

Board of Pharmacy
Secretary of State, Office of Professional Regulation
National Life Building, North, Floor 2, Montpelier, VT 05620-3402

**Unapproved Minutes
Meeting of April 22, 2009**

1. The meeting was called to order at 9:00 A.M.

Members present: Steven M. Vincent, R.Ph., Chairman; Julie A. Eaton, R.Ph., Vice-Chair; Larry Labor, R.Ph.; Earl W. Pease, Pharm.D.; Emma J. Pudvahand Jeffrey P. Firlik, R.Ph.
Absent: Ann Overton, Secretary.

OPR Personnel present: Larry S. Novins, Board Counsel; Gregg Meyer, State Prosecuting Attorney, Daniel Vincent, Inspector; Carla Preston, Unit Administrator, and Kristy Kemp, Administrative Assistant.

Others present: Kerri Ryan with CVS Pharmacies, Mark Polli with Hannaford Pharmacies, and Bob Frenier with the Chelsea Health Center.

2. The Chair called for approval of the Minutes of the March 25th meeting. On page 8, #22 Other Business, the first sentence was amended to clarify that it pertained to a Telepharmacy Pilot Project. Thesecond sentence was amended to read: Concerns wereraised about the technician who is employed by the Plainfield Health Center but supervised by a pharmacist at the Community Health Pharmacy in Colchester. Ms. Eaton made a motion, seconded by Mr. Pease, to approve the Minutes of the March 25, 2009 meeting as amended. Motion passed unanimously.

3. **Guests:**

Bob Frenier, a Trustee with the Chelsea Health Center, attended the meeting to discuss their proposal for a type of mailbox system for patients to pick up their medications at the Chelsea Health Center which have been filled by the Price Chopper Pharmacy in West Lebanon, NH or by some other pharmacy. He presented the device, a "mailbox unit," to the Board and indicated that it has been approved by the Post Office.

Mr. Frenier explained that their patients are approximately 45 minutes from any drug store. He noted that about 40 percent are elderly and are Medicaid or Medicare patients. They are trying to find a solution for their patients to have easier access to their medications. He said the mailbox unit would be located in the waiting area and the receptionist is in sight of the unit. The pharmacy either owns or leases the unit and would stock it and lock it back up. He said once a patient received a prescription, he or she is given a key to a mailbox. The patient needs an account with the pharmacy. The prescription is forwarded to the drug outlet for a patient and is processed and adjudicated. The prescription is bagged and brought back to the Health Center later in the day and placed in assigned mailboxes. The patient then returns to the health center later in the day or the next day and unlocks the mailbox to retrieve their prescription. The patient then returns the key to the Health Center staff. The physicians and other health center staff have access to the keys. Mr. Frenier described the process as being similar to patients receiving prescriptions via mail. He said the Post Office prohibits duplication of the keys. He said there are steps to ensure that keys cannot be duplicated and noted that it is more secure than an individual's mailbox located at the end of their driveway.

Mr. Frenier said the facility has an alarm system and is temperature controlled. He said he was unsure whether the drug store would fill prescriptions for controlled substances. He said since the unit is located within the health center patients have access to counseling.

3. **Guests** - continued

The Board reviewed Part C, Section 12.1 (Prescription Pick-Up and Delivery) of the Rules to determine whether an amendment would be required to allow the current procedure or if it could be authorized under the current rules. Such proposals could only be granted on a case-by-case basis if demonstrated satisfactorily that it would be in compliance with the law. The Board asked for clarification about the dispensing of controlled drugs and how expired drug medication that are not picked up would be handled.

The Board asked for assurance that patients would have access to a pharmacist for counseling. Contact information for the pharmacist and drug outlet filling the prescription must be provided. The Board and its Counsel agreed that the current rule maybe interpreted to allow this proposal as described. The Board may amend the proposed draft rules under Section 8.17 to include a statement such as, "Upon showing of special circumstances, the Board may approve delivery to and pickup from a secure site in a medical facility under condition approved by the Board."

Mr. Freniers suggested having a plaque or handouts with the name and contact information for the drug outlets so that patients could receive counseling. He said the building is new and is alarmed. The mail boxes would not be in a remote area. He believed that sufficient security measures were in place. He said pharmacy staff will open up the drawer to the medication that had not been picked up.

The Board asked Mr. Frenier to report back to the Board in a year as to how this system was working. The Board indicated that based on the circumstances described, it did not object to controlled drugs being placed in the mailbox so that patients would have access to the medication they needed.

Ms. Preston will send a letter for the Board to Mr. Freniers supporting their proposal as discussed.

4. **Hearings/Stipulation *et al.***

- a. At 9:30 AM the Board considered a Stipulation and Consent Order in the matter of **Price Chopper Pharmacy #165**, Docket Number 2008-223 (RX76-0608). The Respondent was not present. Larry S. Novins presided for the Board. Gregg Meyer was present for the State. Chairman Vincent made a motion, seconded by Mr. Labor, to accept the Stipulation and Consent Order as presented. Motion passed. Ms. Pudvah, Investigating Member, did not participate in the vote.
- b. At about 10:00 AM the Board considered the State's Request for a Summary Suspension, in the matter of **Tara L. Dimick**, Docket Number 2009-21 (RX30-0109). The Respondent was not present. Larry S. Novins presided for the Board. Gregg Meyer was present for the State. Ms. Eaton made a motion, seconded by Ms. Pudvah, to summarily suspend Respondent's technician registration. Motion passed. Chairman Vincent, Investigating Member, did not participate in the vote.

5. **Follow-up Cases**

6. **Reports:**

Dan Vincent, Inspector, attended the meeting. He expressed concerns about persons who were not registered as technicians but who were in the pharmacy area. He said those persons may be cashiers or clerks but do handle prescriptions, have access to medications and to confidential information. He also mentioned other situations in which the store manager must pass through the pharmacy area for various purposes (i.e., use the fax machine).

6. **Reports** - continued

The Board confirmed that anyone who has access to pharmacy technician. This would include store managers when the pharmacist is present. The Board's portion of the pharmacy area as an office.

drug on a regular basis must be registered as a manager (or others) who pass through the pharmacy. The Board discourages store managers from using any

The Board's goal is to ensure tight access to the personnel to be in the pharmacy. The pharmacist should share responsibility to ensure that all personnel are registered (i.e., as pharmacy interns or pharmacy

rescription department and to allow only necessary duty, the pharmacist manager, and the employer working in the prescription department are properly technicians).

In summary, anyone who has access to prescription medication on a regular basis, regardless of their duties, must be registered. For example, if a clerk or cashier only checks out customers, but is located behind the counter in the prescription department, he or she must be registered as a pharmacy technician. This clarification additionally includes persons who have workstations in the pharmacy, package prepared prescriptions or handle prepared prescriptions in the will-call area (Title V.S.A. §2042b). The Board will include this further clarification in its Newsletter. 26

7. **Legislation/Rulemaking:**

The Board reported that Title 18, Sections 4605 and 4606 address electronic prescriptions. The current rule and the proposed section of the rules will also need to be changed to agree with the proposed statutory language.

4606 resubstitution needed to be amended to address the burden for prescribers. In addition, the proposed section of the rules will also need to be changed to agree with the proposed statutory language.

The Board discussed additional public comments submitted regarding the proposed changes to its Administrative Rules many of which pertained to the requirement for monthly Hydrocodone inventories. The issue was discussed at length. Members acknowledged the importance in reducing diversion but also realized that due to various types of systems, multiple wholesalers, and other factors that this requirement would take a considerable amount of time to accomplish. Several options were discussed which included eliminating the mandate altogether, requiring that only a few randomly selected products (purchased and dispensed), and soon. In the end the Board decided to remove the mandate from the regulations. Reminders will be included in the Board's Newsletter for pharmacists to perform an analysis of purchased and dispensed Hydrocodone products to help reduce diversion.

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Attorney Novins prepared the cover pages for the Final Proposed Rules. He said he would file them with the Interagency Committee on Administrative Rules (ICAR) in a few days. He said that based on this schedule he anticipates that the Board could hold a public hearing at its June meeting.

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8. **Complaints/Reports of Concluded Investigations**

9. **Applications for Licensure as a Pharmacist :**

10. **Drug Outlets:**

The Board reviewed the following applications for drug outlets and took action as indicated.

- a. **Kinney Drugs, Inc. #98**, Route 30, Bomoseen, VT submitted a new application to reflect a change in ownership (formerly Harbor Pharmacy). Inspector Vincent reported that he had completed the final

10. Drug Outlets - continued

inspection which was satisfactory. Based on the favorable inspection, Ms. Eaton made a motion, seconded by Ms. Pudvah, to approve this pharmacy for full licensure. Motion passed unanimously.

b. Pharmacy Health Services, Inc. d/b/a/ **Marble Works Pharmacy (Vergennes)** (038-3399), 187 Main Street, Vergennes, VT submitted a new application to reflect a change in ownership. Inspector Vincent reported that he had completed the final inspection which was satisfactory. Based on the favorable inspection, Ms. Eaton made a motion, seconded by Ms. Pudvah, to approve this pharmacy for full licensure. Motion passed unanimously.

c. Rite Aid of Vermont, Inc. d/b/a/ **Rite Aid Pharmacy #2481**, 107 East Main Street, Wilmington, VT submitted a new application to reflect a change in location (formerly Grand Union Shopping Center, 1 East Main Street, Wilmington). Inspector Vincent reported that he had completed the final inspection which was satisfactory. Based on the favorable inspection, Ms. Eaton made a motion, seconded by Ms. Pudvah, to approve this pharmacy for full licensure. Motion passed unanimously.

Instate Manufacturer/Wholesaler:

Equinox Compounding Pharmacy LLC, 34 Ways Lane, Manchester Center, VT, submitted an application for an in-state manufacturer/wholesale distributor. The applicants reported that approval from the Food & Drug Administration (FDA) is not required since they are only dealing with animal drugs. Based on that information, Ms. Eaton made a motion, seconded by Ms. Pudvah, to approve this drug outlet for full licensure as a manufacturer and wholesaler. Motion passed unanimously.

11. **Change in Pharmacist Manager:**

Mr. Laborn made a motion, seconded by Ms. Pudvah, to approve the changes in pharmacist managers for completed applications as indicated below. Motion passed unanimously.

a. **Rite Aid Pharmacy #10314**, (038-3360), located at 194 North Street, Bennington, Vermont, changed pharmacist managers from Kristin Hill to Mary Catalano-Tozier.

b. **Walgreens Pharmacy #01756**, (038-3345), located at 10 Woodstock Avenue, Rutland, Vermont, changed pharmacist managers from Donald Maloy to Laura McAllister.

c. **Costco Pharmacy #314**, (038-3117), located at 218 Lower Mountainview Drive, Colchester, Vermont, changed pharmacist managers from Thomas Drougasto to Marcie Jorgensen.

12. **Non-Resident Pharmacies:**

Ms. Eaton made a motion, seconded by Ms. Pudvah, to approve the following non-resident pharmacy for licensure. Motion passed unanimously.

a. **Lextron Animal Health**, 1117 West Main, Manchester, IA.

13. **Non-Resident Wholesaler/Manufacturer Drug Outlets:**

Ms. Eaton made a motion, seconded by Ms. Pudvah, to approve the following non-resident wholesale distributors and/or manufacturers for licensure based on their completed applications. Motion passed unanimously.

13. Non-Resident Wholesaler/Manufacturer Drug Outlets - continued
 - a. **Hospira Worldwide, Inc.**, 12 Forge Park Road, Franklin, MA.
 - b. **Midlothian Laboratories**, 780 Industrial Park Boulevard, Unit C, Montgomery, AL.
 - c. **The Proctor & Gamble Distributing, LLC**, 1832 Lower Muscatine Road, Iowa City, IA.
 - d. **Johnson & Johnson**, 3955 East Holmes Road, Memphis, TN.

14. **Drug Outlet remodeling, changes in Officers/Directors, hours of operation, etc.:**
 - a. Pharmacare Direct #1700, Largo, FL, reported that it closed as of March 31, 2009. Noted.

15. **Continuing Professional Education Requests:**

Chairman Vincent made a motion, seconded by Ms. Pudvah, to approve the following continuing professional education requests as indicated. Motion passed unanimously.

 - a. **“Vermont DUR Board Meeting,”** submitted by Andrew Miller, was approved for 2.5 hours of live (didactic) continuing professional education credit which was held on February 10, 2009. The approval number issued is CE335(L)-0409.
 - b. **“Highlight of the American Society of Clinical Oncologists 2009 Annual Meeting,”** submitted by Natalie Remillard with University of Vermont, was approved for 6.5 hours of live (didactic) continuing professional education credit which will be offered on June 19, 2009. The Board noted that this program is already approved as AMAC category 1 credits. The approval number issued is CE334(L)-0409.
 - c. The Vermont Pharmacists' Association submitted a request for approval of its four-hour program to be offered on June 7, 2009. Topics included: **“Safety in Vermont Community Pharmacies”** (1/2 hour), **“Pharmacy Safety and RX Patrol”** (1 hour), **“Reducing Controlled Substance Misuse—A New Tool for Vermont Pharmacists”** (1/2 hour) and **“Update on 2009 Pharmacy Board Rule Changes”** (1 hour). The program was approved for a total of four hours and issued number CE336(L)-0409.

16. **Intern/Preceptor application(s)**

Ms. Pudvah made a motion, seconded by Ms. Eaton, to take action on the following applications as indicated. Motion passed unanimously.

 - a. **Anthony J. Somaini**— submitted Intern's Evaluation of Internship Period and Preceptor's Affidavit of Internship Hours and was approved for the 500+ hours she earned during the period of May 20, 2006 through June 23, 2007 while working at Brooks Pharmacy #726, 355 North Main Street, Barre, Vermont.
 - b. **Nathan D. Mah**— submitted an Application for Registration of Intern and was approved.
 - c. **Matthew S. Covich**— submitted an Application for Registration of Intern and was approved.
 - d. **Kayla M. Manahan**— submitted an Application for Registration of Intern indicating three separate locations. Only one pharmacist was registered as a Preceptor at one of the locations. Additional information is needed.

17. **Pharmacy Technicians:** Total number of Active Registered Technicians is **1,536** (1288 Resident, 248 Non-Resident).

18. **Newsletter Topics!**

Topics for the next issue of the Newsletter will include the DEA's updated requirements for reporting Theft or Loss of Controlled Substances, an update as to the statutes of the proposed rules and anticipated rns, timeline, an article regarding wireless alarm systems, registration reminders for technicians and interns, reminder about renewals and specific information requested by the Board re types of pharmacies, updating the list of preceptors, etc.

19. **Miscellaneous Correspondence**

- a. The Board reviewed and discussed the March 30, 2009 E-mail from Jocelyn DePaolis-Thivierge, R.Ph. regarding DAW on an electronic prescription. The Board agreed that these provisions were outdated and burdensome to prescribers. This discussion prompted the Board's proposed statutory change to Title 18 V.S.A. §§4605 and 4606 to address this issue. Ms. Eaton agreed to respond to Ms. DePaolis-Thivierge.
- b. The Board reviewed and noted the April 17, 2009 letter from URAC, an organization which accredits pharmacy programs, the most recent pharmacy accreditation program being Mail Service Pharmacy Accreditation and Specialty Pharmacy Accreditation. The information will be kept on file as out-of-state pharmacies may seek accreditation from URAC and provide that information to the Board.
- c. The Board reviewed and noted the April 21, 2009 E-mail from Meika Zilberberg with the Vermont Department of Health, regarding the Vermont Prescription Monitoring System (VPMS) which has opened its registration process for Vermont license d Health Care Providers and Dispensers as of Monday, April 20, 2009.
- d. The Board reviewed and noted other miscellaneous correspondence.

20. **National Association of Boards of Pharmacy (NABP) Correspondence:**

- a. The Board reviewed and noted miscellaneous NABP correspondence.

21. **Public Comment**

Comments from guests were addressed above.

22. **Other Business Introduced**

23. The next meeting is scheduled for **Wednesday, May 27, 2009** at 9:00 AM.

Meetings in 2009 are scheduled as follows: **June 24th; July 22nd; August 26th; September 23rd; October 28th; and December 2nd.**

24. There being no further business, the meeting was adjourned at 1:30 PM.

Respectfully submitted,

Carla Preston, Unit Administrator
Office of Professional Regulation