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BOARD OF PHARMACY OPEN SESSION MINUTES MONMOUTH CONFERENCE ROOM, 7TH FLOOR APRIL 24, 2013

I. CALL TO ORDER

The Open Meeting of the New Jersey Board Of Pharmacy was called to order by the Board Vice President Thomas Bender in the Monmouth Conference Room at 124 Halsey Street, Newark, New Jersey on April 24, 2013, at 9:15 a.m. All members were duly notified of the time, place and all pertinent materials were provided to members.

II. SUNSHINE LAW ANNOUNCEMENT

Vice President Thomas Bender, read a statement that the newspapers and appropriate elected officials had been notified of the meeting according to the requirements of Open Public Meetings Act N.J.S.A., Chapter 231, PL 1975,C.10:4-8

III. ROLL CALL

Edward G. McGinley, R.Ph.
Thomas Bender, R.Ph.
Margherita Cardello, R.Ph.
Marc Sturgill, R. Ph.
Richard Palombo, R.Ph.
Mahesh Shah, R.Ph.
Stephen Lieberman, R.Ph.

President late arrival 9:50 a.m.
Vice President
Late Arrival 9:25 a.m.

OTHERS IN ATTENDANCE

Anthony Rubinaccio
Linda Brodie
Matthew Wetzel
Megan Cordoma
Debra Levine
Maryann Sheehan

Rachel Glasgow

Executive Director
Customer Service Rep.
Government Rep.
Deputy Attorney General
Deputy Attorney General
Deputy Director, Division of
Consumer Affairs
Regulatory Analyst

The Executive Director reported for the month of March, \$40,500 was collected in fines and penalties. The following permit, licenses, and registrations were issued during the month of March :

- Technicians -159
- Pharmacists - 31 (14 by examination / score transfer and 17 by reciprocity)
- Out-of- state pharmacies - 15
- In-state-pharmacies - 3
- Pharmacists receiving immunization approval -6
- Interns (foreign graduates) - 8

V. OLD BUSINESS

1. Orders Filed
 - a) **Denise Roman 3/14**
 - b) **MedPrep 3/15**
 - c) **Alfredo Balleras, Jr. 3/21**
 - d) **MedPrep 3/22**
 - e) **Dia Woodford 3/25**
 - f) **Srinivasa Raju 3/25**
 - g) **Antoinette Wallace 3/25**
 - h) **MedPrep 4/5**

2. Compounding Regulations Responses

Compounding regulations promulgated twenty responses. There is a motion to adopt regulations with a minor change related to flooring. Flooring does not have to be vinyl. Marc Sturgill moved, seconded by Richard Palombo to adopt the regulations and incorporate the minor flooring change. **Motion passed 6-0.**

VI. NEW BUSINESS

1. Kathleen Gialanella, Esq. Requesting reinstatement for her client, **Thomas Gates, R.P.**

In accordance with his Consent Order filled October 13, 2009 his license was suspended for three years for theft, he must complete an ethics course, continue with his enrollment of NJPAP and comply with all directives, supply the Board with resolution of any criminal charges, and appear before the Board to discuss his readiness to reenter the practice, before he can be reinstated.

Based on recommendations from NJPAP and others Richard Palombo moved, second by Marc Sturgill to schedule Mr. Gates for an Investigative Inquiry. **Motion passed 6-0.**

2. **Mark Tyrell, R.P.** - Requesting reinstatement/modification of his Consent Order

Mr. Tyrell is requesting the Board change his status from suspension to inactive to allow him to find work outside the profession of pharmacy.

Richard Palombo moved, seconded by Stephen Lieberman to grant Mr. Tyrell's petition via Consent Order. He will have to follow all terms set in the Order including an appearance before the Board if he ever decides to change the status again. **Motion passed 6-0.**

3. Pamela Mandel, Esq. is requesting reinstatement for her client, **Michael Stavitski, R.P.**

Mr. Stavitski license was revoked on March 14, 2002 for health care claims fraud. Richard Palombo moved, seconded by Margherita Cardello motioned to deny request for reinstatement at this time due to his egregious conduct and non-response to the POD issued 12/12/03. **Motion passed 6-0.**

4. **Alan Kay, R.Ph.** - Request for modification of Consent Order

The Board reviewed all documentation received. Marc Sturgill moved, seconded by Margherita Cardello, that before the Board offers a decision Mr. Kay is to complete item number one of his Consent Order. Thomas Bender was recused due to his affiliation with Walgreens. **Motion passed 6-0.**

VII. MITIGATION/HEARING REQUEST

1. **Aarti Shah, RPIC** - Rite Aid pharmacy Department # 1670, Peth Amboy, NJ

Marc Sturgill moved, seconded Mahesh Shah by to mitigate the cite N.J.A.C. 13:39-7.19(b)2 for telephone number of patient not entered into patient profile system. Margherita Cardello was recused due to her affiliation with Rite Aid. **Motion passed 6-0.**

2. **Avelino Avelenda, RPIC** - Broadway Continental Drugs, North Bergen, NJ

Marc Sturgill moved, seconded by Stephen Lieberman to deny mitigation request for cite N.J.A.C. 13:39-7.19(b)9(i) for allergies, idiosyncracies, and chronic conditions not entered into patient profile system. **Motion passed 7-0.**

3. **Crystal Clark, RPIC** - Newton Pharmacy, Newton, NJ

Thomas Bender moved, seconded by Richard Palombo to deny mitigation request for cite N.J.A.C. 13:45H-5.5(a) and N.J.A.C. 13:45H-5.7 for biennial CDS inventory not being conducted/ available. **Motion passed 7-0.**

4. **Awad Ibrahim, RPIC** - University Pharmacy & Surgical, New Brunswick, NJ

Richard Palombo moved, seconded by Marc Sturgill to remove cite N.J.A.C. 13:39-7.12(a)12 for prescription label “use by” deficiency because there were no violation.
Motion passed 7-0.

5. **George Ruuloj, RPIC** - Bell Pharmacy, Edison, NJ

Chair Direct: The mitigation request is being tabled until there is proof that a compounding central fill application has been received.

VIII. INFORMATIONAL

Richard Palombo moved, second by Thomas Bender to amend Open Minutes of January 23, section VIII, from Independence Pharmacists Association (IPA) to Independent Pharmacy Alliance (IPA). **Motion passed 7-0.**

IX. COMMITTEE REPORTS

X. APPROVAL OF MINUTES

Richard Palombo move seconded by Stephen Lieberman, to approve March 27, 2013 Open Session Minutes as amended.

XI. REVIEW OF MEDPREP

The Board reviewed the April 19, 2013 Order and submissions from the Attorney General and MedPrep regarding supplement action that Order. At 11:05 a.m. Richard Palombo moved, seconded by Stephen Lieberman to go into executive session for deliberations and advice of counsel. **Motion passed 6-0**

At 3:44 Richard Palombo moved, seconded by Marc Sturgill to go back into open session.

DAG Megan Cordoma read the Board’s Motion into the record: The Attorney General made application to supplement the Board's Order entered verbally on the record on April 12th and subsequently by written Order on April 19th.

The application sought clarification on fourteen separate points. Respondent submitted a response agreeing to the vast majority of these points.

Having reviewed the committee's order, materials submitted by the parties, and all of the transcripts and evidence that was entered on the record in this matter, the Board ratifies, in essence, the Committee's Order and makes the following clarifications:

The Board would like to clarify the Committee's order to limit the prior pharmacist in charge to duties that do not include managing or supervising other pharmacists.

If he passes all training required as outlined in the Order, he should be able to prepare sterile compounds in the cleanroom as a staff pharmacist in addition to other pharmacist responsibilities.

Furthermore, we will require affidavits from the new pharmacist in charge, cleanroom supervising pharmacists and owner, that they understand the new role for the prior pharmacist in charge.

Med Prep has submitted the credentials of Nancy Mac Elvane as the proposed new RPIC to the Board for approval. The Board notes that she has an impressive resume and approves her as RPIC.

The new RPIC shall not report to the former RPIC. Should an individual other than Lou Diorio, R.Ph., serve as the site monitor, the monitor, LTD, shall submit that person's credentials to the Board in advance for its approval.

Med Prep has submitted to the Board the requisite paperwork regarding the remodeling of the cleanroom, to include a new pass-through. Inspector Tony Qi preliminarily inspected the pass-through.

The pass-through is approved for use in compounding products for fulfillment of customer orders, provided that all staff has been trained in the appropriate way to use it and the Policies and Procedures Manual is amended to include appropriate, training, cleaning, sanitizing and maintenance procedures for the pass-through. The Board reached that conclusion after review of all required documentation regarding the pass-through.

Med Prep shall be required to adhere to the entire Med Prep Policies and Procedures Manual prepared by LDT Health Solutions, Inc.

Batch size shall be limited to five-hundred units. Any increases in size of compounding batches above five-hundred units shall be subjected to Board approval following validation by the completion of a media fill process under the challenging conditions in a dynamic environment using tryptic soy media incubated under USF 71 conditions to show that the can be conducted under control.

The Board has determined not to amend the Committee's Order regarding item number eight in the Attorney General's application to supplement. The Board considers syringes to a low risk manipulation. There has been no evidence of contamination in syringe products recalled from Med Prep.

Compounding operations shall be limited to one shift of personnel per day, five days per week. A shift shall consist of the same number of hours per day a shift was comprised of prior to the shut down.

No recall products shall be distributed. Only product compounded after the Board approves the reopening shall be distributed from Med Prep.

Med Prep shall retain units of product from each and every batch of controlled sterile product for a period of thirty days beyond the use by date and inspect those retained units for visible contamination at two week intervals, for an minimum of six months and until further order of the Board.

The Board notes, for the record, that we do have the authority to inspect the pharmacy at any time.

Consequences of any significant failure to honor the terms and conditions set by the Board as set forth in the Order, shall result in the immediate cessation of compounding operations and an opportunity afforded to show cause why the permit to operate a pharmacy should not be revoked or suspended forthwith.

Further, the Board amends the Committee's Order to reflect MedPrep's agreement to run sterility tests on a sample of every batch of drug produced and to refrain from shipping to out-of-state hospital pharmacies until they have a valid central fill agreement approved by the Board.

Finally, in all instances where the Order requires Board approval, the Board authorizes the Board President or a committee of the Board, to decide on the Board's behalf if time is of the essence.

The Board has also reviewed and considered the monitoring reports submitted by LDT. And here finds that the Board cannot approve Med Prep resuming operation until it receives written documentation from LDT that all employees who will engage in packaging, labeling and compounding, are trained pursuant to numbered paragraph 4 in the Order .

Employees classified as labeler, pharmacist, quality control personnel and technicians, are included within this training requirement.

Finally, Med Prep represents that it will not begin to fill customer orders for IV bags until it has successfully demonstrated completion of production simulation under the most challenging conditions in a dynamic environment and has received permission from the Board in writing to resume this practice.

Richard Palombo moved, seconded by Marc Sturgill to accept motion, as read by the DAG. **Motion passed 6-0**

XI11. ADJOURNMENT

At 11:12 a.m. Thomas Bender moved, seconded by Mahesh Shah, to adjourn Public Session and move into Executive Session for review of 8 Complaints, 2 Old Business Items, 7 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 March 27, 2013 Executive Session Minutes.