

**NEW JERSEY STATE BOARD OF PHARMACY
MINUTES OF OPEN SESSION
December 15, 2004**

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 Morris Room, 6th Floor at 124 Halsey Street, Newark, New Jersey on December 15, 2004 at 9:08 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
Anthony Alexander, R.Ph.
Sophie Heymann Public Member (left at 11:20 a.m.)
Robert Kowalski, R.Ph. Government Member (Left at 3:25 p.m.)
Edith Tortora Micale, R.Ph.
Richard Palombo, R.Ph. (Left at 3:45 p.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:

Ira Katz, R.Ph.
Mona Doyle Public Member

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

Robert Kowalski moved, seconded by Edith T. Micale 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 Anthony Alexander to accept the Continuing Education Report. The motion passed unanimously.

VI. VIOLATIONS PAID FOR THE MONTH OF NOVEMBER

N/A

VII. OLD BUSINESS

1) Definition of Root Cause Analysis

At the 9/8/04 Board Meeting (item VIII 2) it was requested that the Executive Director obtain an operational

definition of Root Cause Analysis as referenced in the Continuous Quality Improvement (CQI) Draft Regulations. Joanne Boyer distributed information from both the VA National Center for Patient Safety and the JCAHO "Framework for a Root Cause Analysis and Action Plan in Response to a Sentinel Event."

Edward McGinley moved, seconded by Richard Palombo the following:

- 1) To determine where the draft regulation are within Consumer Affairs.
- 2) To determine if the Board can obtain legislative support through the Division of Consumer Affairs to protect the CQI information in Retail Pharmacies from discovery.
- 3) To refer this information to the CQI committee along with the information on Root Cause Analysis.
- 4) For the Board members to forward any comments and/or changes to the CQI draft regulations to Richard Palombo.

The motion passed unanimously.

VIII. NEW BUSINESS

- 1) NABP News Release regarding National Drug Advisory Coalition

The Board decided to send this recommendation to the Department of Health. In addition, Robert Kowalski will draft a letter from the Board to the Commissioner of the Department of Health, regarding the Board's recommendation as to pharmaceutical wholesalers. Bob will forward this draft to the Executive Director no later than January 3, 2005 for distribution in the next Board packet.

- 2) Seymour Berson, R.Ph. – Requesting a waiver of NJAC 13:39 – 3A.1(a)

Sophie Heymann moved, seconded by Anthony Alexander to deny Mr. Berson's request to waive the 10 live credits. If Mr. Berson cannot meet the criteria, he has the option of having his license placed on inactive status. The motion passed unanimously.

- 3) Geriscript Pharmacy, Totowa, NJ – Requesting a waiver of NJAC 13:39 – 4.4

Anthony Alexander moved, seconded by Sophie Heymann to deny Geriscript Pharmacy's request for the waiver of transfer of ownership, since it did occur and was different than the initial transfer. The motion passed unanimously.

- 4) Eulena B. Horne – Requesting a waiver of NJAC 13:39 – 3.9(a)1

Sophie Heymann moved, seconded by Edward McGinley to grant the waiver and accept Ms. Horne's experience at Medco Health as it meets the requirements for the practice of pharmacy. The motion passed unanimously.

Richard Palombo was recused due to his affiliation with Medco.

- 5) Philip W. Stern – Requesting a waiver of NJAC 13:39 – 3.9(a)2

Edward McGinley moved, seconded by Anthony Alexander to deny Mr. Stern's request for a waiver because, he has no recent practical pharmacy experience in his previous positions with Organon and Bristol Myers Squibb. The motion passed unanimously.

- 6) Thomas A. Mitro, VP, Sales and Marketing, ISTA Pharmaceuticals – Regarding Istalol

The Chair directed that a discussion of A-rated and B-rated medications, and the responsibility of pharmacists be included in the next newsletter.

Although the Board cannot endorse a product, the article can include information to let pharmacists know that the FDA ratings are not limited to just oral products.

7) Robert Wood Johnson University Hospital, Hamilton awarded Malcolm Baldrige National Quality 2004 Award, Health Care

Of note is the highlight on page 3 which states that "Between 2001 and the first quarter of 2004, Robert Wood Johnson University Hospital, Hamilton's many safeguards to prevent patients from receiving the wrong medication, were successful in about 93% of cases, far exceeding the national median of approximately 64 percent."

This item was treated as an FYI.. A congratulatory letter will be sent to the Pharmacy Director at Robert Wood Johnson University Hospital, Hamilton.

8) Proposed Board Meeting Dates – 2005

The Board made two changes to the Proposed Board meeting dates for the year 2005. In November, open and executive session will be held on the 9th and the 30th. In December, open and executive session will be held on the 14th only.

9) Keynote Speech from Citizens Advocacy Committee Conference

A copy of the presentation by Mark Yessian was provided by Sophie Heymann and distributed to the Board. The Chair thanked Sophie for obtaining this presentation and Board recommended that this item be referred to the CQI committee.

10) Review of Assembly Bill No. 3546 – Requires written prescriptions to be legibly written or typed

Robert Kowalski moved, seconded by Sophie Heymann not to support the bill as it does not address the problem that exists with hand written prescriptions as they relate to patients' safety. The national efforts are striving to move toward electronic and non-hand written prescriptions. The motion passed with a 6 to 1 vote.

11) Review of Senate Bill No. 2075 – Facilitates vaccine production by NJ pharmaceutical manufacturers

Robert Kowalski moved, seconded by Edward McGinley to support this bill. The Board feels it is a good idea, both for business and for the public. The motion passed unanimously.

12) Review of Assembly Bill No. 3501 – Emergency Health Powers Act would require pharmacists to report prescription related events that could lead to a public health emergency

Anthony Alexander moved, seconded by Edward McGinley to accept the concept of the bill as presented. The Board would also like to note that the bill excludes non-government emergency services such as the Red Cross and that the author of this bill, Assemblywoman Loretta Weinberg, should work with and consult these voluntary groups and include them in the bill. The motion passed unanimously.

13) Interviews of Swarup Patel and Rupal Patel in response to their request for a waiver of the TSE

Robert Kowalski moved, seconded by Edith Micale to grant both Swarup Patel and Rupal N. Patela waivers since, based on their interviews, they found that both applicants' command of the English language was satisfactory. They notified both candidates that, if they receive a New Jersey license, they may not be able to reciprocate their New Jersey license to another state. The motion passed unanimously.

The Board asked the Executive Director to find out what states allow passing of the TSE with a score of 45 instead of 50. One of the problems with the current process may be related to the time allotted for the applicants to respond to questions.

IX. CONFERENCES

1) National Council for Prescription Drug Programs Annual Conference, March 6-9, 2005, Phoenix, AZ

The Board members felt that there was nothing applicable at this meeting to current Board issues and there is no interest in sending any Board members to this meeting.

X. COMMITTEE REPORTS

1) Pharmacy Practice Act – Technician Workgroup

Anthony Alexander

Sophie Heymann moved, seconded by Edith T. Micale to postpone Board approval of the draft grid that was developed by the Executive Director for Workgroup review and input and then for use in reviewing technician training manuals until the January 12, 2005 Board meeting so that Technician workgroup can meet on January 5, 2005 to finalize information related to the process. The motion failed 4 to 3. Further lengthy discussion occurred and criteria related to the testing component of the manuals was added to the grid. Ed McGinley moved, seconded by Bob Kowalski to title the grid " Minimum Criteria for Training Program Content" and to use this to evaluate the training manuals that have been submitted and report the results with recommendations for approval or modifications of the manuals and/or grid back to the Board at a future meeting. The motion passed unanimously. The Executive Director distributed manuals to Board members to take home with them for detailed review.

2) Pharmacy Practice Act – Collaborative Practice Workgroup

Pamela Allen

3) Pharmacy Practice Act – Immunization Workgroup

Ira Katz

The Executive Director has asked Tony Miragliotta to contact Executive Director of the Board of Medical Examiners to determine what the status is of the draft regulations for both of the above items currently being reviewed by the BME.

XI. APPROVAL OF MINUTES

1) December 1, 2004

Robert Kowalski moved, seconded by Edith T. Micale to accept the December 1, 2004 open minutes as amended. The motion passed unanimously.

XII. ADJOURNMENT

At 12:13 p.m., Robert Kowalski moved, seconded by Edward McGinley to move into the executive session to review (5) complaints, (3) inspection reports, (11) retail and IV permits. The motion passed unanimously.