

**BOARD OF REGISTRATION IN PHARMACY
MINUTES
BOARD MEETING
TUESDAY, APRIL 23, 2002
239 CAUSEWAY STREET, ROOM 206
BOSTON, MASSACHUSETTS 02114**

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

The following Board members were present: Donna M. Horn, R.Ph., Secretary, Dan Sullivan (10:50 a.m.), 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 (10:45 a.m.), 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 & Investigative Conference Meeting

Introductions

James D. Coffey introduced Peter J. Dolan, Board Extern, Northeastern University School of Pharmacy. Dolan provided a summary of a telephone survey of 15 NABP member Boards of Pharmacy regarding quality related event (medication error) complaint protocols and dispositions. He reported other pharmacy boards are looking more closely at systemic workplace conditions that may contribute to quality related events. Also noted few boards hold investigative conferences for first time reported pharmacist medication errors provided that the patient experienced no harm and the matter did not involve alleged erroneous counseling.

Chuck Young introduced Dr. Arthur Chaput, recently accepted PT Quality Assurance Surveyor position. Dr. Chaput has over 23 years of practical experience in retail, hospital and long-term care pharmacy areas and has implemented CQI policies in current position as Manager of Record for a long-term care pharmacy.

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.

Application Forms were reviewed with the Board.

- 12/31/02: the expected date by which the majority of MA pharmacy technicians should be registered by the Board.
- FAQ: final version will be posted on the Board's website.
- Fees: \$85 Professional Credential Services (PCS) application fee and a \$38 Board registration fee.

Review of Albertson's (Osco Drug) request for Board approval of employer administered pharmacy technician assessment examination.

Recusal: Donna Horn.

The Board reviewed the examination and determined all required knowledge areas were covered.

A **Motion** was made by Jim DeVita to approve the Albertson's (Osco Drug) examination. Seconded by Bob Paone.

Vote: In support: Karen Ryle, Bob Paone, Jim DeVita; Opposed: none; Recused: Horn. The motion carried.

Carmen Cingeounce, Executive Vice President for MPHA, reported MPHA's Board-approved pharmacy technician assessment examination would be ready for distribution shortly. The examination would be available for purchase by pharmacy employers - \$30 for non-MPHA members/\$15 for members. MPHA will provide 3 sets of the examination - employer will be responsible for copying the examination for administration.

3. 10:00 a.m. to 10:50 a.m.

MassMedline Presentation

Pharmaceutical Strategies - Dennis G. Lyons, Pres. and MCPHS

Worcester Dean Dr. Douglas J. Pisano.

Dennis Lyons and Doug Pisano described the MassMedline program - a public-private partnership providing medication education to healthcare providers and patients. Lyons described opportunities for MCPHS students to be involved in drug therapy management initiatives and stated most calls involve payment issues.

Dr. Pisano suggested that MCPHS may approach the Board with MassMedline related proposals including clinical waivers for students to receive internship credit for MassMedline participation; development of a MassMedline counseling center at MCPHS; and expansion of current Board internship supportive personnel ratios.

4. 11:00 a.m. to 11:50 a.m.

OxyContin® Discussion.

The Board continued its discussion of OxyContin® related matters. Alan A. Wartenberg, M.D., an internal medicine addiction specialist, did not appear as scheduled.

Susan Manning provided a summary of the March 25, 2002 NACDS meeting, attended by Board staff and several Board members, regarding OxyContin® and related concerns. The Board reviewed draft language prepared for Board consideration: "Effective July 1, 2002 and continuing until further notice, the Board of Registration in Pharmacy (Board) will not require pharmacies or pharmacy departments to stock OxyContin® to comply with the requirements of 247 CMR. 6.02(4). Pharmacy and Pharmacy departments that discontinue stocking of OxyContin® must provide adequate notice to both patients and appropriate prescribers that OxyContin® will no longer be provided by a particular pharmacy. Information as to alternative sources should also be provided to interested parties. The Board 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."

Chuck Young noted that no complaints had been registered with the Board regarding any clinic pharmacy's decision (BMC or HVMA) to delete OxyContin® from formulary.

After extensive discussion regarding the proposed vote and shared concern as to assured continued access for legitimate pain management patients and possible adverse effects such vote could have on such patients, a Motion was made by Donna Horn to adopt a revised OxyContin® policy, with any agreed upon revisions to the final wording of such policy - the essence of the vote being that, effective July 1, 2002, the Board would not require pharmacies or pharmacy departments to stock OxyContin® to comply with 247 CMR 6.02. Seconded by Karen Ryle.

Vote: In support: Jim DeVita, Donna Horn, Karen Ryle, and Marilyn Barron. Support of absent member President Harold Sparr noted for record. Opposed: Bob Paone and Dan Sullivan. The motion carried.

Board members agreed the policy and related OxyContin® conversion charts should be posted on the Board's website.

5. 11:50 a.m. to 12:20 p.m.

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

Mr. Cinqueonce provided update regarding legislative affairs affecting the practice of pharmacy. In addition, MPHA requested to meet with the Board to discuss Senate Bill 2268 (formerly Senate Bill 395).

Update:

Medical Malpractice Bill #1039 (still in Ways & Means), Massachusetts

Division of Medical Assistance claims reimbursements (meetings ongoing with involved law firms with the intent to bring closure to the matter, Senator Moore's Healthcare Bills, the Medical Malpractice Bill, and the Standardized Prescription Benefit Card (in House) and the Mail Order related Bill (if it does not pass MPHA will seek to re-introduce Bill). He noted NACDS has expressed concerns for the Bush Drug Discount Card proposal. MPHA supports both the Emery / Ross Bill (pharmacists cognitive services) and the Conyers Bill (health care providers). MPHA may conduct community education programs and put forth a pharmacist related reference manual regarding HIPAA.

MPHA remains opposed to the revised fining bill. Mr. Cinqueonce requested the Board reconsider its support for Senate Bill 2268 until further dialogue with MPHA.

A **Motion** was made by Donna Horn to schedule 1 hour on the May 07, 2002 Board Agenda for continued discussion with MPHA regarding Senate Bill 2268. Seconded by Jim DeVita. The motion carried.

A **Motion** was made by Jim DeVita to schedule 2 hours on the May 07, 2002 Board Agenda for continued discussion of Board Strategic Planning. Seconded by Bob Paone. The motion carried.

6. 12:20 p.m. to 1:20 p.m.

Lunch

7. 1:20 p.m. to 2:00 p.m.

Investigative Conference: DS-02-052 & PH-02-061

In the matter of Walgreens Pharmacy #2699, 54 East Street, Ludlow, MA, 01056 (Permit #2129) and Registrant, Joseph G. Godek, R.Ph., (License # 15314).

The complainant alleged that on or about December 07, 2001, the Registrant Dispensed Zyrtec 10mg tablets rather than Levoxyl 0.2mg tablets as prescribed while employed at Walgreens Pharmacy #2129, 54 East Street, Ludlow, Massachusetts.

Investigator: Leslie S. Doyle

Consumer: Not present

RPH: Michael G. Godek

Manager of Record: Michael G. Godek

Walgreens Representative: Steve Pashko, District Manager

Godek stated he had previously appeared before the Board regarding a medication error complaint (Summer 01) in capacity as Manager of Record. In this matter, two prescriptions were dispensed in one bag with one receipt. He said he was informed by a staff technician (Kelley) that the complainant returned the incorrectly dispensed medication to the pharmacy.

According to the technician, the patient ingested three tablets before the error was reconciled and was doing well. Godek stated that an apology was offered to the complainant.

Godek reported that a staff in-service was conducted after the incident to review proper checking and or verification procedures to include an NDC check and pill imaging review at the verification terminal.

Steve Pashko, Walgreens Pharmacy Supervisor, stated that according to computer records, Godek data entered and verified the prescription at issue late on a Wednesday evening while he was on duty alone. On the incident date, Pashko stated that approx. 170 prescriptions were processed over a 14-hour period with two pharmacist shifts.

Godek stated no Walgreens facility required pharmacists to check hardcopy prescription upon first refills. He stated this pharmacy does not have image technology specific to scanned prescriptions.

Pashko described training procedures as including a Walgreens PTCB certified pharmacy technician conducting all new hire training with regard pharmacy supportive personnel, who are directed to solicit communication with the patient/agent during with prescription pick-up including seeking patient/agent address.

Godek was compliant regarding 2000 and 2001 CE requirements.

Board Decision:

A **Motion** was made by Bob Paone to issue an Advisory Letter to both the Godek and Walgreens Pharmacy for the failure to fill a prescription properly and require filing of a USP PRN Medication Error Report (copy to the Board) and completion of a two hour ISMP CE Program for Medication Error Reduction (original CE Certificates to the Board within thirty (30) days). Seconded by Karen Ryle.

Discussion: Jim DeVita amended the motion to require Pashko to submit information to the Board detailing corrective measures implemented by Walgreens corporation to assure that pharmacy patients receive correctly packaged medications following pharmacist final product verification (any such measures may include consideration for clear bagging techniques).

Vote: Unanimous in favor.

8. 2:00 p.m. to 2:40 p.m.

Investigative Conference: DS-02-026 & PH-02-049 & PH-02-065

In the matter of Nantasket Inc., 480 Nantasket Avenue, Hull, MA, 02045 (Permit #2038) and Registrants, Joan A. Tyrell, R.Ph., (License # 20272) and Brigida P. Panetta, R.Ph., (License # 24813).

The complainant alleged that on or about August 27, 2001, Registrants dispensed Zyrtec Syrup rather than Zantac Syrup as prescribed while employed at Nantasket Pharmacy Inc., 480 Nantasket Avenue, Hull, Massachusetts.

Investigator: Alan Van Tassel

Consumer: Not present

RPH: Tyrell & Panetta

Nantasket Pharmacy Inc. representative: Tenaglia

Nantasket Pharmacy Inc. Manager of Record: Tenaglia

Registrants were determined to be complaint with 2000 and 2001 CE requirements. No prior appearances before the Board.

Tyrell acknowledged responsibility for the medication error. Tyrell stated that the incorrectly dispensed medication was returned to the pharmacy for consult. The pharmacist on duty compared the medication dispensed with pharmacy stock products and determined by means of both a visual and smell tests that an error occurred (berry or cherry smell vs. lime).

Tyrell stated that according to the complainant, the patient ingested 3 to 4 doses of incorrect medication. The complainant discovered the error because the patient had been on the Zantac medication previously without incident. Tyrell indicated that at the time of the incident both Zantac and Zyrtec were stocked side by side on the pharmacy shelf.

Tenaglia reported that the pharmacy did not have a formal policy in place for reporting and error follow-up at the time of this incident. The pharmacy has been awarded a grant from the Department of Employment and Training providing for a 10 week training program and consultant to develop pharmacy policies related to decreasing prescription, errors, medication error incident reporting, and proper pharmacy staff training.

Tenaglia stated that the pharmacy did speak to the prescriber about the medication error. Tenaglia reported he reviewed checking and verification procedures with pharmacy staff and separated look alike sound a-like drugs on the pharmacy shelves. A written policy is being developed regarding medication error reporting.

Tyrell stated that she spoke to patient about the medication incident the day after it was reported to the pharmacy. Tyrell said that the patient was upset because she wanted to speak to the Pharmacy Manager about the incident but he was away for Labor Day weekend.

Dispensing Pharmacist of Record Tyrell reported the pharmacy was adequately staffed on the incident date – approx. 289 prescriptions were filled that day by one pharmacist and one technician. Tyrell stated she was likely

was distracted at the time of the misfill.

Board Decision:

A **Motion** was made by Jim DeVita to Dismiss the PH-02-065 complaint against Brigida P. Panetta due to insufficient evidence. Seconded by Karen Ryle. The motion carried unanimously.

A **Motion** was made by Bob Paone to issue an Advisory Letter to both the Registrant (Tyrell) and Nantasket Pharmacy Inc. for the failure to fill a prescription properly and require the filing of a USP PRN Medication Error Report (copy to the Board) and completion of a two (2) hour ISMP CE Program for Medication Error Reduction (original CE Certificates to the Board within thirty (30) days). In addition, the Nantasket Pharmacy Inc. Manager of Record (Tenaglia) shall submit the Board a copy of pharmacy policies and procedures specific to medication error (quality related event) consumer incident reporting and appropriate pharmacy follow up protocols. Seconded by Jim DeVita.

Vote: The motion carried unanimously.

9. 2:40 p.m. to 3:20 p.m.

Investigative Conference: DS-02-051 & PH-02-059

In the matter of CVS Pharmacy #860, 6 Post Office Square, Harwichport, MA 02646 (Permit # 1406) and Registrant, Nancy K. Barsic, R.Ph., (License # 21269).

The complainant alleged that on or about August 06, 2001, the Registrant dispensed Seroquel rather than Serzone as prescribed while employed at CVS Pharmacy #860, 6 Post Office Square, Harwichport, Massachusetts.

Investigator: James C. Emery

CVS Representative: Board requests that the CVS corporate office be provided with a notice for appearance.

Registrant: Nancy Barsic

CVS Manager of Record: Lawrence Favreau (no longer employed by CVS)

Consumer: Brother of complainant present with Anne Marie Maguire, Esq.

Recusal: Board member Jim DeVita recused himself from the conference.

Board Counsel Susan Manning advised the Board that the investigative conference may proceed as scheduled without CVS corporate representatives; Board may schedule investigative conference for CVS in future.

Lawrence Favreau, CVS Pharmacy Manager of Record, and Charlie Martineau, CVS Regional Healthcare Manager, are not currently employed by CVS.

Investigator Emery's report was disputed only as to number of days medication allegedly taken (4v. 3).

Registrant Barsic suggested error might be related to fact the medications at issue were stored side by side on the pharmacy shelf. She was the only pharmacist on duty during the shift at issue (1st Monday of the month).

Manager of record Favreau stated that an overlap pharmacist is usually available on Mondays but no secondary pharmacist coverage was available on the incident date.

Barsic stated she believed that a manufacturer's unit of use bottle was dispensed by CVS to the complainant and that the manufacturer unit of use label was partially covered over by the CVS pharmacy prescription and auxiliary labels.

Favreau stated that traditionally on weekdays between 4 -6pm, many physician phone calls and drug interaction reviews take place.

Barsic stated that in May she had verbally requested additional pharmacist coverage from CVS. She reported her requests were "repeatedly rebuffed" by management. She noted management would often call her in the morning regarding staffing availability. On the incident date, she was the only pharmacist on duty responsible for receiving new physician orders, checking prescriptions and counseling patients. She and Manager Favreau would routinely come into the pharmacy early and stay late to keep up with prescription volume. No interns worked at the pharmacy.

Registrant Barsic said that around the 3rd Monday of June, the CVS District Manager advised her no additional pharmacy staffing was available. She stated that she advised her CVS District Manager that she would be sick the following day. Barsic reported she was later disciplined by CVS as "insubordinate" for the sick notice that day.

Manager Favreau reported that an incident report was filed with CVS headquarters. Favreau said that he was on duty when the original prescription at issue was returned to CVS by the complainant's family. Favreau stated that he contacted the prescriber's office about the incident. Favreau stated that the CVS "EPIC" system was in place at the time of the incident. He stated he discussed the incident with pharmacy staff and reinforced the NDC medication checking method and affirmed that written pharmacy policies and procedures are in place at the pharmacy. On the incident date, one pharmacy intern, one pharmacy technician (Marybeth), one pharmacist were on duty along with cashiers and/or front store personnel. The pharmacy did not have the automated "IVR" system in place at the time of the incident. Favreau reported the typical summer weeks prescription volume to average 1800 -1950 prescriptions in that pharmacy, with the vast majority being new prescriptions for new patients.

Troy Dobson (non-pharmacist) advised the Board that he was the CVS Pharmacy District Manager at the time of the incident and was responsible for overseeing staffing matters.

As to post incident measures, Barsic reported that the medications at issue were separated on the pharmacy shelves. She noted that the CVS "Quality First" pharmacist education program was not offered by CVS in that geographic area at the time of the incident. No bar code scanning was in place at the store specific to the incident.

According to complainant's counsel, the patient's family asked for copy of the CVS incident report but such was not provided.

Board Decision:

A Motion was made by Bob Paone to take the matter under advisement pending investigative conference with CVS Pharmacy. Seconded by Karen Ryle. The motion carried unanimously (DeVita recused).

10. 3:20 p.m. to 4:45 p.m.

Administrative Business Meeting: included 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) In the matter of DS-02-028 & PH-02-031: Board re-discussion related to March 26, 2002 Board decisions (no handout/Board staff will review). Discussion: Board staff reviewed the complaint file with the Board and the Board decided that the former decision would remain unchanged.
- b) Newsday Home Healthcare Association Newsletter, April 2002: page 3 "HHS Amends HIPAA Rules": FYI.
- c) Joint Commission of Pharmacy Practitioners memorandum regarding "JCPP Considers Roles of Pharmacists and Pharmacies in Emergency Preparedness and Response: FYI.
- d) FDA Notice regarding Nicotine Lollipops & Lip Balm: FYI.
- e) Registrant, Frank C. Condella, Jr., License Number 16817 / Expiration 12/31/2000: request for Board CE and reinstatement guidance based on personal circumstances described in correspondence.

Vote: Approve X Deny Conditions:

A Motion was made by Dan Sullivan to approve the request for reinstatement provided that Condella remedies 3 CE's for each CE deficient and passes the MPJE examination. Seconded by Karen Ryle. The motion carried unanimously.

- f) In the matter of PH-99-050, Registrant Lydia Lau, License Number 21806, request for removal of probation (conditional documentation outlined in the consent agreement was previously submitted to the Board: compliant)

Vote: Approve: X Deny: Motion:

A **Motion** was made by Dan Sullivan to approve the Registrant request for removal of probation. Seconded by Karen Ryle. The motion carried unanimously.


- g) NABP Delegate Certification Notice for NABP's 98th Annual Meeting, May 18-22, 2002, Phoenix, Arizona: "Procedures for Delegates and Alternates": FYI.
- h) NABP's 98th Annual Meeting Proposed Resolutions: for related Board discussion and vote: Discussion Tabled until May 07, 2002.
 - Resolution No. 98-1-02: Reformulation of OxyContin®: support/oppose
 - Resolution No. 98-2-02: Public Service Announcement: support/oppose Resolution
 - No. 98-3-02 Support for HR Bill#2173: support/oppose
 - Resolution No. 98-4-02 Collaborative Interventions to Reduce Medication and Dispensing Errors: support/oppose
 - Resolution No. 98-5-02 Support for Senate Bill #974: support/oppose
 - Resolution No. 98-6-02 Consumer Representative on Executive Committee: support/oppose
 - Resolution No. 98-7-02 Education and Compliance with Current Standards of Practice of Preparation and Adm. of Cytotoxic Drugs: support/oppose
 - Resolution No. 98-8-02 Scheduling of Carisoprodol to Schedule IV: support/oppose
 - Resolution No. 98-9-02 Impaired Pharmacists and Pharmacy Technicians: support/oppose
 - Resolution No. 98-10-02 NCPDP Unique Prescriber Number: support/oppose
 - Resolution No. 98-11-02 Financial Information Reporting: support/oppose
 - Resolution No. 98-12-02 Flavoring of Prescription Medications by Pharmacists: support/oppose
 - Resolution No. 98-13-02 Impaired Pharmacists Peer Review: support/oppose
- i) 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.
- j) 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). The Board re-affirmed the decision previously approved.
- k) Final Policies on Return for Re-dispensing of Medications from Long term Care Facilities: FYI. (handout) FYI
- l) May 09, 2002 "Unit Dose Training Session for Nursing Facilities" related to new return and reuse policy: Lombardo's in Randolph 9 am to 12 pm: for Discussion regarding Board involvement: Dr. Paone volunteered to represent the Board at the training session.
- m) Potassium Iodide NABP Resolution proposed by Chuck Young: for Discussion: Chuck Young provided the Board with an overview of his request to draft a "KI" policy. The Board encouraged Mr. Young to draft a related policy for submission to NABP for related consideration (130mg adult KI dose / 16mg child KI dose).
- n) Grand Rounds Presentation (Hospital / Industry consortium): June 12, 2002: for Discussion: Chuck Young advised the Board that the CE program would begin at 6 p.m. on June 12, 2002 and would involve on or about 4 case study models review and discussion.

- o) April 16, 2002 Boston Globe article "Punishment Infrequent for Pharmacists in Massachusetts: for discussion: FYI.
- p) Overview of Division of Medical Assistance (DMA) position: Chuck Young advised the Board that according to DMA representatives contract pharmacies may bill a patient cash for a "non-covered DMA prescriptive service".

11. 4:45 p.m.

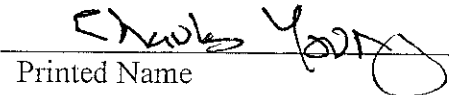
A Motion was made by Donna Horn to adjourn the meeting. The motion was seconded by Bob Paone. The motion carried. Meeting adjourned.

Respectfully submitted by:


Executive Director

7.1.02

Date


Printed Name

Reviewed by counsel: June 20, 2002

Draft approved: June 20, 2002

Board adopted: June 25, 2002