

**NEW JERSEY STATE BOARD OF PHARMACY  
OPEN SESSION MINUTES OF MARCH 28, 2007**

**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 Somerset Room, 6th floor at 124 Halsey Street, Newark, New Jersey on March 28, 2007 at 9:07 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 the 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**

Edward McGinley, R.Ph President  
Thomas Bender, R.Ph. Vice President (Arrived at 11:15 a.m.)  
Pamela Allen, R.Ph.  
Jennifer Barron Government Member  
Peter Halecky, R.Ph  
Margherita Lafragola, R.Ph.  
Elvy T. Paiva, R.Ph.  
Marc Sturgill, PharmD

**OTHERS IN ATTENDANCE**

Joanne Boyer Executive Director  
Marianne Greenwald Deputy Attorney General  
Kiran Shamlall Clerk Typist

**EXCUSED**

Thomas Egan, Pharm.D  
Axel Miranda Public Member

**IV. UPDATE BY EXECUTIVE DIRECTOR**

N/A

**V. CONTINUING EDUCATION REPORT**

N/A

**VI. OLD BUSINESS**

1) Sudhirkumar Patel – Asking Board to reconsider his request for a waiver of TSE This item was last before the Board on 10/25/06 Based on the respondent's failure to demonstrate good cause, Elvy Paiva moved, seconded by Jennifer Barron, to deny his request for a waiver of the TSE. The motion passed unanimously.

2) Items VII.-6 & 7 from the 02/28/07 Minutes The Chair directed that both respondents submit formal responses back to the Board.

## VII. NEW BUSINESS

1) Cheryl Ann Lawrence McDaniel, President, Direct Success, Farmingdale, NJ – Regarding application for pharmacy to distribute Metopirone The Chair directed that in order to validate the need for a specialized permit the respondent must provide the following: an affidavit of the agreement with Novartis from authorized Novartis employee or present a copy of the agreement with Novartis, which must demonstrate full compliance with N.J.A.C.13:39-4.15(b). In addition, Novartis is to provide a copy of the dispensing protocol. The Board has waived N.J.A.C.13:39-4.10, however, Direct Success is to adhere to their 3-5 p.m. hours of operation as listed on the application and comply with N.J.A.C.13:39-7.19(e)4. In regards to the pharmacy published phone number request, the Board needs further clarification on how the triage line operates. The Board advised Direct Success that their number should be on the label and as protocol highly recommends Novartis' number be provided to the patient. The Board denied the request for a waiver of the "Patient Counseling" reference as required by N.J.A.C.13:39-5.8 (a)1. In regards to the minimum equipment request, Direct Success needs to be compliant with N.J.A.C.13:39-5.8(a)18. Direct Success also needs to request a waiver of N.J.A.C.13:39-6.2(f), which requires a registered pharmacist-in-charge to work minimum of 35 hours a week. They are to amend their application to state that the two employees working in the pharmacy are not going to serve as pharmacy technicians. Additionally, they are to ensure compliance with N.J.A.C.13:39-7.12(a)13 and all other updated labeling regulations. The Board wishes to re-state that this application is only to dispense Metopirone.

2) NABP Report of the 2006 – 2007 Task Force on Standardizing Student Pharmacist Experiential Requirements Also included are the ACPE Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Degree (effective 7/1/2007) which are referenced in the Task Force report Pamela Allen moved, seconded by Peter Halecky, to refer this item to the Rules and Regulations Committee for further action. The motion passed unanimously

3) Ravindranadha Alluri – Request for waiver of TSE Pamela Allen moved, seconded by Margherita Lafragola, to deny his request for a waiver of the TSE based on the respondent's failure to demonstrate good cause including documentation from a medical professional as to his speech impediment. The motion passed unanimously.

4) Maryam Javdan – Foreign Graduate, not registered as an intern, requesting that the hours spent working as an intern in New York satisfy the requirements as stated in NJAC 13:39Subchapter 8. (Update – Ms. Javdan submitted Intern Application on 2/28/07) Based on the magnitude of the accumulated licensed work experience, Jennifer Barron moved, seconded by Pamela Allen, to have the respondent complete a 250 hour practicum. The motion passed unanimously.

5) Annapurna Maddali, President, Brockman's Pharmacy – Requesting to retain same permit number upon transfer of ownership Elvy Paiva moved, seconded by Jennifer Barron, to approve his request to retain the same permit number upon transfer of ownership. Additionally, there will be an inspection and if there is a change of the registered pharmacist-in-charge, then they must have an RPIC inventory and pay all required fees. The motion passed unanimously.

6) Festus Mgbeme – Request for reinstatement This item was moved to the Executive Session for advice of counsel.

7) Dave Krishna, RPIC, Enclara Health, West Deptford, NJ – Submission of new pharmacy application with a request for a waiver of NJAC 13:39 – 5.3(a), 5.8(a)2 and 5.8(a)17 Elvy Paiva moved, seconded by Peter Halecky, to approve item number 2, which pertains to the signage being posted on the door of the pharmacy that will read Enclara Health. Item number 1(two DURC placards) cannot be waived since this is a statute and the Board of Pharmacy does not have the authority to waive a statute. In regards to Item 3 (schedule V record book), they are to follow N.J.A.C.13:39-5.8(a)2 and N.J.A.C.8:65-7.19(a)5. The motion passed unanimously.

8) Carol Katz, Katz Government Affairs, Trenton, NJ and Mark Fankhanel, VP Carecenter Strategies– Regarding Caremark initiative involving an electronically monitored kiosk program Pamela Allen moved, seconded by Marc Sturgill, to approve the pilot program with certain criteria pending approval of the Division of Law and the Director's Office. The criteria for the pilot program are as follows: amend application of servicing pharmacy to

include the device as part of the permitted area, they are limited to dispensing non controls, deliver both new and refill prescriptions, acquire a secure and temperature control location, the program must occur on a campus of a New Jersey employer, will be stocked on a daily basis and medication will be removed if not picked up after seven days, they are to provide a copy of the operating protocols for SOP's and the security recording mechanism will be able to be reviewed.

If all issues are resolved, then they may extend their program to include controlled dangerous substances. The pilot metrics will be determined at the time of approval. In addition, Caremark is to provide a list of the nine states where a kiosk operation is approved if attached to the pharmacy and a list of the states where approval is pending for a remote kiosk. The motion passed unanimously.

9) Joseph W, Braviak, Director of Pharmacy Services, St. Mary's Hospital, Passaic, NJ – Requesting to retain same permit number upon transfer of ownership Elvy Paiva moved, seconded by Thomas Bender, to approve their request to retain the same permit number upon transfer of ownership and to request that they provide a copy of their 222 forms to show the transfer of schedule II meds to the new location.. The motion passed unanimously.

10) Linda Witzal, Director of Pharmacy, Partners Pharmacy, Cranford, NJ – Requesting if return of unit dose medications as described in NJAC 13:39 – 9.18(a) can be applied to county correctional facilities Elvy Paiva moved, seconded by Peter Halecky, to inform the respondent that a correctional facility is not the same as a healthcare facility. Correctional facilities are classified under the Department of Corrections not the Department of Health & Senior Services. The motion passed unanimously.

11) Michael Madura, R.Ph. – Request for a waiver of didactic continuing education requirement (NJAC 13:39 – 3A.1(a)) Based on his medical condition, Margherita Lafagola moved, seconded by Marc Sturgill, to grant the waiver for this reporting period only, which ends on 04/30/07. However, he must have thirty (30) credits of continuing education. The motion passed 6 to 2.

12) William Adamshick – Request for reinstatement Elvy Paiva moved, seconded by Margherita Lafragola, to bring the respondent in for an investigative inquiry. The motion passed unanimously.

13) Caremark Pharmacy, Fairfield, NJ – Requesting to retain same permit number upon change of ownership Elvy Paiva moved, seconded by Jennifer Barron, to grant the request to retain the same permit number upon change of ownership. The motion passed unanimously.

14) Narendra Dalal – Request for reinstatement Elvy Paiva moved, seconded by Jennifer Barron, to bring the respondent in for an investigative inquiry. The motion passed unanimously.

15) Kwado Agyemang – Request for reinstatement Pamela Allen moved, seconded by Peter Halecky, to bring the respondent in for an investigative inquiry. The motion passed unanimously.

## **VIII. MITIGATIONS**

N/A

## **IX. COMMITTEE REPORTS**

N/A

## **X. APPROVAL OF MINUTES**

1) February 28, 2007 Pamela Allen moved, seconded by Marc Sturgill, to approve the draft minutes of February 28, 2007 as amended. The motion passed unanimously.

2) March 14, 2007 This item will be re-scheduled for the next meeting.

## **XI. ADJOURNMENT**

At 9:42 a.m., Pamela Allen moved, seconded by Elvy Paiva, to move into the Executive Session for advise of counsel regarding Item VII (1), Direct Success application for pharmacy to distribute Metopirone. The motion passed unanimously.

At 10:25 a.m., Elvy Paiva moved, seconded by Jennifer Barron, to move back into the Open Session to review the remaining items on the agenda. The motion passed unanimously.

At 12:17 p.m., Jennifer Barron moved, seconded by Marc Sturgill, to move into the Executive Session for review of (1) Old Business, (3) New Business, (2) Secretary's Reports for Retail, Institutional and IV Permits, (10) Inspection Reports, (30) Special Inspection Reports and (2) Investigative Inquiries. The motion passed unanimously.