NEW JERSEY STATE BOARD OF PHARMACY
MINUTES OF THE OPEN SESSION OF SEPTEMBER 8, 2004

DRAFT

I. CALL TO ORDER

The Open meeting of the New Jersey State Board of Pharmacy was called to order by Board President Pamela Allen in the Union Room, 3th Floor at 124 Halsey Street, Newark, New Jersey on September 8, 2004 at 9:45 a.m. All members were duly notified of the time and place and all pertinent materials had been provided.

II. SUNSHINE LAW ANNOUNCEMENT

Pamela Allen 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

Pamela Allen, R.Ph President
Edward McGinley, R.Ph Vice-President
Mona Doyle Public Member (Arrived at 10:00 a.m. & left at 2:50 p.m.)
Sophie Heymann Public Member
Ira Katz, R.Ph
Robert Kowalski, R.Ph Government Member (Left at 3:30 p.m.)
Richard Palombo, R.Ph (Arrived at 9:55 a.m.)

OTHERS IN ATTENDANCE:

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

EXCUSED:

Edith Micale, R.Ph
Anthony Alexander, R.Ph

IV. SECRETARY’S REPORT AND RECOMMENDATION FOR REGISTRATION BY RECIPROCITY, EXAMINATION AND GRADE TRANSFER

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

V. CONTINUING EDUCATION REPORT

Robert Kowalski moved, seconded by Edward McGinley to accept the Continuing Education Report. The motion passed unanimously.

VI. VIOLATIONS PAID FOR THE MONTH OF AUGUST

Edward McGinley moved, seconded by Robert Kowalski to accept the Violations Paid report for the Month of August. The motion passed unanimously.
VII. OLD BUSINESS

(1) In the Matter of Burt Friedman – Notification that Stay Pending Appeal has been granted The DAG updated the Board on the above current status of the Burt Friedman case. She stated that Paul Kenny, State Prosecutor, has filed for an expedited review of the appeal and has requested that the money for the fines be put in escrow until the decision on the appeal rendered.

(2) Medco Health – In regards to CADS Dispensing Area At the 7/28/04 Board Meeting Medco was requested to submit metrics in regards to the error rate that occurs in the CAD area as it is currently staffed.

John Sisto, Medco Representative, forward to the Executive Director a statistical review of the errors related to the manual dispensing process known as CADS. The data was gathered from one year of logs (known as the "Back End Cancels") that are maintained at the Quality Assurance 2 area. The actual logs were also available at the meeting for Board review.

For purposes of reporting to the Board, the errors were manually sorted into four categories: Quantity Errors, Direction Errors, Special Shipping Errors and Other Errors. In addition, each of the errors was evaluated for clinical significance, i.e. those that could have resulted in the patient either receiving the wrong medication or using the medication incorrectly. There were 683 Back End Cancels from second quarter 2003 through first quarter 2004. During this same time period, there were 16,321,329 prescriptions dispensed. Of the 683 total errors, 122 were specific to the Automated Dispensing System and 561 were identified in the manual dispensing area, 32 of which were deemed to be clinically significant. Twenty-nine of the 32 errors involved medications that could be dispensed by a technician in the proposed extension of the automated process.

The above logs do not contain errors that were identified after the patient received their medication. Mr. Sisto will forward these to Joanne Boyer for the Board to review. The

Board also requested that a list of the medications that will, initially, be included and excluded from the proposed technician extension of the automation process be provided to the Bureau of Enforcement Inspector at the time the process is inspected. The medications that are excluded are known as PVSV (Pharmacist Validation System Verification) medications. Mr. Sisto informed the Board that they will notify the Executive Director when they are ready for the inspector. It is anticipated that they will be ready by the end of September or early October.

Richard Palombo left the table and was recused from discussion of this item because of his employment with Medco. are included in the PVSV system as well as those not included in the system. Mr. Sisto informed the Board that they will call the Executive Director by the end of the month to have an inspection.

(3) Ben Thankachan, R.Ph., Director, Professional Services and Government Relations, Wal-Mart – Requesting Board’s opinion on 3 different drive thru scenarios This was reviewed at the 8/11/04 Board Meeting at which time the Board requested information regarding the dispensing process and communicating with the consumer.

Sophie Heymann moved, seconded by Richard Palombo to accept the three scenarios as described by Wal-Mart with the understanding that the security of the medications must be maintained by assuring that all filled prescriptions are kept in the permitted area until dispensed and that the patient’s privacy is maintained throughout the process. In addition, at a minimum, the person receiving the prescription must be able to be visually seen by pharmacy personnel for security purposes. The motion passed with a vote of 6 to 1.

Robert Kowalski moved, seconded by Mona Doyle to indicate that the area(s) in which the prescription is actually received is to be considered as part of the permitted area of the pharmacy or pharmacy department and must meet all security requirements. In addition, a remodeling permit must be filed and approved prior to use. The motion passed with a vote of 6 to 1.

This item is to be forwarded to the Rules and Regulations committee for rule making.

(4) Upcoming Board Meetings-
VIII. NEW BUSINESS

(1) David Schwed, R.Ph., Woodruff's Drugs, Bridgeton, NJ – Communication regarding Medication Therapy Management Services

The Board asked the Executive Director to see if she can find out if there is a preemption as it relates to the contractual rights between the prescription benefit managers (PBM’s) and the payers with regard to the Medication Therapy Management Services to see if the Board can move on with the regulatory process.

(2) CQI Draft regulations- Report by Committee Chair Richard Palombo The Board decided that there is a need of an operational definition of "root cause analysis" which will be researched by the Executive Director. The need to guarantee protection from discovery of the information gathered in a root cause analysis also continues to be a barrier to proceeding with these regulations. Once these issues are researched, the draft will be sent back to the committee.

(3) Home News Tribune Article dated 8/13/04 regarding action taken by the Board in response to a consumer complaint

This item was treated as an FYI.

(4) NABP – Communication regarding importing controlled substances from Canada and other foreign countries

This item will be published in the January newsletter edition.

(5) Executive Director requesting Board opinion regarding status of license transfer of eligible candidates from Florida

Edward McGinley moved, seconded by Robert Kowalski, to allow the reciprocity of any Florida pharmacists who took the NAPLEX exam and who meets all other qualifications. The motion passed with a vote of 5 to 2.

(6) Jace Pharmaceuticals – Regarding marketing project with Edison Pharmacy, Edison, NJ The DAG advised Jace Pharmaceuticals that their request to have co-pays paid by a third party payer is not lawful since it is considered a discount and waiving co-pays is considered to be insurance fraud.

(7) Manish S. Shah – Requesting preliminary approval to have a pharmacy in his home (converted sun porch)

The Board decided that in order to review Mr. Shah’s request to have a retail pharmacy outlet in a residential area, he must receive a zoning approval letter from the town of West Caldwell. In addition, he must obtain a letter from various nursing homes and assisted living homes he will be working with. Once he has received these letters, he is to present them to the Board for approval.

(8) NABP – Communication regarding electronic transmission of prescriptions This item was treated as an FYI.

(9) Selection of Advisory Panel member as noted in section 10 of bill A-2825 Edward McGinley moved, seconded by Mona Doyle to solicit possible applicants for the advisory panel by contacting the professional associations in New Jersey and the Rutgers College of Pharmacy. The candidates will be asked for a letter of interest and a curriculum vitae. In addition, these candidates must be a NJ licensed pharmacist with a minimum of 5 years experience in the practice of pharmacy.

(10) Rebecca Greenberg, MD, R.Ph. – Candidate applying for reinstatement requesting approval of CME credit in place of ACPE courses The Chair directed the Executive Director to send a letter stating that the Board needs detailed information of the course content.
IX. CONFERENCES

(1) 20th Annual NASCA Conference, October 19-23, 2004, San Diego, Ca This item will be forwarded to Edward Tuminello, Enforcement Bureau.

(2) FSMB Educational Workshop Series – Promoting Balance and Consistency in the Regulatory Oversight of Pain, various dates and locations

Edward McGinley moved, seconded by Richard Palombo to have Mona Doyle attend one of the Las Vegas workshops and Joanne Boyer attend the Boston Workshop. The motion passed unanimously.

(3) NABP/AACP District II Meeting, October 21-23, 2004, Chester, WV Information to be distributed at meeting

Richard Palombo, Sophie Heymann, Edward McGinley, Anthony Alexander, Joanne Boyer and Edith Micale will be attending the NABP/AACP District II meeting.

(4) NABP Meeting, November 11-14, 2004

The Board recommended that the DAG, Ira Katz and Edward McGinley attend this meeting. Richard Palombo, who is a member of the NABP Executive Committee, will also be in attendance.

X. COMMITTEE REPORTS

(1) Pharmacy Practice Act – Technicians Workgroup, Chairman Anthony Alexander

A phone conference must be scheduled with the committee which consists of Richard Palombo, Anthony Alexander, Pamela Allen, Edward McGinley, Joanne Boyer and Danielle, the regulatory representative from the Division of Consumer Affairs.

(2) Pharmacy Practice Act – Collaborative Practice Workgroup, Chairman Pamela Allen

A draft of the regulations are to be sent to the BME executive committee. It is anticipated that they will want any background material that was used to draft these regulations.

(3) Pharmacy Practice Act – Immunization Workgroup, Chairman Ira Katz This item was given to the Division of Consumer Affairs regulatory writer to have changes made. These changes will be discussed before the Board at a future meeting prior to presenting them to the BME.

IX. APPROVAL OF MINUTES

(1) DRAFT OF August 11, 2004 MINUTES

Robert Kowalski moved, seconded by Sophie Heymann to accept the draft of the August 11, 2004 minutes as amended. The motion passed unanimously.

XII. ADJOURNMENT

At 2:50 p.m., Edward McGinley moved, seconded by Sophie Heymann to enter into the executive session to review (7) retail and IV permits, (19) inspection reports and (4) complaints. The motion passed unanimously.