

FINAL

**NEW JERSEY STATE BOARD OF PHARMACY
MINUTES OF THE OPEN SESSION OF NOVEMBER 5, 2003**

I. CALL TO ORDER

The Open meeting of the New Jersey State Board of Pharmacy was called to order by Board President Edward McGinley in the Essex Room, 7th Floor at 124 Halsey Street, Newark, New Jersey on November 5, 2003 at 9:05 a.m. All members were duly notified of the time and place and all pertinent materials had been provided..

II. SUNSHINE LAW ANNOUNCEMENT

Edward McGinley read a statement that 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.10:4-18.

III. ROLL CALL

Present:

Edward McGinley, R.Ph. President
Edith Micale, R.Ph. Treasurer
Anthony Alexander R.Ph. (Arrived at 12:20 p.m.)
Pamela Allen, R. Ph.
Mona Doyle Public Member
Sophie Heymann Public Member
Richard Palombo, R.Ph.

OTHERS IN ATTENDANCE:

Marianne Greenwald Deputy Attorney General
Joanne Boyer, R.Ph. Executive Director
Shonnette Messiah Principal Clerk Stenographer
Kiran Shamlall Principal Clerk Stenographer

EXCUSED:

Ira Katz, R.Ph.
Robert Kowalski, R.Ph.

IV.1 APPROVAL OF DRAFT MINUTES OF OCTOBER 8, 2003

Sophie Heymann moved, seconded by Edith Micale, to accept the draft minutes of October 8, 2003 as amended. The motion passed unanimously.

IV.2 APPROVAL OF FINAL MINUTES OF SEPTEMBER 24, 2003

Mona Doyle moved, seconded by Edith Micale, to accept the minutes of September 24, 2003 as amended. The motion passed unanimously.

IV.3 APPROVAL OF FINAL MINUTES OF SEPTEMBER 10, 2003

Sophie Heymann moved, seconded by Edith Micale, to accept the minutes of September 10, 2003 as amended. The motion passed unanimously.

V. SECRETARY'S REPORT AND RECOMMENDATION FOR REGISTRATION BY RECIPROCITY, EXAMINATION AND GRADE TRANSFER

Sophie Heymann moved, seconded by Edith Micale, to accept the Secretary's Report and Recommendation for Registration by Reciprocity, Examination and Grade Transfer. The motion passed unanimously.

VI. CONTINUING EDUCATION REPORT

Edith Micale moved, seconded by Sophie Heymann to approve Continuing Education request presented for review for Rutgers University, Student Health Services, Critical Issues for College Students: Understanding the Impact on Their Health. This item will be further reviewed for the possibility of partial credit. The motion passed unanimously.

VII. VIOLATIONS PAID FOR THE MONTH OF OCTOBER

Sophie Heymann moved, seconded by Mona Doyle to approve the report of Violations paid for the month of October. The total amount paid was \$29,125.00. The motion passed unanimously.

VIII. CONFERENCES

(1) NABP 100th Annual Meeting and Centennial Celebration Poster Session, April 24-27, 2004, Chicago, Ill

Edith Micale, Richard Palombo, Anthony Alexander, Sophie Heymann, Edward McGinley, and Joanne Boyer expressed desire to attend the NABP 100th Annual Meeting. There was also discussion about how the board could successfully participate in the poster session. Since there are so many members interested in attending this conference, it will be important to seek early funding approval from the Division. The Chair asked that the conference information be forwarded to Deputy Anthony Miragliotta.

(2) NABP 2004 MPJE Time and Task Schedule

2a. Item-writing workshop, January 9-11, 2004, Rosemont, Ill

Joanne Boyer will be attending the January 9-11, 2004 writing workshop accompanied by a designated Board member. Pam Allen expressed interest in attending meeting if her schedule permits this.

2b. State-specific Review Meeting #1, January 23-25, 2004, Phoenix/Scottsdale, Ar.

Joanne Boyer will be attending the January 23-25, 2004 meeting accompanied by a designated Board member. Richard Palombo expressed interest in attending meeting. Ira Katz will also be asked if he has an interest in attending.

2c. State-specific Review Meeting #2, August 13-15, 2004, Rosemont, Ill.

This item has been re-agendized to the next meeting to confirm Board member attendance.

IX. OLD BUSINESS

(1) Consumer's Report Article

October, 2003, Volume 68, No.10, "Drug Stores"

The Board commented briefly on the article and it was accepted as an FYI.

(2) NABP Report - Standards for Electronic Prescribing (Page 2 missing when originally distributed.)

The Board requested that the Executive Director provide Tony Miragliotta with a copy of this report.

X. NEW BUSINESS

(1) NJ Association of Long Term Care Pharmacy Providers Re: the Board was asked to address the need for a return drug policy for Assisted Living Facilities similar to the one allowed for Long Term Care Facilities by Robert Fusco.

After discussion Sophie Heymann moved, seconded by Mona Doyle to adopt a policy that pursuant to NJAC 13:39-9.3(b), a pharmacy servicing assisted living facilities (ALF) may accept for return into active drug stock unit dose medications appropriately labeled, stored and secured in compliance with NJAC13:39-9.15, from those ALF's that are staffed with a registered professional nurse or qualified persons under the nurse's immediate supervision for the administration of medications to the patient.

This policy will be put in place until a regulation can be written. The motion passed unanimously.

(2)MEDCO Health-John Sisto, Director of Regulatory Affairs- -Proposal for dispensing OTC medications

After some discussion, the Board advised Mr. Sisto that the matter needs to be further reviewed and it was then moved to the Executive Session for advice of counsel.

XI. COMMITTEE REPORTS

(1) Technology Committee

The Technology Committee comprised of Pamela Allen, Mona Doyle, Edward McGinley and Joanne Boyer met on 10/22/03 and formulated a letter to Cardinal Health regarding additional information needed on the Pyxis Envoy Medication System. The Pyxis Envoy medication system must also meet Department of Health automated system regulations.

(2) CQI Committee

Richard Palombo presented to the Board a proposed concept of an in-house reporting system in which pharmacists report their own errors without being punished unless their error results in harm to a patient(s). As part of the proposal a sub-committee would be formed to review the reported errors. Richard Palombo stated that Ira Katz felt that the requirements for procedure manuals should be more specific.

Edith Micale requested that the DAG review the proposed plan from a legal point of view in order to move forward with the plan.

This item is to be placed on the next agenda.

XII. FYI

(1) DEA - "Control Substances Registration and Reregistration Application Fees"

New fees to be effective 12/1/03.

(2) NABP - Notification of DEA Rule titled - Implementation of the Methamphetamine Anti-proliferation Act;

Thresholds for Retailers and for Distributors Required to Submit Reports under 21 U.S.C. 830(b)(3)"Mail Order Reports; Changes to Mail Order Reporting Requirements"

This item has been considered as an FYI.

(3) ACCP News Release - Availability of "Pharmacotherapy Self-Assessment Program", Fourth Edition

This item has been considered as an FYI.

(4) Statement of Janet Heinrich, Director, Health Care - Public Health Issues, "Prescription Drugs, State and Federal Oversight of Drug Compounding by Pharmacies"

(5) Statement by Steven K. Galson, MD, MPH, Acting Director Center for Drug Evaluation and Research, FDA - Before Senate Committee Hearing on " Federal and State Role in Pharmacy Compounding and Reconstitution: Exploring the Right Mix to Protect Patients"

Edith Micale requested that the compounding issues referred to in items 4 and 5 be presented for discussion in the next meeting.

The Board President, Edward McGinley congratulated Richard Palombo on being re-elected as Mayor of Beesley's Point, NJ. The Board congratulated Sophie Heymann on her re-election to the Closter Counsel.

XIII. ADJOURNMENT

At 11:27 a.m., Edith Micale moved and seconded by Richard Palombo to move into the Executive session to review (35) inspection reports (15 for Oct. 8 and 20 for Nov. 5.), (11) IV permits for Nov. 5, and (21) complaints. The motion passed unanimously.

At 12:55 p.m., Mona Doyle moved and seconded by Richard Palombo to move back to the open session to review the last 2 CE reports. The motion passed unanimously.

In addition, the Board reviewed a notice of proposal Sept. 18th in regards to NJBP prescription program. The Board commented that the verbage on page 4176 Section 13:45A-27.3(c) of The New Jersey Register should read as follows:

"A separate NJPB shall be utilized for each prescription written. No other medication shall appear on the prescription." Section (d) shall be omitted entirely. The second line in Section (f) shall include after the word substance "to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intra spinal infusion..." In addition the same shall be included in the third line of section (f) 1. after the word substance. Edith Micale moved, seconded by Edward McGinley to have these amendments reflected on page 4176 Section 13:45A-27.3(c) of the New Jersey Register. The motion passed unanimously.

At 1:05 p.m., Mona Doyle moved and seconded by Anthony Alexander to move back into the Executive session. The motion passed unanimously. At 4:12 p.m. Edward McGinley moved and seconded by Richard Palombo to adjourn the Executive session. The motion passed unanimously.