

FINAL

**NEW JERSEY STATE BOARD OF PHARMACY
MINUTES OF THE OPEN SESSION OF NOVEMBER 19, 2003**

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 Monmouth 7th Floor at 124 Halsey Street, Newark, New Jersey on November 19, 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 (Left at 11:00 a.m.)
Anthony Alexander, R.Ph. (Left at 11:00 a.m.)
Pamela Allen, R.Ph. (Arrived at 9:15 a.m.)
Mona Doyle Public Member (Left at 2:50 p.m.)
Ira Katz, R.Ph.
Robert Kowalski, R.Ph (Left at 3:20 p.m.)
Richard Palombo, R.Ph. (Left at 1:25 p.m.)

OTHERS IN ATTENDANCE:

Marianne Greenwald Deputy Attorney General (Left at 2:50 p.m.)
Joanne Boyer, R.Ph. Executive Director
Shonnette Messiah Principal Clerk Stenographer
Kiran Shamlall Principal Clerk Stenographer

EXCUSED:

Sophie Heymann Public Member

IV. APPROVAL OF MINUTES

(1) DRAFT OF NOVEMBER 5, 2003 MINUTES

Richard Palombo moved, seconded by Mona Doyle, to accept the minutes of November 5, 2003 as amended. The motion passed unanimously.

(2) FINAL OF OCTOBER 8, 2003 MINUTES

Robert Kowalski moved, seconded by Anthony Alexander, to accept the minutes of October 8, 2003 as amended. The motion passed unanimously.

(3) FINAL OF SEPTEMBER 24, 2003 MINUTES

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

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

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

VI. CONFERENCES

(1) ASAP Industry and Technology Issues Conference, January 22-24, 2004, St. Pete Beach, Florida

Edith Micale moved, seconded by Mona Doyle, to ask for approval from the Director's office to allow Anthony Alexander and Joanne Boyer to attend the American Society for Automation in Pharmacy conference from January 22-24, 2004. The motion passed unanimously.

(2) NABP 2004 MPJE Time and Task Schedule

Reagendized from November 5, 2003 meeting

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

Joanne Boyer and Pamela Allen confirmed that they will be attending the writing workshop being held January 9-11, 2004 at Rosemont, Ill.

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

Joanne Boyer and Ira Katz confirmed that they will be attending the State-specific Review Meeting #1, January 23-25, Phoenix/Scottsdale, Ar.

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

This item will be re-visited in May of 2004.

(3) NABP District II Report/Feedback

Anthony Alexander, Edith Micale, Richard Palombo, and Edward McGinley attended the NABP District II Meeting Oct 19-21 2003 in Richmond, Virginia. The meeting included updates from each of the attending states on legislative, regulatory, and professional issues affecting the practice of pharmacy in their jurisdictions, several timely continuing educations seminars, and AACP and NABP reports including updates from NAPB President Donna Horn, the District II Resolutions Committee, and the District II Nominating Committee. Board Member Alexander was appointed to the District II Resolutions Committee, and Edward McGinley was appointed as an Alternate. All meeting materials will be available in the board of pharmacy office should board \ members wish to review them in detail.

Board member Palombo provided a verbal report on his recent attendance at the District I NABP Meeting. As of January 1, 2004 all District I States will register technicians. NABP will be used as a clearinghouse for technician registration. Rhode Island is now allowing technicians to accept new prescriptions, and no longer has technician ratios. The FDA is willing to work with individual states to pursue reimportation activities.

(4) CAC Conference

Mona Doyle attended the Citizen Advocacy Center Conference, November 13-15 2002 in Arlington VA. Ms. Doyle provided a written report which discussed the theme of the meeting-"Quality Improvement and the Role of Health Oversight Organizations", and a synopsis of the four key topics discussed at the meeting: pain management, quality improvement, communications, and continuing competence.

VIII. OLD BUSINESS

(1) Center Pharmacy - requesting to switch permit from Retail to Institution,

Marianne Greenwald, Deputy Attorney General informed the Board that after discussions with Center Pharmacy in regards to their proposed application to switch their permit from retail to institutional that Center Pharmacy has withdrawn their institutional pharmacy permit application and will continue to operate as a retail permit holder.

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

(3) 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"

These two statements are to be retained for future reference. In addition Edith Micale, Joanne Boyer and Richard Palombo expressed interest in attending a member tour at the USP facility to gain further information on this subject. Copies of USP Chapters 795, 797, and 1075 will be distributed to Board members. Edith Micale suggested that after Board members receive these documents, this issue be re-agenized and a determination made whether to pursue a tour of the USP facility.

(4) CQI Regulations

Richard Palombo moved, seconded by Mona Doyle, to have the proposal forwarded to Maryanne Sheehan and request she put them into regulatory format. The motion passed unanimously.

(5) Reference & Texts

Joanne Boyer spoke to ACPE and was informed that they do not have a recommended list of approved reference texts. The Chair directed that this item be placed on the Enforcement Liaison Committee's agenda.

IX. NEW BUSINESS

(1) Duane Reade - Request for Approval of Pharmacy Kiosk

Duane Reade is requesting approval for installation of a kiosk in a medical facility that will enable a consumer to transmit written prescription via facsimile to a New Jersey registered pharmacy.

The DAG requested this item to be tabled pending review by the Director's Office. The Chair directed the Executive Director to call and send a letter stating that Duane Reade should cease and desist any and all installations of kiosks in the State of New Jersey at this time. This item should also be forwarded to the Board of Medical Examiner's for review.

(2) David H. Schwed, Woodruff's Drugs, Bridgeton, NJ - Formulary Enforcement by Federally Qualified Health Center (FQHC)

Mr. Schwed is inquiring if the above stated needs to be approved by the Board of Pharmacy or through clarification of existing statute from the DOH. Ira Katz moved, seconded by Robert Kowalski to obtain a copy of the formulary agreement the doctor is signing, and a copy of the P&T statement that explains the substitution, process and also ask for clarification as to what happens when a physician writes a non-formulary medication. The motion passed unanimously.

(3) Phillip C. Polillo, M.S., R.Ph., Director of Pharmacy, St. Francis Medical Center, Trenton, NJ - Requesting a waiver from the requirements of N.J.A.C. 13:39 11.11 (a) 3.

St. Francis Medical Center is utilizing the Pyxis MedStation 2000 and Pyxis Intravenous Drug (IV) Tower units and is requesting a waiver from the requirement stated above in regards to Manufacturer's Premixed Drugs and those prepared using ADD-Vantage and Mini-Bag Plus, that are stored in an automated system.

Robert Kowalski moved, seconded by Richard Palombo to approve the waiver as long as the IV solutions are part of an automated system that complies with sub-chapter N.J.A.C 13:39-10. The motion passed unanimously.

(4) Role of Technicians

After the Board members considered the information presented, the Chair directed Richard Palombo to draft a policy with regards to the role of pharmacy technicians as related to who should be excluded in the 2 to 1 ratio. This proposal will be reviewed by the Board and if approved, then forwarded to the Director's office for consideration.

(5) Newsletter Topics

The deadline for submitting newsletter items is the end of November 2003. Topics to be included: Regulations effective 9/15/03 on electronic and facsimile transmitted prescriptions. Summary of C-II prescribing authority. List of approved reference texts. Criminal History Background check over view. Also, extend an invitation for the public to attend open sessions, and USP compounding chapters.

X. COMMITTEE REPORTS

(1) Technology Committee

Review of response from Thomas Kraft, PhD, PE, Director, Product and Regulatory Development, Cardinal Health regarding Pyxis Envoy.

Robert Kowalski moved, seconded by Pamela Allen to advise Cardinal Health it appears that Pyxis Envoy Medication System complies with N.J.A.C. 13:39-10. The system must be inspected and approved by the Board prior to usage. Cardinal Health is to be advised that the Pyxis Envoy Medication System must also meet Department of Health automated system regulations (N.J.A.C. 8:43G-23 et seq.). The motion passed unanimously.

XI. ADJOURNMENT

Robert Kowalski moved, seconded by Richard Palombo to enter into the Executive Session at 11:40 a.m. to review (72) inspection reports for November 19, 2003, (5) Retail IV permits, and (16) complaints. The motion passed unanimously.

Pamela Allen moved, seconded by Edward McGinley to adjourn the Executive Session at 4:10 p.m. The motion passed unanimously.