

**BOARD OF REGISTRATION IN PHARMACY
PHARMACY BOARD MEETING MINUTES
TUESDAY, JUNE 10, 2003
239 CAUSEWAY STREET, ROOM 206
BOSTON, MASSACHUSETTS 02114**

The meeting was called to order by President Donna Horn at 9:30 a.m.

The following Board members were present: Donna Horn, R.Ph., Pres., Harold B. Sparr, R.Ph., MS, Karen M. Ryle, R.Ph., MS, Dan Sullivan, R.Ph. and James T. DeVita, R.Ph.
Absent: Marilyn M. Barron, MSW, Public Member.

The following Board staff were present: Charles R. Young, R.Ph., Exec. Dir., Susan Manning, J.D., Counsel, James D. Coffey, R.Ph., Assoc. Dir., Arthur J. Chaput, R.Ph., Pharm.D., James C. Emery, C.Ph.T., Healthcare Investigator, and Leslie S. Doyle, R.Ph., Healthcare Supervisor.

AGENDA ITEMS

1. 9:30 a.m. Call to Order
Business Meeting
2. 9:35 a.m.
Review of Board Minutes-Tabled
3. 9:45 a.m. to 10:15 a.m.
Discussion regarding Pharmacist Registration Expiration and Renewal.
Jim DeVita provided an overview of proposed amended regulations related to personal registration expiration and renewal.
Motion/Sparr to approve draft regulation amendments (with birthdate renewal deleted). Second/Horn. The motion carried. Motion/Horn to adopt the approved amendments as policy until such time that regulations are published. Second/Sparr. The motion carried. Donna Horn requested that Board counsel provide the Board with an update as to regulation revisions.
4. 10:15 a.m. to 10:45 a.m.
ACCRX Inc., D.B.A. Americas Compounding Center- Application for a new compounding pharmacy department - 950 Watertown Street, Suites 2 and 3, Newton, MA. Proposed Manager of Record: Arthur S. Margolis, R.Ph. (License No. 19228 / Exp. 12/31/04).

Review of compounding pharmacy department application. The applicant requests a waiver of 247 CMR 6.02(4): "The pharmacy department shall maintain on the premises a sufficient variety and supply of medicinal chemicals and preparations which are necessary to compound and dispense commonly prescribed medications in accordance with the usual needs of the community."

Present: Arthur Margolis, R.Ph.

Mr. Margolis provided the Board with an overview of his application for a new compounding pharmacy department. He plans to purchase bulk chemicals from PCCA. No intention to operate a central intravenous admixture service (CIVAS). Margolis said he will both self test and outsource non-sterile compounded products for quality assurance purposes. The pharmacy will use a patient medical history form to be updated with each successive prescription filling for drug utilization review. Compounding pursuant to and in anticipation of prescriptions (no bulk compounding).

The Board advised Margolis to resubmit a more detailed waiver specific to the compelling public interest required by waiver regulation.

Motion/Horn for applicant to provide a more detailed statement as described above. Second/Ryle. The motion carried.

5. 10:45 a.m. to 11:15 a.m.

PGT Pharmacy Corporation, D.B.A Auburn Apothecary- Application for a new pharmacy department – 469 Southbridge Street, Auburn, MA. Proposed Manager of Record: Dr. Bertram Nichols, R.Ph. (License No. 14835 / Exp. 12/31/04)

Present: Charles Pearlmutter, MCPHS 2003 graduate & Dr. Bertram Nichols, R.Ph.

Dr. Nichols and Charles Pearlmutter provided the Board with an overview of the application for a new pharmacy department. Both received compounding training from Professional Compounding Centers of America (PCCA). Pearlmutter said that after he receives his pharmacist license he plans to apply to become the Manager of Record. None of the pharmacy stockholders are practitioners with prescribing privileges. The Board advised Bertram and Pearlmutter that the pharmacy is required to purchase bulk chemicals from an FDA approved company. Pearlmutter said that he is planning to operate a central intravenous admixture service (CIVAS) (Microsphere®) and will have appropriate equipment and reference sources on site. Pearlmutter said he will both self test and outsource non-sterile compounded products for quality assurance purposes. And noted that the import and export reference on the application applies to over the counter merchandise not prescription medications. The pharmacy will maintain certificates of analysis for all bulk chemicals and plans to outsource non-sterile compounded products for quality assurance purposes. The pharmacy is not planning to do bulk compounding but will compound specific to prescriptions and will maintain all related formulation records in a readily retrievable manner for pharmacist reference. All compounded prescriptions will be labeled with a beyond use.

Motion/Sparr to approve the application subject to compliant inspection and provided the Manager of Record is present in the pharmacy. Second/Ryle. The motion carried.

6. 11:15 a.m. to 11:30 a.m.
Discussion regarding DRAFT Policy on Inspection of New Retail Pharmacies. Exec. Dir. Chuck Young provided an overview of the draft policy. Leslie Doyle outlined resource limitations specific to the inspection process.
Motion/Sparr to approve the draft policy to be utilized at the discretion of the Board and Compliance Coordinator. Second/DeVita. The motion carried.
7. 11:30 a.m. to 11:45 a.m.
Discussion regarding DRAFT Policy regarding Pharmacist and Staff Self Assessment of Medication Errors and Practice Site. The DRAFT Policy was distributed to the Board on May 13, 2003 by Dr. Robert P. Paone.
General discussion regarding the draft policy.
Motion/Sparr to approve the draft policy "concept" for Drug Store complaint resolution to be utilized at the discretion of the Board (responsibility of the Manager of Record to reconcile) (not to be reported to the Board but rather to ISMP).
Motion/not seconded.
Motion/Horn for the Board to consider utilizing the self assessment as a tool for resolution of medication error complaints when deemed appropriate (if requested by the Board the Manager of Record shall complete the survey and forward such to ISMP with only an acknowledgment of survey receipt directed to the Board and no CE's will be issued by the Board. Second/Ryle. The motion carried. The motion carried but not in policy format.
8. 11:45 a.m. to 12:30 p.m.
Continuous Quality Improvement (CQI) Program modified draft regulations.
Discussion and Vote related to draft regulations distributed at the April 8, 2003 and May 13, 2003 meetings.
Exec. Dir. Chuck Young and Board Counsel Susan Manning provided an overview of the modified draft regulation. The Board discussed the possibility of developing a related CQI CE program. The Board agreed the concept of CQI is positive but prefers to review the draft regulation line by line for comment. The Board agreed with the concept of a consultation area and suggested that the following language be incorporated into the working draft "To protect patient confidentiality".
Action Item: Chuck Young to forward the Connecticut & Massachusetts CQI language to Jim DeVita for review to be reconsidered at a future meeting.
9. 12:30 p.m. to 1:30 p.m.
Lunch
10. 1:30 p.m. to 2:00 p.m.
Administrative Business Items
 - A) Lexi-Comp, Inc.- request for Board approval as reference source 247 CMR 6.01(6)(a)(2). Motion/Horn to approve. Second/Ryle. The motion carried.
 - B) Decision - In the matter of DS-03-046 & PH-03-058 - CVS Pharmacy #672, 36 Pleasant Street, Malden and Tassarwar Hussain, R.Ph. (License No. 24757).

Complaint taken under advisement on May 27, 2003 pending review of additional information.

Recused: Jim DeVita

Jay Emery provided an overview of additional information requested by the Board.

Vote of Decision.

Motion/Sparr consent agreement with 1-year suspension (not to be stayed), followed by 3-years probation, the Registrant may not serve as Manager of Record while on probation, pass MPJE and shall complete a Board approved course on professional ethics (minimum of 10 hours). Second/Ryle. Vote: The motion carried unanimously.

C) Request for Advisory Opinion regarding continuing education for Monalisa Patnaik, R.Ph. (License No. 22323 / Exp. 12/31/04).

Motion/Sparr to accept the CE forwarded by the Registrant. Second/DeVita. The motion carried.

D) Request for Advisory Opinion regarding Canadian Council on Continuing Pharmaceutical Education (C.C.C.E.P.) for Cathy Mirecki, R.Ph. (License No. 17642 / Exp. 12/31/04).

Motion/Sparr to grant the Registrant a one-time live CE waiver. Second/DeVita. The motion carried.

E) Board Counsel – pending legal matters.

In the matter of PH-00-107- Registrant: Christopher Comfort, License No. 20758.

Board counsel stated that the final decision and order was mailed June 9, 2003.

Motion/Sparr to convene Exec. Session to discuss pending legal matters.

Second/Horn. The motion carried.

Motion to exit Executive Session. Second/Ryle. The motion carried.

Return to Open Session 1:50 p.m.

F) SureScripts correspondence - Motion/Sparr to invite SureScripts representatives to the Board on July 8, 2003 for informational and demonstration purposes.

Second/Horn. The motion carried. In addition, the Board requested that designees from DPH/DCP also be invited to the meeting.

11. 2:00 p.m. to 3:00 p.m.

Compliant File Review.

In the matter of PH-03-084: Registrant - Arthur P. Vergados, License No. 15438.

Motion/Sparr for Formal Reprimand and pass MPJE in 120 days unless the Registrant can provide compliant CE to the Board in 30 days. Second/DeVita. The motion carried.

12. 3:00 p.m.

Motion/Sparr to adjourn. Second/Horn. The motion carried. Meeting adjourned.

Respectfully submitted by:

 7-21-03
Executive Director Date

Charles Young
Printed Name

Reviewed by counsel: July 8, 2003

Draft approved: July 8, 2003

Board adopted: July 8, 2003

EXECUTIVE SESSION MINUTES

Time: 1:45 p.m.

General discussion regarding correspondence from Shoppers Drug counsel related to proposed consent agreements. The Board decided not to grant an appearance to Shoppers Drug and referred the matter to DPH Office of Prosecutions.

Motion to return to Open Session: 1:50 p.m.