

**NEW JERSEY STATE BOARD OF PHARMACY
MINUTES OF THE OPEN SESSION
JANUARY 9, 2008**

I. CALL TO ORDER

The Open Meeting of the New Jersey Board of Pharmacy was called to order by Board President Edward McGinley, R.Ph. in the Somerset Room, 6th Floor at 124 Halsey Street, Newark, New Jersey on January 9, 2008 at 9:14 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.
Jennifer DeVenio Government Member(left at 2:30pm)
Margherita Lafragola, R.Ph. (Arrived at 9:20 am)
Elvy T. Paiva, R.Ph.
Marc Sturgill, R.Ph.
Richard Palombo, R.Ph. (Arrived at 10:15 am)

OTHERS IN ATTENDANCE

Joanne Boyer, R.Ph. Executive Director
John Hugelmeyer, Esq. Deputy Attorney General
Megan Cordoma, Esq. Deputy Attorney General

EXCUSED

Peter Halecky, R.Ph.
Axel Miranda Public Member

IV. UPDATE BY EXECUTIVE DIRECTOR

The Executive Director announced that \$27,950.00 was collected in fines and penalties during December, 2007. There were 33 pharmacists licensed during the month of December, 2007. Six by reciprocity and 27 by examination/score transfer. There were 11 pharmacy permits issued during the month of December, 2007. These were issued as the result of transfer of ownership or new pharmacies opening.

Beginning in 2008, the New Jersey Board of Pharmacy will discontinue printing and mailing the quarterly newsletter and instead distribute the newsletter electronically. Now, each time a new issue is published, individuals who subscribe to the notification listing will receive an e-mail notification containing a link to the current issue. Individuals may subscribe to the notification listing by going to:
<http://www.nabp.net/indexnjbop.asp>. Current and past issues of the Board's newsletter may be viewed at this website. All active, licensed pharmacists will be receiving a notice from the Board regarding this change. As new pharmacists are licensed, they will receive a notification of the process for accessing the newsletters. The Executive Director has requested that the Division post the notice sent to pharmacists and the link to the website

on the Board's website (www.njconsumeraffairs.gov/medical/pharmacy.htm)

The Division has not yet completed the online pharmacy technician registration process. Originally, all technicians were to be registered by March 3, 2008. The Division will be requesting an extension to the time frame in which all technicians must be registered due to this delay. Once this process is completed a notice will be sent to all pharmacies and information will be posted on the Board's website.

Senate Bill No. 1604 was signed into law by the Governor on January 4, 2007. This law establishes the Prescription Drug Monitoring Program in the Division of Consumer Affairs and provides the Division with authority over registration and control of controlled dangerous substances. Also included is the approval to order schedule II CDS via an electronic form, and the provision that New Jersey Prescription Blanks for each prescriber or healthcare facility be numbered consecutively and include the National Provider Number (NPI) if the prescriber of healthcare facility has such a number. The Prescription Drug Monitoring portion of the law takes effect on the first day of the 19th month after the date of enactment, section 22, which deals with the New Jersey Prescription Blanks and NPI number remain inoperative until May 23, 2008. All other sections of the law took effect upon enactment.

V. CONTINUING EDUCATION REPORT

N/A

VI. OLD BUSINESS

N/A

VII. NEW BUSINESS

1) L.D. King, Executive Director, International Academy of Compounding Pharmacists (IACP) – Correspondence with FDA regarding compounding

The Board accepted this as an FYI.

2) Manuprasad Parikh – Request for reinstatement

Thomas Bender moved, seconded by Jennifer DeVenio to schedule Mr. Parikh for an Investigative Inquiry. Mr. Parikh is to provide the Board 16 additional continuing education credits to meet the requirements of NJAC 13:39 – 3A.1. The motion passed unanimously.

3) Lisa Banks, BS, PharmD, CGP – Reciprocity candidate requesting a waiver of NJAC 13:39 – 3.2(a)3 Richard Palombo was recused since Ms. Banks contacted Mr. Palombo regarding this matter.

Pamela Allen moved, seconded by Elvy Paiva to deny Ms. Banks's request for a waiver of the internship requirement as stated in NJAC 13:39 – 3.2(a)3. Ms. Banks may complete a 1,000 hour internship as a long term care consultant under a Board approved preceptor. Upon successful completion of the internship she may then proceed with reciprocating her license to New Jersey. The motion passed unanimously.

4) Donald Winters, R.Ph., MPA, Investigational Drug Pharmacist, Jersey Shore Medical Center, Neptune, NJ – Regarding in hospital use of patient's own medications which have been imported into the United States

Chair directs to notify Mr. Winters that under advice of counsel it is not in the Board's jurisdiction to interpret Federal regulations but cautions him that NJAC 13:39 – 6.2(f)9 requires that the pharmacy and pharmacy personnel are to comply with all Federal and State statutes, rules and regulations governing the practice of pharmacy.

5) Christopher Pozarycki, R.Ph., Director of Pharmacy, Solutions Healthcare, Cranford, NJ – Regarding labeling

of IV solutions for long term care facility

Thomas Bender moved, seconded by Margherita LaFragola that the sample label of the prescription(s) as presented is not in compliance with NJAC 13:39 – 11.10 since it is not a compounded product when it is dispensed from the pharmacy. Solutions Healthcare should work with the facilities Pharmacy & Therapeutics Committee and the Department of Health to resolve this matter. The motion passed unanimously.

6) Elmer Hometown Pharmacy, Lindenwold, NJ and Riverside Drug, Riverside, NJ– Request to maintain same permit number upon transfer of ownership

Pamela Allen moved, seconded by Jennifer DeVenio that once the applications are amended to reflect accurate information that Elmer Hometown Pharmacy and Riverside Drug may retain the same permit numbers upon transfer of ownership. In addition, for violation of NJAC 13:39 – 4.5(a) (operating a pharmacy under an existing permit for more than 60 days following a change in ownership) , the Board determined to fine Ernest Skultety, owner, \$1,000 (\$500 for each pharmacy. The motion passed unanimously.

7) Drug Enforcement Agency Final Rule published 11/19/07, effective 12/19/07 – "Issuance of Multiple Prescriptions for Schedule II Controlled Substances"

The Board accepted this as informational and makes note that since the New Jersey Controlled Dangerous Substances regulations (specifically NJAC 8:65 – 7.5(a)) are more restrictive than this new final DEA rule that the New Jersey regulation is the one that must be followed. NJAC 8:65 – 7.5(a) states in part that all prescriptions for controlled substances, regardless of schedules, shall be presented to the pharmacist for filling within 30 days after the date when issued. This issue was addressed in the January, 2008 issue of the New Jersey Board of Pharmacy Newsletter. This newsletter may be reviewed at www.nabp.net/indexnjbop.sp.

Elvy Paiva moved, seconded by Richard Palombo to forward this matter to the Rules & Regs Committee of the Board for potential changes to the state CDS regulations. The motion passed unanimously.

8) Official Delegate Certificate and Travel Grant Program for NABP's 104th Annual Meeting, May 17 – 20, 2008, Baltimore, MD

Pamela Allen moved, seconded by Richard Palombo to designate Edward McGinley as the official voting delegate at the NABP Annual Meeting to be held May 17 – 20, 2008. Elvy Paiva and Thomas Bender were designated as the 1st and 2nd alternate delegates respectively. The motion passed unanimously.

9) Erik J. Heikkenen, Senior Manager Licensure & Certification, Coram, Denver, Co. – Agreement of Merger between Apria and Coram

Elvy Paiva moved, seconded by Thomas Bender that this is not a change of ownership as defined in NJAC 13:39 – 4.5(a) but does qualify as a change of stock ownership of a publicly traded corporation as stated in NJAC 13:39 – 4.6 and accept this correspondence as the required affidavit. The motion passed unanimously.

10) Amit Datwani, R.Ph./Owner, Professional Prescription Center, East Orange, NJ – Request to maintain same permit number upon transfer of ownership

Pamela Allen moved, seconded by Richard Palombo to approve the request to allow Professional Prescription Center to maintain the same permit number upon transfer of ownership. The motion passed unanimously.

11) ACPE Standards, adopted 6/20/07, released 10/5/07 and effective 1/1/09, regarding designation of CE activity for pharmacists and technicians

The Board accepted this as informational. A future edition of the Board Newsletter will address the changes in the ACPE standards. Those ACPE continuing education courses/programs ending in "T" will not be accepted by the Board as acceptable continuing education courses/programs for pharmacists. These courses/programs are

intended for pharmacy technicians.

VIII. MITIGATION/ HEARING REQUESTS

1) Veronica T. Vizzi, RPIC, Advantage Pharmacy Solutions, Cherry Hill, NJ

Jennifer DeVenio moved, seconded by Marc Stugill to mitigate the \$1,000 penalty imposed pursuant to NJAC 13:39 – 11.14(b)5. The motion passed unanimously.

2) Vincent A. Procopio, RPIC, Wellness Care Group, Ramsey, NJ

Richard Palombo moved, seconded by Marc Sturgill to deny the request for mitigation of the \$1,500 fine imposed pursuant to NJAC 13:39 – 4.8(a) & (b) and NJAC 13:39 – 4.9. The motion passed unanimously.

3) Anthony Cioce, RPIC, Allwood Pharmacy, Clifton, NJ

Thomas Bender moved, seconded by Elvy Paiva to mitigate the \$500 fine imposed pursuant to NJAC 13:39 – 6.2(f). The motion passed unanimously.

4) Vishal Sood, RPIC, Valdes Drugs & Medical supplies, Union City, NJ

Pamela Allen moved, seconded by Elvy Paiva to mitigate all fines imposed pursuant to inspection report #8-5617-07-863 and issued to Vishal Sood, RPIC. The Board determined to issue the following penalties imposed pursuant to inspection report #8-5617-07-863 to Alfredo Valdes, owner:

NJAC 13:39 –4.5(a) \$250

NJAC 13:39 –4.17(a)&(b), 6.2(f)7, 7.16(c)2&3, 7.18 \$200

NJAC 13:39 –4.17(a)&(b), 7.12(a)10, 7.19(b)6 \$50

NJAC 13:39 –7.12(a)13 \$250

NJAC 8:65 –7.13(b) Warning

The motion passed unanimously.

5) David Krauthem, RPIC, Phormula Pharmacy, Totowa, NJ

Thomas Bender moved, seconded by Richard Palombo to move this matter into Executive Session for advice of counsel. The motion passed unanimously.

Thomas Bender moved, seconded by Elvy Paiva to deny the request for mitigation of all fines imposed pursuant to Inspection #8-5037-07-782. In addition, Phormula Pharmacy is to be re-inspected to ensure that they are now in compliance. The motion passed unanimously.

At 2:43 pm, Pamela Allen moved, seconded by Richard Palombo to move back into Executive Session.

6) Gregory Hochstein, RPIC, Safe Drug Company, Fairview, NJ

Thomas Bender moved, seconded by Richard Palombo to mitigate the \$250 fine imposed pursuant to NJAC 13:39 – 4.9(a)3. The motion passed unanimously.

7) Karen Spano, RPIC, Bioscrip Infusion Services, Morris Plains, NJ

Thomas Bender moved, seconded by Richard Palombo to deny the request for mitigation of the \$500 fine imposed pursuant to NJAC 13:39 – 11.17(g). The motion passed unanimously.

Elvy Paiva moved, seconded by Thomas Bender to schedule Ms. Spano for an appearance before the Board to discuss her request for a waiver of NJAC 13:39 – 11.17(g). The motion passed unanimously.

IX. COMMITTEE REPORTS

1) Quality Event Project

Margherita LaFragola, Committee Chairperson, reported that the Committee had met via teleconference on 12/24/07 and 12/31/07. An excel spreadsheet was formulated to be utilized for gathering information from the consumer complaints received by the Board. Board members are to review the proposed spreadsheet and provide feedback to Ms. LaFragola. It was suggested that the Committee also gather information as to how the problem identified in the consumer complaint was rectified at the pharmacy.

X. APPROVAL OF MINUTES

1) December 12, 2007

Margherita LaFragola moved, seconded by Jennifer DeVenio to approve the minutes as amended. The motion passed unanimously.

XI. ADJOURNMENT

At 11:42 am Elvy Paiva moved, seconded by Jennifer DeVenio to move into Executive session for the review of 7 complaints, 2 Old Business items, 11 New Business items, Secretary's Report and Recommendation on Retail and Institutional Permits, Secretary's Report and Recommendation on Inspection Reports, and approval of minutes. The motion passed unanimously.