we can lock them in the examination room. The examination room is located in a secure building, the examination room is locked, and the medications will be stored in a locked draw. Access to the room is only available to the lieutenant of the Special Victim's Unit and me. When Dr. Kennedy-Little is in the building she shares my office with me.

On consultation with a local pharmacy it appears that they can only dispense prescriptions to a specific patient. In order to ensure we comply with all regulations we seek your assistance with a limited waiver to allow a pharmacy to dispense prescriptions above to a “Jane Doe for Ocean County Prosecutors Office”

Currently, all 21 Counties in New Jersey have a Sexual Assault Response Team (SART). Ocean County is the first county to have an examination room in the child advocacy center and using it to conduct forensic medical examinations.

To recap, the medications are not narcotic, will remain secure (under triple lock), are ordered by a physician, and will be administered by a Registered Nurse following a telephone order from the doctor.

Please feel free to contact me if you need any further information or advice or guidance on a solution to be able to provide the sexual assault victims of Ocean County with comprehensive, compassionate, and respectful care.

*Respectfully submitted,
Rita M. O’Connor BSN, RN, FN-CSA, SANE-P”*

Chair Direct: The Board office will inform Ms. O’Connor that an acceptable course of action to satisfy this requirement is for the Medical Director to purchase medications from the local pharmacy via a purchase order, and be invoiced for the medication.

VII. MITIGATION/HEARING REQUEST

1) Jeffrey Voris, RPIC - Walgreens Pharmacy, Bound Brook, NJ

Mr. Voris requested to have the fine mitigated and to be relieved from the penalty. His request was based on the fact that in accordance with N.J.A.C. 13:39-7.16, the medication that was returned to stock that could not be properly returned to the original manufacturer's container was held in the pharmacy in the labeled container in which it was repackaged. A yellow label designed specifically for this purpose was added to the container in which it was repackaged that contains the following information: the name of the medication, manufacturer, NDC#, date the vial was filled, and expiration date of 6 months from date the vial was filled.

Marc Sturgill moved, seconded by Margherita Cardello, to mitigate the fine and remove the citation for violation of N.J.A.C. 13:39-6.2f(7). Thomas Bender was recused due to his affiliation with Walgreens. **Motion passed 4-0.**

2) Leon Marsh, RPIC - Shop Rite Pharmacy, Lincoln Park, NJ

Mr. Marsh, RPIC, requested mitigation of the fine of \$ 1,000 for violation of N.J.A.C.13:39-7.21(d). He enclosed, with his letter, a pharmacy bag which was used to deliver all prescriptions to patients who either pick up at the pharmacy or receive delivery to their house. On the bag it states if there are any questions about the patient's medication, that they should call the pharmacy at the number on the prescription label/receipt. His contention is that this is a notification, in writing, to counsel in the event of any questions. At the time of the inspection the only documentation reviewed was the pharmacy's delivery slips which require a signature for prescription receipt and insurance billing verification.

Mahesh Shah moved, seconded by Thomas Bender, to deny this mitigation request. The Board determined that simply having information on the bag does not meet the requirements of providing an offer to counsel. **Motion passed 6-0.**

VIII. INFORMATIONAL

N/A

IX. COMMITTEE REPORTS

Long Term Care Committee

On February 13, 2014, Richard Palombo, Thomas Bender, Matthew Wetzel and Anthony Rubinaccio met to review a series of questions sent to Mr. Wetzel from various stakeholders in the Long Term Care community. After a thorough discussion, it was determined that the committee still required additional information to provide informed and accurate answers to these questions. The committee will be sending a letter to various stakeholders requesting various policies and procedures, descriptions of how automated dispensing systems are being used today throughout the community. The committee will seek to convene a stakeholder meeting in mid to late April 2014.

X. APPROVAL OF MINUTES

January 29, 2014 Public Session Minutes

Richard Palombo moved, seconded by Marc Sturgill, to approve the January 29, 2014 Public Session Minutes as amended. **Motion passed 5-0.**

Marc Sturgill moved, seconded by Margherita Cardello, to adjourn the Public session and move to Executive session at 11:57 a.m.. **Motion passed 5-0.**