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BOARD OF PHARMACY OPEN SESSION MINUTES MONMOUTH CONFERENCE ROOM, 7TH FLOOR FEBRUARY 27, 2013

I. CALL TO ORDER

The Open Meeting of the New Jersey Board of Pharmacy was call to order by Board President Edward McGinley in the Monmouth Conference Room at 124 Halsey Street, Newark, New Jersey on February 27, 2013 at 9:26am. All members were duly notified of the time, place and all pertinent materials were provided to members.

II. SUNSHINE LAW ANNOUNCEMENT

President Edward McGinley, 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, PL 1975,C.10:4-8

III. ROLL CALL

Edward G. McGinley, R.Ph.	President
Thomas Bender, R.Ph.	Vice President
Margherita Cardello, R.Ph.	Late Arrival 9:50 a.m.
Marc Sturgill, R.Ph.	Excused Absence
Richard Palombo, R.Ph.	
Mahesh Shah, R.Ph.	
Stephen Lieberman, R.Ph.	

OTHERS IN ATTENDANCE

Anthony Rubinaccio	Executive Director
Linda Brodie	Customer Service Rep.1
Matthew Wetzel	Government Rep.
Megan Cordoma	Deputy Attorney General
Rachel Glasgow	Regulatory Analyst
Maryann Sheehan	Deputy Director
Michael Westenberger	Supervising Investigator

IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of January, \$22,950 was collected in fines and penalties. The following permits, licenses, and registrations were issued during the month of January:

- Technicians - 143
- Pharmacists - 24 (22 by examination and 2 by reciprocity)

- Out-of-state pharmacies - 13
- In-state pharmacies - 6
- Pharmacists receiving immunization approval -24
- Interns (foreign graduates) -10

V. OLD BUSINESS

1. **Jennifer Peralta** - POD to be finalized

Richard Palombo moved, seconded by Stephen Lieberman to find that service was effective on respondents address of record, respondent has not submitted a response and the Provisional Order of Discipline should be finalized without modification by default . Thomas Bender was recused due to his affiliation with Walgreens. **Motion passed 4-0.**

2. **Joby George** - POD to be finalized

Thomas Bender moved, seconded by Stephen Lieberman to find that service was effective on respondents address of record, respondent has not submitted a response and the Provisional Order of Discipline should be finalized without modification by default . **Motion passed 5-0.**

3. **Best Practices for Pharmacy Security 2013** - For Board review

Deputy Director Sheehan described the background for the creation of the Best Practices for Pharmacy Security document. The Division held a Pharmacy Security Summit in January 2012, and followed up by a subsequent meeting in May 2012. The Summit was attended by representatives from various stakeholders related to pharmacy, including retail pharmacy (chains and independent store owners), institutional pharmacy, law enforcement, pharmaceutical manufacturers, pharmacy educational institutions, and various pharmacy organizations. The results of many hours of discussions on how to prevent illegal drug diversion and theft, and improve pharmacy security were compiled into the Best Practices for Pharmacy Security document. The document was released for comments from the pharmacy community. Comments received were reviewed and discussed, and the document was updated accordingly to reflect points raised by the pharmacy community.

The Best Practices are intended to be recommendations and not regulations; there are no penalties associated with them. The intent of the document is to provide pharmacists with guidelines and tools to help reduce illegal prescription drug diversion and medication theft.

In order to make the pharmacy community aware of the document, there will be a press release next week to coincide with Consumer Protection Week. In addition, it will be posted to the Board of Pharmacy website and printed in the New Jersey State Board of Pharmacy quarterly Newsletter.

Richard Palombo moved, seconded by Mahesh Shah to endorse the Best Practices for Pharmacy Security document. **Motion passed 5-0.**

4. **Nick Stamatiadis, R.Ph.** - Request for clarification of motion

Upon request for clarification of the December 12, 2012 minutes by DAG Cordoma, Consent Order of Reinstatement with continued PAP NJ monitoring until Mr. Stamatiadis is released from PAP. His license will remain on probation until July 11, 2013, and he must show the Order to employers. He may not be a preceptor, an owner or a pharmacist-in-charge.

Thomas Bender moved, seconded by Stephen Lieberman for DAG Cordoma to offer a new Consent Order of Reinstatement. **Motion passed 4-0.**

VI. NEW BUSINESS

1. **Bill A3677**- Comment Request Concerning Ephedrine and Pseudoephedrine

The Board notes that safeguards are already in place in the State which are sufficient for protecting the public. Unnecessary safeguards will increase overall healthcare costs, and make availability of the product difficult for New Jersey patients to attain for legitimate medical purposes. Regular purchases are not the issue, but the illegal importing, from outside the country, is the main contributing factor to this problem.

Thomas Bender moved, seconded by Richard Palombo to oppose Bill A3677 because it impedes patient access to effective medicine, alternatives don't work as well, safety measures are currently in place, and it is not a major problem in New Jersey.

Motion passed 5-0.

2. **Draft New Jersey Emergency Volunteer Health Practitioners Act** - Comment Request

David Liston, Legislative Law Clerk with New Jersey Revision Commission (NJLRC) is writing on their behalf. NJLRC is currently considering the uniform Emergency Volunteer Health Practitioners Act (UEVHPA), a statute proposed and drafted by the Uniform Law Commission (ULC) that would facilitate the deployment of volunteer health practitioners in the event of a declared emergency.

Since the Board of Pharmacy is among the health practitioner licensing Boards named in NJEVHPA, they wanted to inquire as to whether the mentioning of the Board of Pharmacy as it currently appears in the draft Act are appropriate in the Board's opinion. They also wanted to give the Board the opportunity to comment generally on the proposed Act to ensure that pharmacists' concerns are sufficiently addressed.

Though the New Jersey Board of Pharmacy provided pharmacists with the flexibility to use their professional judgement in providing refills to displaced patients during hurricane Sandy, this act will give New Jersey pharmacists the authority to act more quickly in an emergency.

The Board appreciates the outreach, is in favor of the Act and fully supports it. It is a

comprehensive, well thought out document.

Richard Palombo moved, seconded by Thomas Bender to support the Act.
Motion passed 5-0.

3. **Genoa Healthcare of New Jersey, LLC- Bayville, NJ** - Requesting to dispense samples to patients free of charge

Genoa Healthcare of New Jersey is requesting a waiver for N.J.A.C. 13:39-7.18 to distribute sample medication. Products are limited to **CPC** formulary and products for treatment of mental health disorders.

Thomas Bender moved, seconded by Richard Palombo to grant a waiver to N.J.A.C. 13:39-7.18. **Motion passed 6-0.**

4. **Genoa Healthcare of New Jersey, LLC- Cape May Court House, NJ**- Requesting to dispense samples to patients free of charge

Genoa Healthcare of New Jersey is requesting a waiver for N.J.A.C. 13:39-7.18 to distribute sample medication. Products are limited to **CPC** formulary and products for treatment of mental health disorders.

Thomas Bender moved, seconded by Richard Palombo to grant a waiver to N.J.A.C. 13:39-7.18. **Motion passed 6-0.**

5. Pamela Mandel Esq. request reinstatement for her client **Alfredo Balleras, R.Ph.**

This item was moved to the end of the open session.

Mr. Balleras was suspended pursuant to a Consent Order File 12/9/2010. He is petitioning for reinstatement through his attorney Pamela Mandel.

At 10:57 am Thomas Bender moved, seconded by Richard Palombo to move into Executive Session for advise of counsel.

At 11:13 am Richard Palombo moved, seconded by Mahesh Shah to go back into Open Session.

Richard Palombo moved, second by Stephen Lieberman to table this item in order to give DAG Cordoma the opportunity to negotiate a Consent Order. **Motion passed 6-0.**

6. **American Academy of Ophthalmology** - Wishes to maintain an active dialogue with the Board. Would like for the New Jersey Board of Pharmacy to adopt USP 797 guidance for sterile compounds. Also is requesting review of potential or current restrictions on office use where a patient name is not always available.

Chair Direct: Wishes to maintain an active dialogue with the Board: the Board is willing to establish an open dialog with the Academy.

Would like for the New Jersey Board of Pharmacy to adopt USP 797 guidance for sterile compounds: are included in the new guidelines of proposed compounding regulations which will be published and available to review on the Board of Pharmacy website.

Requesting review of potential or current restrictions on office use where a patient name is not always available: are included in the new guidelines of proposed compounding regulations which will be published and available to review on the Board of Pharmacy website.

7. Rules and Regulation draft N.J.A.C. 13:39-5.8 (b)(12) Assorted stock of prescriptions containers and child safety closure caps that meet...

This item was added to the agenda late.

Rachel Glasgow presented the draft to the Board. The Rules and Regulation Committee has agreed on the draft and would like the Board's approval.

Thomas Bender moved, seconded by Margherita Cardello to approve language as proposed. **Motion passed 6-0.**

VII. MITIGATION/HEARING REQUEST

1. Mary Ann C. Van Pelt, RPIC - Deborah Heart & Lung Center Pharmacy, Browns Mills

Thomas Bender moved, seconded by Richard Palombo to remove the citation for violation of N.J.A.C. 13:45H-5.7. **Motion passed 6-0.**

2. David Kishna, RPIC - Enclara Health, West Deptford

Thomas Bender moved, seconded by Mahesh Shah, to remove the citation for violation of N.J.S.A. 45H:5.7. **Motion passed 6-0.**

3. Byron V. Barahona, RPIC - Continental Drugs, West New York

Stephen Lieberman moved, seconded by Thomas Bender to deny mitigation of the citation for violation of N.J.A.C. 13:39-7.19(b)9(i). **Motion passed 6-0.**

4. Henry Gialanella, RPIC - Andover Pharmacy, Andover

Thomas Bender moved, seconded by Richard Palombo for the Board office to obtain additional information on how Mr. Gialanella was able to prepare the DEA 106 report without the most recent inventory report being available. **Motion passed 6-0.**

5. Shrey Patel, RPIC - Walgreens Pharmacy, Perth Amboy

Richard Palombo moved, seconded by Margherita Cardello to remove the citations for

violations of N.J.A.C. 13:39- 6.15(d) and N.J.S.A 45:14-80(d) for the technician.
Thomas Bender was recused due to his affiliation with Walgreens. **Motion passed 5-0.**

6. Tonja Watson, RPIC - Walgreens Pharmacy, Somerset

Richard Palombo moved, seconded by Margherita Cardello to remove the citations for the violations of 21 CFR1301.21 and 21 CFR1301.44B . Thomas Bender was recused due to his affiliation with Walgreens. **Motion passed 6-0.**

VIII. INFORMATIONAL

1. Emily Jerry Foundation - Issues technician regulation scorecards for each state based on the state's requirements for technicians

The Board accepted this as informational.

IX. COMMITTEE REPORTS

Rules and Regulations

To-do list updated and re-prioritized

- Remote processing, and technology are the priority
- CII changes - list of changes that pharmacist can and can not make(Jodi Krugman, DAG will follow up with additional information)
- Committee would like a definition of compounding provided by the Board
- Proposed changes in the regulations for technicians duties published on 2/4/13
- Proposed language changes for USP 671 was approved by Board vote
- Compounding regulations will be published on March 4, 2013 with a 30 day comment period

Thomas Bender participated in Ernest Mario School of Pharmacy - Rutgers University ACPE re-accreditation process.

Tom indicated that his observations show that the Pharmacy school at Rutgers is in great shape. The quality of students and the curriculum is outstanding. They are, or will soon be offering dual degree programs: PharmD/PhD, PharmD/MD, PharmD/MPA, PharmD/MBA and PharmD/JD. There is also a \$30 million building expansion, and a good working relationship between professors and students. Overall high praises for the Pharmacy school from the Rutgers administration.

M. Westenberger gave an update on the Enforcement Bureau digital conversion program, it is going well and should be on line within two to three months.

X. APPROVAL OF MINUTES

Richard Palombo moved, seconded by Stephen Lieberman to approve January 23, 2013 Open Session Minutes as amended.

XI. ADJOURNMENT

At 11:13 am Richard Palombo moved, seconded by Stephen Lieberman to adjourn public Session and moved into Executive Session for review of 15 Complaints, 5 Old Business Items, 4 New Business Items, the Secretary's Report and Recommendation on Retail and Institutional Permits, the Secretary's Report and Recommendation on Inspection Reports, and approval of the January 23, 2013 Executive Session Minutes.