BOARD OF REGISTRATION IN PHARMACY PHARMACY BOARD MEETING MINUTES TUESDAY, MAY 13, 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., Robert P. Paone, R.Ph., Pharm.D., Sec, Karen M. Ryle, R.Ph., MS, and James T. DeVita, R.Ph. Absent: Marilyn M. Barron, MSW, Public Member, Harold B. Sparr, R.Ph., MS and Dan Sullivan, R.Ph.

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., QA Surveyor 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
- 9:35 a.m. Review of Board Minutes
 Review of February 11, 2003 Board Minutes: Motion/Paone to approve as amended.
 Second/Horn. The motion carried. Minutes adopted.
 Review of February 25, 2003 Board Minutes: Motion/Paone to approve as amended.
 Second/Ryle. The motion carried. Minutes adopted.
 Review of April 08, 2003 Board Minutes: Motion/Ryle to approve as written.
 Second/Horn. The motion carried. Minutes adopted.
- 3. 9:45 a.m.-10:15 a.m. Review of ACPE correspondence "Invitation to Comment- Education and Training of Pharmacy Technicians".

After extended discussion, the Board approved a response letter to ACPE.

 10:15 a.m.-11:00 a.m.
 Compounding Task Force Chair Karen M. Ryle, R.Ph., MS and Task Force members Ernie Gates, R.Ph., Hank Abbott, R.Ph. and Barry Cadden, R.Ph.
 Review of DRAFT Compounding Guidelines and Sterile Procedures

General discussion related to DRAFT Compounding Guidelines and Sterile Procedures. Karen Ryle noted new NABP model compounding guidelines will be considered. Abbott suggested that 20 additional CE's should be required for compounding pharmacists. Discussion of adopting document as guidelines or

regulations. Gates commented that USP compounding standards may be too restrictive for compounding pharmacies as such relate to manufacturing standards. Discussion of USP standards incorporation by reference as typical regulatory model.

Dr. Paone suggested temperature logs be added as requirement.

Board stated noted other changes may be made as required by new NABP guidelines, such as certificate of analysis to be obtained for all compounded batches if purchased form non-approved FDA registered facility. Also, pharmacists may be required to label compounded products distributed to physicians: "Not to be Re-Sold".

The Board discussed the need to review 247 CMR 7.00 (Wholesale Distributor) to permit pharmacists to distribute compounded products for practitioner's office use. Young advised matter would be reviewed by the interagency Pharmacy Workgroup.

Motion/Horn for the task force to review the new NABP new model guidelines for incorporation as necessary. Second/Paone. The motion carried.

Pres. Horn noted a public comment period would be scheduled for review of Compounding Guidelines and Sterile Procedures Best Practice Recommendations once draft document is finalized for comment.

5. 11:00 a.m. to 11:15 a.m.

In the matter of Louis G. Artzberger, R.Ph. (License 15831/Surrendered 12/14/93) - applicant for Pharmacy Technician Registration

Motion/Horn to convene Exec. Session related application for pharmacy technician registration. Second/DeVita. The motion carried. Applicant present.

Motion/Horn to exit Exec. Session. Second/Paone. The motion carried.

Return to Open Session at 11:15 a.m.

Motion/Horn to refer Mr. Artzberger for assessment prior to application. reconsideration. Second/Paone. The motion carried.

6. 11:15 to 11:30 a.m.

Collaborative Practice Update Collaborative Practice Task Force Chair Robert P. Paone, R.Ph., Pharm.D.

Dr. Paone summarized April 28, 2003 legislative hearing. Pres. Horn thanked Dr. Paone on behalf of the Board for his contributions as Chair of the Collaborative Practice Task Force and other Board initiatives to include CQI and the development of Best Practice Recommendations.

7. 11:30 a.m. to 12 p.m.

IVPCare, Inc.-Application for a new pharmacy department - 260-D Fordham Road, Wilmington, MA. Proposed Manager of Record: T. DeWayne Manning, R.Ph., Sr. V.P. Operations (License No. 24031 / Exp. 12/31/04).

Review of an amended pharmacy department application. Applicant appeared before the Board on March 11, 2003 and submitted 27 original CE certificates in compliance Board request.

Mr. Manning stated that the location of the proposed pharmacy department changed to Wilmington due to a permit issue. IVPCare, Inc. withdrew waiver application as full retail pharmacy services now planned. Manning stated that IVPCare, Inc is a publicly held company. IVPCare, Inc does have a business relationship with INTEGRAMED but is not owned by such company. IVPCare, Inc. is the preferred but not exclusive pharmacy provider for INTEGRAMED patients.

Motion/Paone to approve IVPCare, Inc. the application as a retail pharmacy department subject to compliant inspection. Second/DeVita. The motion carried.

8. 12 p.m. to 12:15 p.m.

Continuous Quality Improvement Board Quality Assurance Surveyor: Arthur J. Chaput, R.Ph., Pharm.D.

Review of a community pharmacy CQI report.

Dr. Chaput reported pharmacy ran smoothly on the date of the survey and that pharmacy staffing seemed appropriate. The Manager of Record had also initiated a policy regarding mandatory counseling for all new prescriptions.

New Business: Dr. Paone distributed a draft policy regarding "Pharmacist and Staff Self Assessment of Medication Errors and Practice Site" - to be reviewed at June 10, 2003 meeting.

- 9. 12:15 p.m. to 1:30 p.m. Lunch
- 10. 1:30 p.m. to 2:30 p.m. Administrative Business Items
 - A) NACDS correspondence -Board member invitation to 2003 NACDS Pharmacy & Technology Conference (8/23-27/03), Philadelphia, PA Pres. Horn is designee.
 - B) Mosby's Drug Consult request for approval as reference source (247 CMR 6.01(6)(a)(2). Dr. Chaput overview of reference. Motion/Ryle to approve. Second/Paone. The motion carried.
 - C) MCPHS Pharmacy Grand Rounds CE Program (June 11, 2003) Discussion related to MCPHS request for Board involvement with program planning. DeVita and

Donna Horn not available to attend. Board chose to cancel the meeting and or schedule an MPRS program initiative.

D) Certified Pharmacy Technician Duties and Responsibilities re: Schedule VI prescription transfer processing. The Board supports the concept.

E) In the matter of Marc Mathieu (License No. 15544 /Exp. 12/31/98); Request for Reinstatement.

Motion/DeVita to approve reinstatement subject to completion of NAPLEX, MPJE, 750 experiential hours in a pharmacy department; and payment of required fees. Second/Horn. The motion carried.

F) In the matter of PH-02-024 - David J. Little (License No. 22830). Request for termination of suspension.

Motion/DeVita to approve. Second/Paone. The motion carried.

G) In the matter of PH-97-012 - Michael H. Ouimet (License No. 17000)

(Lic. Sur. 03/24/99). Request to reapply. Discussion.

Motion/Paone to refer Ouimet for assessment provided his pharmacist license, with license reinstatement to be considered not sooner than three years in program.

Additional conditions similar to initial licensure requirements to be determined by the Board at a future date. Second/Ryle. The motion carried.

H) In the matter of PH-94-013 - Francis A. Najarian (License No. 14100). Request for Reinstatement. Discussion.

Motion/Ryle to Deny reinstatement request. Second/Paone. The motion carried.

I) Decision - In the matter of PH-03-033 - James A. Doolittle (License No. 21107). Complaint taken under advisement on February 25, 2003 pending review of complaint history.

Recused: Donna Horn (exited the meeting room)

Inv. Leslie Doyle provided an overview of the complaint and licensee complaint history.

Motion/Paone to propose Reprimand with 2-hour medication error reduction CE program and completion of an ISMP self assessment study. Second/Ryle.

Vote: In support: Ryle, Paone and DeVita. Opposed: none. The motion carried.

I) Decision - In the Matter of DS-03-024 - CVS Pharmacy #281 (Rockland) and PH-03-054 - Deanne Wigley (License No. 21778). Complaints taken under advisement on March 25, 2003.

Recused: Jim DeVita (Exited the meeting room)

DS-03-024: The Board requested that counsel send a letter to CVS/pharmacy requesting an action plan specific response to the CQI survey.

PH-03-054: Motion/Horn to issue an Advisory Letter to Ms. Wigley to include a 2-hour medication error reduction CE program. Second/Paone. The motion carried.

K) Decision - In the Matter of DS-02-082 - CVS Pharmacy #155 (Winchester) and PH-02-084 and PH-02-085- Robert J. Cheney (License No. 19814) and Mehri Pourshadi (License No. 21285). Complaints taken under advisement on September 24, 2002.

Recused: Jim DeVita (exited the meeting room).

DS-02-082/CVS Pharmacy: Motion/Horn to issue CVS /pharmacy an Advisory Letter. Second/Paone. The motion carried.

PH-02-084/Pourshadi: Motion/Horn to issue an Advisory Letter to Pourshadi for the

failure to fill a prescription properly to include a 2-hour medication error reduction CE program. Second/Paone. The motion carried.

PH-02-085/Cheney: Motion/Horn to issue an Advisory Letter to Cheney for poor customer communication to include a 2-hour home study continuing education program regarding pharmacist communication skills. Second/Paone. The motion carried.

L) Board Counsel - pending adjudicatory matters.

Motion/Ryle to convene Exec. Session at 1:50 p.m. Second/Paone. The motion carried.

Motion/Paone to exit Exec. Session. Second/DeVita. The motion carried. Return to Open Session: 2:15 p.m.

In the matter of PH-03-009/James McCabe: Following review of the layout of the prospective work setting, Board approved setting.

In the matter of DS-03-006/CVS/pharmacy S.Dennis

Recused: Jim DeVita (exited meeting room)

Board counsel overview of CVS/pharmacy legal response. CVS/pharmacy amenable to Formal Reprimand. Motion/Paone for Board counsel to offer a Formal Reprimand with condition that all pharmacy staff complete an ISMP self assessment study and all such assessments should be summarized for report back to the Board for review. Second/Horn. The motion carried.

In the matter DS-02-051/CVS/pharmacy Harwichport: Board counsel reviewed proposal from CVS/pharmacy counsel.

Motion/Paone to propose Reprimand to CVS/pharmacy Harwichport with the following conditions: CVS/pharmacy shall forward pharmacy staffing reports (with reference to prescription volume) to the Board's Quality Assurance Surveyor for review for one year, describe pharmacy technician staffing in such reports, describe pharmacy policies and procedures regarding sick coverage and outline steps taken to ensure that adequate pharmacy staffing is provided for the summer month. Second/Horn. The motion carried.

In the matter of Minh Tran's inquiry regarding internship application to be filed in 2-3 years: Board to notify Tran that future application will be reviewed with consideration of prior history vs. the passage of time since offense.

Proposed Revisions to 247 CMR: Board counsel said she will provide an updated memorandum to the Board at the June Board meeting.

M) In the Matter of PH-00-107 - Christopher Comfort (License No. 20758). Vote: Final Decision and Order.

Motion/Horn to issue final decision and order revoking license with no conditions for future reinstatement. Second/Paone. The motion carried. Second/Horn.

Vote: In support: Ryle, DeVita, Paone and Horn. Opposed: none. The motion carried.

- N) Board approves provisional pharmacy permit numbers provided pharmacy inspection occurs within 60 days due to limited inspection resources.
- R) The Board will consider the notion of conducting File Review with de-identified documents.

11. 2:30 p.m.

General discussion regarding draft regulations. Exec. Dir. Chuck Young and Board counsel Susan Manning

Preliminary Test of Spoken English: The Board shall consider the impact upon candidates for MA reciprocity. The Board approved the draft TSE regulations and requested that such be forwarded to counsel for incorporation into bundled regulations.

Patient Counseling regulations tabled for future discussion. Jim DeVita will provide draft a patient counseling recommendations for consideration at a future Board meeting.

12. 2:45 p.m.

Continuous Quality Improvement (CQI) Program modified draft regulation. Discussion related to draft regulations distributed at the April 8, 2003 meeting. Exec. Dir. Chuck Young and Board Counsel Susan Manning.

Exec. Dir. Young suggested that the long-term solution may require peer review legislation protection but in the meantime pharmacies need to consider systems improvement.

Dr. Paone stated that the Board should consider changing from the "CQI" Program to the "Performance Improvement" Program (PIP) and that PIP should begin with an ISMP self-assessment study.

The Board decided to re-discuss and vote on the CQI Program modified draft regulations at the July 08, Board meeting.

13. 3:30 p.m.

Assoc. Dir. James D. Coffey provided the Board with a summary of compliance related to the 2001 & 2002 Continuing Education Audit. The Board will consider portfolio CE development in the future.

14. 3:45 p.m. Adjourn.

Respectfully submitted by:

Printed Name

Reviewed by counsel: September 2, 2003
Draft approved: September 2, 2003
Board adopted: September 9, 2003

EXECUTIVE SESSION MINUTES

TIME: 11:00 a.m. to 11:15 a.m.

In the matter of Louis G. Artzberger, R.Ph. (License 15831/Surrendered 12/14/93) - applicant for Pharmacy Technician Registration

Motion/Horn to convene Exec. Session to discuss personal circumstances related to an application for pharmacy technician registration. Second/DeVita. The motion carried.

Discussion of pharmacist license surrender; employment since surrender; current employment and Pharmacy Technician application.

Mr. Artzberger said his pharmacy license was suspended by the Board nine years ago for reason of substance abuse. Artzberger indicated that he has been involved with recovery efforts for ten years. Artzberger stated that he complied with the Boards fluid monitoring agreement for a while but financial hardship caused him to discontinue the program. Artzberger said that he has not complied with Board CE requirements.

Mr. Artzberger stated that former Exec. Dir. Lori Bassinger advised him he could work in a pharmacy as a pharmacy technician. Artzberger said he started employment as a pharmacy technician with CVS/pharmacy in the fall of 2002 and stopped working in the spring of 2003. Artzberger said CVS/pharmacy was aware of his recovery circumstances. Artzberger stated that he recently spoke with DPL MPRS Coordinator Tim McCarthy regarding the MPRS program.

Motion to return to Open Session: 11:15 a.m.

TIME: 1:50 p.m. to 2:15 p.m.

L) Board Counsel - pending legal matters.

Motion/Ryle to convene Exec. Session. Second/Paone. The motion carried.

In the matter of PH-03-009/James McCabe: Board counsel overview. DPL MPRS Coordinator Tim McCarthy said that McCabe is still under contract with MPRS. McCarthy stated that a prospective employer requested approval from the Board to employ McCabe as a data entry pharmacist in a separate room with no access to controlled substance medications. Following review of the layout of the proposed work setting the Board approved the request.

In the matter of DS-03-006/CVS/pharmacy S.Dennis

Recused: Jim DeVita (exited meeting room)

Board counsel overview of CVS/pharmacy legal response. CVS/pharmacy amenable to Formal Reprimand. Motion/Paone for Board counsel to offer a Formal Reprimand with condition that all pharmacy staff complete an ISMP self assessment study and all such assessments should be summarized for report back to the Board for review. Second/Horn. The motion carried.

In the matter DS-02-051/CVS/pharmacy Harwichport: Board counsel reviewed a counteroffer proposal from CVS/pharmacy counsel.

Motion/Paone to offer a Formal Reprimand to CVS/pharmacy Harwichport with the following conditions: CVS/pharmacy shall forward pharmacy staffing reports (with reference to prescription volume) to the Boards Quality Assurance Surveyor for review for one year, describe pharmacy technician staffing in such reports, describe pharmacy policies and procedures regarding sick coverage and outline steps taken to ensure that adequate pharmacy staffing is provided for the summer month. Second/Horn. The motion carried.

In the matter of PH-03-035/Robert E. Cataldo: Board counsel to prepare consent agreement based upon Michigan Board of Pharmacy decision.

Minh Tran request for guidance regarding prospective application for Internship to be filed in 2-3 years. Board counsel overview of felony charge (codeine syrup).

M) In the Matter of PH-00-107 - Christopher Comfort (License No. 20758). Board counsel overview. Board counsel represented that Mr. Comfort did not appear for a scheduled sanction hearing.

Motion to return to Open Session: 2:15 p.m.