

**NEW JERSEY STATE BOARD OF PHARMACY
OPEN SESSION MINUTES
FEBRUARY 27, 2008**

I. CALL TO ORDER

The Open Meeting of the New Jersey Board of Pharmacy was called to order by Board President Edward McGinley in the Somerset Room, 6th Floor at 124 Halsey Street, Newark, New Jersey on February 27, 2008 at 9:15 a.m. All members were duly notified of the time and place and all pertinent materials were provided to the members.

II. SUNSHINE LAW ANNOUNCEMENT

Mr. Edward McGinley, President read a statement to the effect that the newspapers and appropriate elected officials had been notified of the meeting according to the requirement of the Open 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
Pamela Allen, R.Ph.
Peter Halecky, R.Ph.
Margherita Lafragola, R.Ph.
Elvy T. Paiva, R.Ph. Left at 3:20 pm
Marc Sturgill, R.Ph.
Richard Palombo, R.Ph.

OTHERS IN ATTENDANCE

Joanne Boyer, R.Ph. Executive Director
Marianne Greenwald, Esq. Deputy Attorney General

EXCUSED

Jennifer DeVenio Government Member
Axel Miranda Public Member

IV. UPDATE BY EXECUTIVE DIRECTOR

N/A

V. CONTINUING EDUCATION REPORT

N/A

VI. OLD BUSINESS

1) Asbury Park Press – Reporting of indictments against Barbara Ann and Roy Pesciotta by Ocean County Prosecutor

The Chair directs that DAG Marianne Greenwald follow up with any convictions as a result of the indictments for potential additional action by the Board.

2) Jay Stuman, Manager, Pharmacy Operations, Baxter Healthcare, McGaw Park, IL – Follow-up correspondence regarding their request for a special permit for Baxter's Renal Dialysis Program This matter was last before the

Board on 9/26/07, at which time the Board requested additional information within 30 days. A letter was sent to Mr. Stuman on 10/16/07. It is to be noted that date on the Baxter letter is "November 16, 2007". This letter was received in the Board office on January 29, 2008 after repeated calls for the information.

At 10:10 am Pamela Allen moved, seconded by Thomas Bender to move into Executive Session for advice of counsel in this matter. The motion passed unanimously.

At 10:53 am Peter Halecky moved, seconded by Margherita LaFragola to move back into Open Session. The motion passed unanimously.

Pamela Allen moved, seconded by Peter Halecky to approve Baxter's request for a specialized pharmacy permit as allowed in NJAC 13:39 – 4.15 pending the submission of the following information:

- a) an updated schematic of the proposed permitted area which will show the warehouse area, the caged area and the pharmacist's office
- b) a copy of the agreement with Cardinal which spells out their business arrangement
- c) a copy of the consultant agreement with Frank Breve, R.Ph., proposed RPIC, which should include a statement that Mr. Breve performs a 100% review of all new prescriptions
- d) a copy of the policies and procedures manual as noted on page 3 of the June 19, 2007 correspondence to the Board
- e) a copy of the written procedures for the support personnel who pick, process and deliver orders as noted on page 4 of the June 19, 2007 correspondence to the Board and with the following conditions;

- a) the permit is limited to the dispensing of peritoneal dialysis solutions, dialysate solutions & legend devices including bloodlines and peritoneal dialysis tubing and associated disposable connectology
- b) the area of the warehouse housing these items is in a separate, caged area

In regards to the requested waivers of Board regulations in the June 19, 2007 correspondence to the Board, the Board has determined to approve the request of a waiver for the following regulations:

- a) NJAC 13:39 – 4.10(a)
- b) NJAC 13:39 – 4.10c
- c) NJAC 13:39 – 4.14(b)4
- d) NJAC 13:39 – 4.14(b)5
- e) NJAC 13:39 – 4.14.(b)8
- f) NJAC 13:39 – 5.2
- g) NJAC 13:39 – 5.3
- h) NJAC 13:39 – 5.5(a)
- i) NJAC 13:39 – 5.6(a)
- j) NJAC 13:39 – 5.8(a)1, 4 thru13, 15 thru18
- k) NJAC 13:39 – 5.11
- l) NJAC 13:39 – 6.6

The Board determined to deny the request for a waiver of NJAC 13:39 – 5.8(a)3. In addition, the Board has agreed to waive NJAC 13:39 – 7.12. The label provided is acceptable to the Board. The Board determined to approve the request for a waiver of NJAC 13:39 – 4.14(b)3 with the modification that Baxter will store the dialysis solutions within the confines of the caged area. The pharmacy office and the caged area will remain secure from the rest of the building. The request for waivers of NJAC 13:39 – 5.4 & 5.7 are now not applicable since the dispensed items will be in a permitted, caged area.

Any additional requests for waivers will need to be submitted by Baxter to the Board. The motion passed unanimously.

3) Perry Bernocchi, Executive Vice President, Operations, Byram Healthcare, White Plains, NY – Requesting a 90 day extension for submission of Board requested information This matter was last before the Board on 12/12/07

Elvy Paiva was recused since she is a consultant for Byram Healthcare

Marc Sturgill moved, seconded by Richard Palombo to approve Mr. Bernocchi's request for a 90 day extension until 5/11/08. The motion passed unanimously.

VII. NEW BUSINESS

1) Ronald Hyman – Request for reinstatement

Pamela Allen moved, seconded by Richard Palombo to have Mr. Hyman submit the following documentation:

- a) original state of licensure
 - 2) status of Pennsylvania license and any attempts to reinstate license
 - 3) copy of Pennsylvania Board Action
 - 4) proof of completion of 100 hours of community service
 - 5) proof of payment of \$5,000 fine
- The motion passed unanimously.

2) OAG Press Release – Settlement with Medications4Less

The Board accepted this as informational.

3) FDA Warning Letters regarding the compounding and sale of phenylbutazone products issued to:

Stokes Pharmacy, Mt. Laurel, NJ
Wedgewood Pharmacy, Swedesboro, NJ

Elvy Paiva moved, seconded by Peter Halecky to accept this as informational with no further action to be taken at this time since no violations of federal regulations are noted. The motion passed unanimously.

4) Purnima Shah, R.Ph., 50% owner, DeRosa Pharmacy, Newark, NJ – Regarding the ability to have a podiatrist or physician practice within the pharmacy premises

Elvy Paiva moved, seconded by Margherita LaFragola to have Ms. Shah appear before the Board to further explain her proposal. The motion passed unanimously.

5) Michael Segal, RPIC, Chem Rx, South Plainfield, NJ – Requesting approval to maintain same permit number upon transfer of ownership Chem RX has submitted a transfer of ownership application and a remodeling application

Chair directs that Mr. Segal have Chem Rx's legal counsel (Troutman and Sanders) contact DAG Marianne Greenwald for review of information needed for a complete, accurate transfer of ownership application. This is to include a list of employees and what functions they perform.

6) Senate Bill No. 906 – Requires pharmacists to notify consumers when prescribed medications are substituted with generic drugs

Thomas Bender moved, seconded by Elvy Paiva to oppose this proposed Bill since currently generics are acceptable to the majority of the public (>50%), requirement for the dispensing of generics is mandated by managed care (including state & federal programs), 40% of prescriptions are not picked up by the consumer, mail order not being addressed and 18% of all retail prescriptions are obtained via mail order, may lead to negative impact on overall cost of healthcare and there is statute in effect which requires a pharmacist to substitute. The motion passed unanimously.

7) Assembly Bill No. 1934 – Requires electronic recording of purchases of over the counter drugs used to

manufacture methamphetamine

Thomas Bender moved, seconded by Peter Halecky to oppose this proposed Bill since federal regulations allow the manual tracking of purchases. The only advantage would be if there was a common database to track purchases. The motion passed unanimously.

VIII. MITIGATION/ HEARING REQUESTS

1) Jorge Parrales, RPIC, Pharmacy Value, Guttenberg, NJ

This matter is to be rescheduled.

2) Vincent Matthew, RPIC, Holmdel Village Pharmacy, Holmdel, NJ

Thomas Bender moved, seconded by Margherita LaFragola to deny Mr. Matthew's request for mitigation for the \$1,000 fine imposed pursuant to NJAC 8:65 – 5.7. The motion passed unanimously.

3) Dinesh C. Ganatra, RPIC, Walter J. Lewit Drugs, Newark, NJ

Elvy Paiva moved, seconded by Peter Halecky to deny the request for mitigation for the \$300 fine imposed pursuant to NJAC 13:39 – 5.11, the \$200 fine imposed pursuant to NJSA 45:14 – 48(a)10 & NJAC 13:39 – 5.8(a)1 and the \$250 fine imposed pursuant to NJAC 13:39 – 7.12(a). The motion passed unanimously.

IX. COMMITTEE REPORTS

N/A

X. APPROVAL OF MINUTES

1) February 13, 2008

Thomas Bender moved, seconded by Richard Palombo to approve the minutes as amended. The motion passed unanimously.

XI. ADJOURNMENT

At 12:42 pm Elvy Paiva moved, seconded by Margherita LaFragola to move into Executive session for the review of 12 complaints, 2 Old Business item, 4 New Business items, Secretary's Report and Recommendation on Retail and Institutional Permits, Secretary's Report and Recommendation on Inspection Reports, conduct 1 Investigative Inquiry and approval of minutes. The motion passed unanimously.