

**BOARD OF REGISTRATION IN PHARMACY
BOARD MEETING MINUTES
TUESDAY, JUNE 11, 2002
239 CAUSEWAY STREET, ROOM 206
BOSTON, MASSACHUSETTS 02114**

The meeting was called to order by President Harold B. Sparr 9:30 a.m.

The following Board members were present: Harold B. Sparr, R.Ph., MS, President, Donna M. Horn, R.Ph., Secretary, Karen M. Ryle, R.Ph., MS, James T. DeVita, R.Ph. (until 12:30 p.m.), Dr. Robert P. Paone, R.Ph., Pharm. D., and Marilyn M. Barron, MSW (10:30 a.m.), Public Member.

The following Board staff were present: Charles R. Young, R.Ph., Executive Director, Susan Manning, J.D., Administrative Board Counsel, James D. Coffey, R.Ph., Associate Director, James C. Emery, C.Ph.T., Healthcare Investigator, Alan Van Tassel, Healthcare Investigator, and Leslie S. Doyle, R.Ph., Healthcare Supervisor and Investigator.

AGENDA ITEMS

1. 9:30 a.m.

Call to order: Business Conference Meeting

Minutes for March 12, 2002: approve ____ amend X

Motion/Karen Ryle to approve the minutes as amended. Second/Donna Horn. Abstain: Bob Paone. The motion carried. Minutes adopted.

Minutes for May 07, 2002: approve ____ amend X

Motion/Karen Ryle to approve the minutes as amended. Second/Bob Paone.
The motion carried. Minutes adopted.

2. 9:45 a.m. to 10:25 a.m.

Board Staff Update

- Pharmacy Technician Registration Update: James D. Coffey.
- Continuing Education Program applications: Comm. Chairman Harold Sparr reviewed continuing education program approval requests with the Board.
- Complaint Committee Review process: Chuck Young distributed draft policy handout for discussion at the June 25, 2002 Board meeting.
- Board Counsel update: Susan Manning, Board Counsel, reviewed topics of Board Member recusal protocol and e-mail communication between meetings. Counsel advised members that board members who are recused from a particular matter should leave the board meeting room while conflict matter is being discussed to avoid the appearance of impropriety. Regarding e-mail communication between board members, Counsel advised that exchanges between meetings be restricted

to ministerial/scheduling related matters. E-mail exchanges amongst members on substantive topics violate the requirements of the Open Meeting Law (G.L. c. 30A, s. 11A1/2).

- Senate proposed budget: Chuck Young described Senate proposed budget section moving Board (and 6 others) to DPH and amending Board composition. The Board requested DPL Director Bill Wood to address the Board regarding the proposal.

- **Board Task Forces**

Karen Ryle: **Compounding Task Force** meeting to be held June 20, 2002. Task force will be comprised of regulators and selected MA pharmacy compounding pharmacists. Bob Paone suggested the group consider the requirement of a "manufacturer's compounding log". Ryle has surveyed other board of pharmacy compounding regulations.

Harold Sparr recommended that Bob Paone act as chairman for a **Collaborative Practice Task Force** and that group Sparr stated that the task force should consider the Rhode Island Board of Pharmacy collaborative practice statute as a draft model.

3. 10:30 a.m. to 12:30 a.m.

OxyContin® Discussion

Harold Sparr made an opening statement related to the OxyContin® vote on April 23, 2002 and provided an overview of the Board's meeting with the Executive Office of Public Safety (EOPS) on June 10, 2002.

Various parties provided oral or written comment (on file with Board) for Board consideration.

A. David Sencabaugh/ Brooks Pharmacy: Described new Brooks policy on OxyContin® (advance notice) and distributed handout. Brooks plans to send informational letter to prescribing practitioners and advise public.

B. Audrey Neely and Steve Pashko/ Walgreens Pharmacy: Ms. Neely described Walgreens new OxyContin® policy and distributed handout. Walgreens will attempt to fill OxyContin® prescriptions within 24 hours. Pashko stated pharmacists have notified (telephone) patients about policy (in effect since 5/17/02). Chuck Young advised representatives to provide mail order patients with a toll-free telephone number for drug therapy counseling inquiries. Neely stated Walgreens provided all pharmacies with procedures to handle situations where patient cannot wait 24 hours.

C. William Cardelli, Harvard Vanguard Medical Associates (HVMA): Cardelli affirmed Dr. Gerstein's 5/28/02 comments to the Board regarding alternative pain management drug therapies. HVMA has not received any consumer complaints regarding company's decision not to stock OxyContin®.

D. Paul Cutroni, Blue Cross Blue Shield: Expressed concern about counseling issues if prescriptions medications prepared by a central fill pharmacy.

E. Jose Vincenty, Dir. Reg. and Leg. Affairs, American Cancer Society: Statement read expressing concern that Board not to allow pharmacies to choose not to stock any pain medication because legitimate medical patients would be inconvenienced.

F. Dave Morgan, Dir., Boston Medical Center (BMC) Out Patient Pharmacy Department: Morgan stated that acceptable alternative pain management therapies are available and that it was inappropriate for the Board to require pharmacies to stock any particular medication (a wholesaler may stock over 25,000 medications). Morgan stated, in his opinion, OxyContin® is dangerous because the oxycodone is highly concentrated: 1 OxyContin® 80mg = 16 Percocet tablets. OxyContin® should not be prescribed in ER settings or for acute pain. BMC removed OxyContin® from hospital's drug formulary approx. 6 mos. prior after consultation with hospital pain management specialists - no complaints reported to date.

G. Dr. Walter H. Jacobs, M.D., P.C: Dr. Jacobs, a family practitioner and member of the legislative committee of the Massachusetts Academy of Family Physicians, read statement expressing his concerns regarding morbidity, mortality, and patient inconvenience associated with decision not to stock the medication.

H. Rigney Cunningham, Ex. Dir., Hospice Federation: Cunningham read a statement expressing her concerns as to continued availability and recommending the Board conduct CE programs for pharmacy stakeholders. Hospice Federation would assist the Board and any other regulatory agency to establish OxyContin® best prescribing practices.

Chuck Young read a statement from Alan Must care of Purdue Pharma. (faxed to Board on 6/10/02). Young noted that no complaints received to date regarding access to OxyContin®.

Bob Paone expressed concern as to Board's ability to monitor the morbidity associated with OxyContin® vote. He encouraged stakeholders in attendance to forward concerns to the Board.

Motion/Jim DeVita to affirm July 1, 2002 effective date with of April 23, 2002 OxyContin® vote, as revised:

Effective July 1, 2002 and continuing until further notice, the Board of Registration in Pharmacy will not require pharmacies or pharmacy departments to stock OxyContin® to comply with the requirements of 247 CMR 6.02(4).

Pharmacies and pharmacy departments that discontinue stocking OxyContin® must provide adequate advance notice to patients and appropriate prescribers that

OxyContin© will no longer be stocked by the pharmacy. Information as to alternate sources to obtain this medication should also be provided to patients.

The Board of Registration in Pharmacy will monitor the availability of OxyContin© to patients and perform ongoing reviews of the continuing appropriateness of this exception to Board regulations and its implications to legitimate pain management treatment.

Second/Donna Horn. **Vote:** In Support: Sparr, DeVita, Horn, Ryle and Barron;
Opposed: Paone; Absent: Sullivan. The motion carried.

Motion/Bob Paone to develop a press release advising consumers how/where to contact the Board with complaints and for Board staff to report to the Board any consumer inquiries and or complaints. Second/Donna Horn. The motion carried unanimously.

4. 12:30 p.m. to 1:30 p.m.

Lunch

5. 1:30 p.m. to 2:00 p.m.

**Application for a New Retail Pharmacy – Petition for Waiver
Long-Term Pharmacy Solutions, Inc., 225 Stedman Street, Unit 27,
Lowell, Massachusetts
Present: Long-Term Pharmacy Solutions Inc. Pres. Steven D. Geoffroy,
R.Ph., proposed Manager of Record**

Waiver request: 247 CMR Sections:

6.01(6)(c)(1): minimum working area of 72 sq. ft.;
Approved: X Denied:

6.01 (6)(c)(2): closed on all sides except for an opening to allow for the passage of materials;
Approved: X Denied:

6.01 (6)(c)(6): the area of the clean room shall be under positive pressure unless the hood is self-venting;
Approved: X Denied:

6.01 (6)(c)(7): clean room to be located directly adjacent to the prescription area/department;
Approved: X Denied:

Primary patient population to be served by the pharmacy – LTC and group home patients. Waiver requested due to fact that the free standing self-contained intravenous admixture unit (Microsphere Microenvironment) to be used (to compound sterile ophthalmic, pain and antibiotic medications) exceeds USP sterile product guidelines (unit

operates in a class 10 environment rather than class 1000). Unit would be certified twice a year and would be bolted to pharmacy wall and would be re-certified if ever moved.

The Board advised Geoffroy that he was not authorized to compound chemotherapeutic medications with the Microsphere.

Motion/Bob Paone to approve application and waivers subject to a compliance inspection. Second/Karen Ryle. The motion carried unanimously.

6. 2:00 p.m. to 3:15 p.m.

Administrative Business Meeting

The Board reviewed correspondence and took actions as described below.

(Note: Agenda items a-d were discussed in the morning session.)

- a) Registrant John M. McGreevy, License Number 12411/ Exp. 12/31/1990: request for Board reinstatement. Vote: Approve X Deny . Conditions X
Motion/Jim DeVita to reinstate with the following conditions: 1) the Registrant shall pass both NAPLEX and MPJE; and /or 2) provide the Board both with a record of good standing from the New Hampshire Board of Pharmacy not less than one (1) year after the Registrant's license to practice pharmacy has been reinstated by the New Hampshire Board and evidence from the Registrant's employer(s) that he has practiced as a pharmacist full time for one (1) year in a New Hampshire pharmacy. Second/Karen Ryle. The motion carried.
- b) Application for Pharmacist Reciprocity (Candidate P.L.S.). Board Review of misdemeanor conviction. Vote: Approve X Deny .
Motion/Donna Horn to license applicant if qualifications met. Second/Karen Ryle. Vote: In support: Paone, Horn, Ryle, DeVita and Barron . Opposed: Sparr. The motion carried.
- c) In the matter of PH-96-051 - William D. Guertin, License Number 19044, request for removal of probation (conditional documentation outlined in the Consent Agreement was previously submitted to the Board: compliant) Vote: Approve: Deny:
Discussion: Board counsel shall confer with MPRS coordinator and Board staff regarding probationary terms. Chuck Young noted MPRS participants usually have a five-year probationary term. James D. Coffey stated Registrant's consent agreement included a three-year probationary term..
Motion/Jim DeVita to take matter under advisement pending Board staff clarification of probationary terms. Second/Bob Paone. The motion carried.
- d) 2002 NACDS Pharmacy & Technology Conference, August 10-14 at the San Diego Convention Center:
Motion/Harold Sparr for Jim DeVita to acts as Board Representative. Second/Karen Ryle. The motion carried.
Motion/Harold Sparr for Karen Ryle to act as Alternate Representative. Second/bob Paone. The motion carried.

- e) In the matters of DS-02-051 CVS Pharmacy, 6 Post Office Square, Harwichport, MA & PH-02-059 Registrant, Nancy K. Barsic:
Discussion related to April 23, 2002 and May 28, 2002 Investigative Conferences. : A **Motion**/Bob Paone to offer CVS Pharmacy #860, Harwichport, Massachusetts a Formal Reprimand for prescription filling matters. Second/Karen Ryle.
Discussion: Harold Sparr amended the motion to add pharmacy department probation (one year) with quarterly pharmacy staffing reports to be submitted to the Board for review by the CVS Manager of Record.
Vote: In support: Paone, Sparr, Barron and Ryle, Opposed: Horn. The motion carried.
Motion/Donna Horn to issue Advisory Letter with stipulations to include: 1) completion of a USP Medication Error Report with USP PRN (copy to the Board); and 2) completion of a two hour home study medication error reduction CE program (original certificate to the Board within 30 days). Second/Bob Paone.
Vote: In Support: Paone, Ryle, Horn and Barron; Opposed: Sparr. The motion carried.
- f) In the matter of DS-02-016 J.E. Pierce Apothecary, 1180 Beacon Street, Brookline, MA & PH-02-066 Stephen L. Grossman, R.Ph.
Discussion related to May 28, 2002 Investigative Conference.
Chuck Young provided the Board with an overview of the prior complaint record of standing.
Motion/Paone to issue Advisory Letter to J.E. Pierce Apothecary and the Registrant relating to compounding procedures to include: 1) Registrant shall complete a two hour home study medication error reduction CE program (original CE certificate to the Board within 30 days); and 2) Registrant shall submit pharmacy quality assurance policies and procedures to the Board for review, outlining proper standards of compounding practice and including a manufacturing log with pharmacist sign-off verification, records of compounding formulas wherein all related mathematical calculations are verified by a pharmacist and accountability procedures (pharmacist sign off on all powder paper compounding weights and measures). Second/Karen Ryle.
Vote: In support: Horn, Paone, Ryle and Barron; Opposed: Sparr. The motion carried.
- g) Lynn Community Health Center (LCHC) application for licensure; Dir. Lori Berry present. Continued discussion of related 340B program considerations (May 07, 2002 and May 28, 2002 Board meetings).
The Board stated that all LCHC prescriptions should be labeled with a LCHC prescription label (not Eaton Apothecary). Chuck Young stated that each prescription filled should be treated as separate confidential prescription record.

Dir. Berry advised the Board that the clinic proposal was limited to Schedule 6 drugs and that the current 340B arrangement with Eaton Apothecary (replacement inventory) would be changed to have a separate Schedule 6 controlled substance clinic inventory. All LCHC patients and physicians will be advised of their right to trade with any pharmacy of their choice. With regard to drug utilization review (DUR) concerns, the Board recommended that the retail and clinic pharmacy obtain permission from patients to access both medication profiles in order to conduct an

effective DUR. **Motion**/Bob Paone to approve application provided Eaton Apothecary affirms pharmacy will conduct a drug utilization review for all LCHC patients prior to any medication dispensing. Second/Harold Sparr.

Vote: In Support: Barron, Sparr and Paone; Opposed: Karen Ryle; Abstain: Donna Horn. The motion carried.

- h) Dr. Paone to review the Stop & Shop Pharmacy Technician Training Program and Pharmacy Technician Assessment Examination for report to the Board at the next administrative meeting.
- i) Grand Rounds Presentation (Hospital / Industry consortium): June 12, 2002. The Board reviewed the CE presentation format.
- j) Proxy Votes: Board Counsel Susan Manning advised the Board that proxy votes related to disciplinary matters are not in accordance with adjudicatory requirements.
- k) Proposed legislation to move the Board of Pharmacy to DPH: DPL Dir. William Wood provided an overview of proposed legislation to relocate certain DPL healthcare boards (7 total including PH) from to DPH.
In response to a Board member inquiry, Board Counsel Susan Manning advised the Board that they may express opposition to the proposed move if they so chose.

9. 3:15 p.m. to 4:45 p.m.

Strategic Planning Meeting

Discussion was tabled until future meeting with Board Counsel and Board staff.

10. 4:45 p.m.

A **Motion** was made by Donna Horn to adjourn the meeting. The motion was seconded by Marilyn Barron. The motion carried. Meeting adjourned.

Respectfully submitted by:


Executive Director

8-14-02
Date


Printed Name

Reviewed by counsel: July 23, 2002

Draft approved: July 24, 2002

Board adopted: August 13, 2002