

**BOARD OF REGISTRATION IN PHARMACY
BOARD MEETING MINUTES
MAY 07, 2002
239 CAUSEWAY STREET, ROOM 206
BOSTON, MASSACHUSETTS
02114**

The meeting was called to order by President Harold B. Sparr at 9:00 a.m.

The following Board members were present: Harold B. Sparr, R.Ph., MS, President, Donna M. Horn, R.Ph., Secretary, Dan Sullivan, R.Ph., Karen M. Ryle, R.Ph., MS, James T. DeVita, R.Ph., Dr. Robert P. Paone, R.Ph., Pharm. D., and Marilyn M. Barron, MSW, 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 December 04, 2001: approve ____ amend ____

Vote: Tabled

2. 9:30 a.m. to 10:00 a.m.

Update on the Pharmacy Registration Process

The purpose of the meeting was to provide Board staff with an opportunity to update the Board with regard to recent pharmacy technician registration developments.

- Applications
- FAQ
- Fees
- Discussion regarding Board strategy for review and approval of pharmacy technician training programs and pharmacy technician assessment examinations.

Jim DeVita recommended a form letter be developed for applicants seeking approval of a pharmacy technician training program or assessment examination. Such letter would require a summary and outline of the training program that demonstrates compliance with Board regulatory requirements

and includes a sampling (not actual exam) of examination questions.

Donna Horn inquired if Professional Credential Services (PCS) could establish procedures by which a company could submit batches of applications to PCS with a single check for the total number of applicants.

Carmelo Cinqueonce, Executive Vice President, Massachusetts Pharmacists Association (MPHA) stated that the Board-approved examination is available for distribution.

**3. 10:00 a.m. to 10:50 a.m.
OxyContin® Discussion.**

OxyContin® continued discussion.

DPL Director William Wood requested the Board to consider the April 23, 2002 decision regarding the exemption of OxyContin® from the requirements of 247 CMR 6.02(4), in response to the expressed interest of Secretary James Jajuga of the Executive Office of Public Safety (EOPS) to meet with Board members to discuss related issues.

A Motion was made by Karen Ryle to suspend the April 23, 2002 OxyContin vote until such time that the Board could meet with Secretary Jajuga. Seconded by Bob Paone. Discussion: Jim DeVita commented that he was encouraged that the Secretary of EOPS was interested in meeting with the Board but was disappointed that it took the Board's April 23, 2002 decision to prompt EOPS's attention. In addition, DeVita stated that the Board's proposed OxyContin policy implementation date of July 1, 2002 provided ample time for the Board to meet with EOPS and other related stakeholders and therefore a suspension of the Board's vote was not necessary.

An amended Motion was made by Karen Ryle to suspend the April 23, 2002 OxyContin vote until the sooner of a meeting with Secretary Jajuga or the May 28, 2002 Board meeting. Seconded by Bob Paone.

Vote: In favor - Ryle, Sparr, Barron, Horn, Paone, Sullivan; Opposed - DeVita. The motion carried.

**4. 11:00 a.m. to 11:45 a.m.
Lynn Community Health Center 340B Program Discussion
Lynn Community Health Center, 269 Union Street, Lynn, Massachusetts
Executive Director Lori Berry.**

Representatives from the Greater Lynn Community Health Center (LCHC) and Eaton Apothecary, joint participants in a 340B initiative, appeared to discuss petition for location of LCHC clinic pharmacy on site of Eaton Apothecary.

Present:

Lynn Community Health Center: Ex. Dir. Lori Berry, Sophie McIntyre, R.Ph.
Eaton Apothecary's Manager of Record; David Dumouchel, Eaton Apothecary;
DPH/DCP - Dr. Grant Carrow, Adele Audet and Michael Mozzer;
DPH/HCQ: Donna Allan

Lori Berry provided an overview of the April 16, 2002 proposal memorandum. Berry stated the objective of the LCHC proposal was to comply with the Comm. of MA Division of Health Care Finance and Policy regulations establishing the conditions to be met for a community health center to Provide prescription medications to qualified individuals under state financed programs and bill the fund referred to as the "Uncompensated Care Pool" for such medications in accordance with all statutory and regulatory requirements. Due to space and financial constraints, and also based on the fact that LCHC has had a successful partnership with Eaton Apothecary (since January 2000 through an expiring demonstration project grant), LCHC seeks to establish a LCHC clinic licensed pharmacy within Eaton Apothecary to service LCHC patients.

David Dumouchel of Eaton Apothecary explained that the LCHC license would generate the third party billings for qualified patients and that LCHC would purchase medications at the LCHC authorized 340B specified program pricing.

DPH representative Dr. Carrow stated the DPH/DCP preliminary agreement with LCHC is limited to Schedule VI controlled substances.

Berry represented that the current arrangement between LCHC and Eaton's has been to replenish the drug utilized (LCHC does not take physical possession of medications). Berry stated that a medication inventory "owe list" is maintained with no problems to date per audit review. All decisions regarding status and program eligibility of LCHC patients are made by LCHC.

Board member Dan Sullivan inquired about the "uncompensated care pool" billing arrangement. Dumouchel explained that the "uncompensated care pool" was established to cover provide prescription medication costs for a specifically defined income eligible patient group.

Ex. Dir. Chuck Young noted that any enrolled 340B program pharmacy was subject to accountability audits from supplier and manufacturer federal authorities. Young noted that Eaton Apothecary and the LCHC pharmacy would be required to maintain separate records and label prescriptions according to which license issued the prescription.

A Motion was made by Harold Sparr to take the matter under advisement. Jim DeVita seconded. The motion carried.

Later in the afternoon, a Motion was made by Jim DeVita to re-open the matter for discussion. Harold Sparr seconded. The motion carried.

Discussion: Susan Manning and Chuck Young stated that current Board regulations included no section that disabled the LCHC proposal.

A Motion was made by Bob Paone to approve the LCHC waiver proposal. The motion was not seconded.

A Motion was made by Bob Paone for the Board to request additional information from LCHC as to expressed financial and space limitations to locate a pharmacy on the clinic site. Harold Sparr seconded the motion. The motion carried.

5. 11:45 a.m. to 12:30 p.m.

MPHA Legislative Update: Carmelo Cinqueonce, Executive Vice President, Massachusetts Pharmacists Association.

The purpose of the meeting was to provide an opportunity for Mr. Cinqueonce and or MPHA representatives to continue discussions with the Board specific to Senate Bill 2336 (formerly Senate Bill 395).

Mr. Cinqueonce updated the Board with regard to the following matters: Massachusetts Division of Medical Assistance claims reimbursements, Senator Moore's Healthcare Bills, the Medical Malpractice Bill, the Standardized Prescription Benefit Card (in House) and the Mail Order related Bill.

With regard to amended Senate Bill 2336, filed jointly by Senators Walsh, Moore and Jacques, MPHA remains opposed to the bill. MPHA is specifically concerned with the fining authority authorized in the bill.

6. 12:30 p.m. to 1:30 p.m.

Lunch

7. 1:30 p.m. to 2:00 p.m.

**Massachusetts Independent Pharmacists Association (MIPA)
Corresponding Responsibility Discussion.**

MIPA will be represented by Attorney Robert C. Pavlan, Jr. R.Ph.

Present: Robert Pavlan, Esq. and Steve Bernardi, R.Ph., Johnson Drug, Waltham, MA.

Steve Bernardi stated that he requested appearance to be proactive regarding policy development in the matter of corresponding responsibility.

Bernardi and Atty. Pavlan provided an overview of a Johnson Drug draft policy regarding corresponding responsibility described as designed to improve communication with prescribing practitioners.

Atty. Pavlan outlined corresponding responsibility scenarios for the Board to consider, including signed and unsigned patient waivers, prescriber communications and documentation related to prescription indication(s) for use.

Bernardi stated that he intended to implement the policy at his pharmacy for selective medications for "chronic" patient administration rather than acute dosing.

Bob Paone remarked that corresponding responsibility is part of the art of the pharmacy profession and noted the Board evaluates all corresponding responsibility related complaints on a case by case basis. He stated the Board seeks to determine whether any pharmacist named in a corresponding responsibility complaint has met the professional practice standards in any particular case

Jim DeVita commented that there are no clear answers to corresponding responsibility issues but pharmacists should exercise good professional judgement in daily practices understanding their activities subject to peer review.

8. 2:00 p.m. to 3:30 p.m.

Administrative Business Meeting: to include Board Counsel update, requests for advisory opinion and monthly correspondences. Charles R. Young, Executive Director, Susan Manning, Board Counsel and James D. Coffey, Associate Director.

The purpose of the meeting was to address the following items with the Board:

- a) NABP correspondence regarding request for 2002-2003 Committee Volunteers: FYI (May 31, 2002 request for response).
Discussion: The Board was advised to contact NABP in writing if any Board members were interested in seeking related committee appointment.
- b) NABP correspondence regarding "Implementation of the Comprehensive Methamphetamine Control Act of 1996": FYI.
- c) State of Rhode Island "Collaborative Pharmacy Practice" legislation: FYI.
Discussion: The Board reviewed the above referenced legislation and commented that the model looked like a good starting template for strategic planning and or related task force consideration. The Board requested Board

counsel to draft a similar collaborative practice model for subsequent review. The Board proposed the following related action steps; 1) work with state pharmacy associations to engender legislative support for future collaborative practice proposals and 2) discuss on the June 11, 2002 Board Agenda, the need and or role for a collaborative practice Board task force.

- d) Application for Intern Registration (Candidate K.D.V). Board Review of disciplinary action.

Vote: Approve Deny .

A Motion was made by Dan Sullivan to approve the internship application.

The motion was seconded by Karen Ryle. The motion carried unanimously.

- e) Registrant, David L. Lambert, License Number 22821 / Expiration 12/31/1996: request for Board reinstatement:

Discussion: The Board reviewed the reinstatement request and requested both David L. Lambert and Dick Sharp (CVS Regional Healthcare Manager) to appear before the Board on May 28, 2002 to discuss the matter.

- f) Application for Intern Registration (Candidate T.W.B). Board Review of disciplinary action.

Vote: Approve Deny Other

The Board reviewed the application and entertained discussion on the matter.

A Motion was made by Harold Sparr to table the vote pending the receipt of additional documentation. The motion was seconded by Bob Paone. The motion carried unanimously. The applicant must notify the MA Board in writing whether the applicant has applied for and been denied internship registration with the Oregon Board of Pharmacy. A record of internship standing shall be requested by MA Board the Oregon Board.

- g) In the matter of PH-97-010, Registrant Susan B. Sullivan, License Number 16446, request for removal of probation (conditional documentation outlined in the consent agreement was previously submitted to the Board: compliant)

Vote: Approve: Deny: .

The Board reviewed the documentation and entertained discussion on the matter. A Motion was made by Jim DeVita to approve the request for removal of probation. Seconded by Donna Horn. The motion carried unanimously.

- h) NABP correspondence regarding "US Dept. of Health and Human Services Proposed Rule to Amend Federal Privacy Regulations":

Discussion: Karen Ryle provided the Board with an overview of the proposed rule to amend Federal Privacy Regulations.

- i) April 16, 2002 Stop & Shop correspondence regarding **OxyContin**.

Discussion: The Board reviewed and discussed the letter.

A Motion was made by Bob Paone for the Board to seek response from Stop & Shop Pharmacy regarding the April 16, 2002 letter and Board regulations compliance. The motion was seconded by Harold Sparr.

Vote: In support: Bob Paone, Harold Sparr, Marilyn Barron and Dan Sullivan.

Opposed: Jim DeVita, Karen Ryle and Donna Horn. The motion carried.

- j) NABP's 98th Annual Meeting Proposed Resolutions: for related Board discussion and vote:

Resolution No. 98-1-02: Reformulation of OxyContin®: support.

- Resolution No. 98-2-02: Public Service Announcement: support.
- Resolution No. 98-3-02 Support for HR Bill#2173: support.
- Resolution No. 98-4-02 Collaborative Interventions to Reduce Medication and Dispensing Errors: support.
- Resolution No. 98-5-02 Support for Senate Bill #974: support but Board stipulated related amendment to S. 974 as well as support for any other bill that recognizes pharmacists as healthcare providers.
- Resolution No. 98-6-02 Consumer Representative on Executive Committee: In support provided the committee representative is added to the existing committee format: Sparr, Ryle, Paone, Barron, Sullivan, DeVita; opposed: Horn. The motion carried for support.
- Resolution No. 98-7-02 Education and Compliance with Current Standards of Practice of Preparation and Adm. of Cytotoxic Drugs: no Board position.
- Resolution No. 98-8-02 Scheduling of Carisoprodol to Schedule IV: support.
- Resolution No. 98-9-02 Impaired Pharmacists and Pharmacy Technicians: support.
- Resolution No. 98-10-02 NCPDP Unique Prescriber Number: support.
- Resolution No. 98-11-02 Financial Information Reporting: oppose interested parties shall instead refer to the NABP Annual Report.
- Resolution No. 98-12-02 Flavoring of Prescription Medications by Pharmacists: oppose.
- Resolution No. 98-13-02 Impaired Pharmacists Peer Review: support.
- Resolution No. 98-14-02 Recognition Resolutions: support.
- k) In the matter of DS-02-034 & PH-02-051: Board re-discussion related to February 05, 2002 Board complaint committee decisions (no handout/ Board staff will review). Discussion tabled (Investigator shall be present).
- l) In the matter of DS-02-040 & PH-02-047: Board re-discussion related to February 05, 2002 Board complaint committee decisions (no handout/ Board staff will review). Discussion tabled. (Investigator shall be present).
- m) NABP's 98th Annual Meeting, May 18-22, 2002, Phoenix, Arizona:
Discussion: The Board reviewed the NABP Annual Meeting Agenda.
- n) Potassium Iodide NABP Resolution proposed by Chuck Young:
Discussion: Chuck Young provided the Board with an overview of the NABP resolution. Young advised the Board that he would invite DPH/ DCP Assistant Director, Adele Audet to a future Board meeting to discuss Potassium Iodide public health initiatives related to labeling, packaging and distribution. Bob Paone stated that NABP should consider means to resolving the dosing issue between Anbex (manufacturer) and the FDA and or suggest that a 16mg Potassium Iodide chewable tablet be formulated. Bob Paone and Chuck Young remarked that medical literature suggests that a daily dose of Potassium Iodide shall be taken by those affected by a nuclear incident until any public emergency period is lifted.
- o) Grand Rounds Presentation (Hospital / Industry consortium): June 12, 2002:
Discussion: Chuck Young advised the Board that 5 questions needed to be developed by the Board for the Grand Rounds CE Program.

- p) Board Agenda: Dan Sullivan requested that Board staff record full names rather than initials of all parties identified on future Board agendas.
- q) Pharmacy Benefit Managers (PBM): Dan Sullivan provided the Board with an overview of PBM rebates specific to switching, performance and access. Dan Sullivan suggested that the Board should discuss role and oversight of PBM's on future Board meeting dates. Donna Horn commented that a related NABP task force report on PBM's would be presented at the NABP Annual Meeting in Phoenix, Arizona.

9. 3:30 p.m. to 4:45 p.m.

Strategic Planning Meeting

**Donna M. Horn, Board Secretary and Chairwoman of the Boards
Strategic Planning Committee.**

The purpose of the meeting was to provide the Board with an opportunity to continue its discussions related to strategic planning. The Board tabled the discussion until June 11, 2002 being that other Board business carried over the outlined time frames.

10. 4:45 p.m.

A Motion was made by Donna Horn to adjourn the meeting. The meeting was seconded by Karen Ryle. The motion carried. Meeting Adjourned.

Respectfully submitted by:

Donna Horn *6-13-02*
Executive Director Date

Charles Youty
Printed Name

Reviewed by counsel: June 06, 2002
Draft approved: June 07, 2002
Board adopted: June 11, 2002