

Board of Pharmacy

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

Unapproved Minutes Meeting of December 3, 2008

1. The meeting was called to order at 9:01 AM.

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

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

Others present: Rachel Thomas, R.Ph., Fred Doltz, District Manager for Rite Aid Pharmacies, Hugh Douglas Bryan, R.Ph., Joshua Diamond, Esq., Crystal Bousquet with Anthony Otis' Office, and Kerri Ryan, R.Ph. with CVS Pharmacies.

2. The Chair called for approval of the Minutes of the October 22nd meeting. On page 4, for further clarification the following sentence was added to the last paragraph under #16, Intern/Preceptor applications: Internship hours must be reported to the Vermont Board of Pharmacy if earned in the State of Vermont. Ms. Eaton made a motion, seconded by Ms. Pudvah, to approve the Minutes of the October 22, 2008 meeting as corrected. Motion passed unanimously.

3. **Guests:**

Inspector Daniel Vincent attended the meeting to review the revised forms for conducting temporary inspections on new facilities and to discuss his recent inspection of a central fill pharmacy and of the Automated Dispensing Unit located at a motel location. Mr. Vincent pointed out minor changes to the Temporary Inspection Form and received Board approval for those changes.

Inspector Vincent said he conducted a final inspection of the Castleton Health Center Pharmacy (See item 10(c) and found it to be in full compliance. He said he also conducted a final inspection of the central fill pharmacy, Community Health Pharmacy in Colchester, (See item 10(a) and conducted an initial inspection of its satellite Automated Dispensing Unit located in Plainfield, Vermont (See item 10(b)). He shared photographs of these pharmacies with the Board. The photographs of the central fill pharmacy showed the conveyor belt, location of the pharmacists, technicians, drug stock, and soon.

Inspector Vincent took several photographs of the Automated Dispensing Unit which showed the Unit, its location within the facility, security, counseling area, etc. The 700 pound Unit is located within a locked room with a service window. He described the process in detail. He said drugs samples are still stored in that room but are not handed out by the pharmacy technician, only by the prescriber. It was noted that drug samples may not be stored within a pharmacy.

Inspector Vincent said the consultation area is of concern due to its size and privacy issues. They are considering the use of an unoccupied examination room. He said they are working on ways to ensure privacy (e.g., headphones versus speakers, telephone, etc.). It was unclear how they would deal with waivers of consultation.

The Board noted that these are acute medications, the first time dispensed, and that it may require counseling. The pharmacy must have a toll free number. The central fill pharmacy provides maintenance drugs via mail order. The examination room must be free of any medications.

3. **Guests** - continued

These issues will be discussed further with Hunt Blair, Marc Comtois and others at the January 2009 meeting. In response to members' interest in visiting these facilities, Inspector Vincents said he would notify them as to when he would be conducting follow-up inspections.

Inspector Vincents said the pharmacist manager who is or will be responsible for the pharmacy is key and indicated that their presence could be made a requirement. There revised rules would allow, with Board approval, a pharmacist who is a manager at the pharmacy to temporarily serve as the manager of another pharmacy.

4. **Hearings/Stipulations et al.**

At 9:30 AM the Board considered **Rachel L. Thomas'** Request for Modification of Conditions, Docket Number RX29-0305. Ms. Thomas was present. In addition, Fred Doltz, District Manager for Rite Aid Pharmacies, was also present on her behalf. Larry Novins presided for the Board. Gregg Meyer was present for the State. The Board voted to go into deliberative session at approximately 9:58 AM and out at 10:08 AM. A written decision will be issued.

At 10:00 AM the Board considered **Hugh Douglas Bryan's** Request for Reinstatement, Docket Number RX15-0303. Mr. Bryan and his Attorney, Joshua Diamond, were present. Larry Novins presided for the Board. Gregg Meyer was present for the State. The Board voted to go into deliberative session at approximately 10:35 AM and out at 11:02 AM. A written decision will be issued.

5. **Follow-Up Cases :**

6. **Reports:**

7. **Legislation/Rulemaking:**

The Board continued its review and discussion of the proposed changes to the Administrative Rules governing the practice of Pharmacy. Ms. Preston reported on proposed changes regarding the inspection process based on her discussion with Inspector Vincent. Accepted changes were incorporated into the draft.

Ms. Eaton noted that as of October 28, 2008, the Drug Enforcement Administration has an updated electronic version of the DEA form 106 for reporting the Theft or Loss of Controlled Substances through its online application system. This updated form requires registrants to include the National Drug Code (NDC), which will help to accurately track controlled substances reported as stolen or lost. With the implementation of the NDC number, DEA will no longer require registrants to enter specific information pertaining to product lost or stolen. The paper version of the DEA Form 106 became obsolete as of October 28, 2008. The proposed draft rule must be updated to reflect the new DEA requirements.

The Board discussed the effective date of the proposed rules in relation to the Multistate Pharmacy Jurisprudence Examination (MPJE) to best deal with the timing of outdated and/or new questions to agree with the new rules. The Board concluded that October 1st would be best to ensure that the questions on the MPJE are accurate and candidates are not confused. Candidates will be notified of the effective dates and would be advised to review both versions of the rules.

7. **Legislation/Rulemaking** - continued

The Board agreed to send out another notice regarding the proposed rule changes as soon as possible in case there have been several changes, although mostly organizational. Another rules hearing would be scheduled for the Board's January 28, 2009 regularly scheduled meeting. The proposed rules would be filed with the Intergovernmental Committee on Administrative Rules (ICAR) around the first of March. The proposed rules would continue through the process with an anticipated effective date of October 1, 2009.

8. **COMPLAINTS :**

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

Mr. Laborn made a motion, seconded by Ms. Eaton, to approve the following applicants for licensure as pharmacists. The question was called and the motion passed unanimously.

Aduke Lola Akere, R.Ph. (Endorsement)
Sanil John, R.Ph. (Examination)
Carolyn C. Mitchell, R.Ph. (Endorsement)
Lisa M. Schaefer, R.Ph. (Endorsement)
Frieda E. Miller, PharmD (Examination)

Robert B. Howard, R.Ph. (Endorsement)
Michelle L. Norcross, R.Ph. (Endorsement)
David A. Russell, PharmD (Endorsement)
Jennifer L. Shippee, PharmD (Endorsement)

Mr. Laborn made a motion, seconded by Ms. Eaton, to approve **Joseph Caputo, R.Ph.** for reinstatement subject to his successful completion of the MPJE. Motion passed unanimously.

10. **Drug Outlets:**

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

- a. Pharmacy Network LLC d/b/a/ **Community Health Pharmacy**, 150 Brentwood Avenue, Colchester, VT submitted a new application for mail order. Based on the Final inspection conducted on October 31, 2008 and Inspector Vincent's report, the Board approved this pharmacy for full licensure.
- b. Pharmacy Network LLC d/b/a/ **Community Health Pharmacy (ADU-Remote Location)**, 157 Towne Avenue, Plainfield, VT submitted a new application for its remote location. Initial inspection has been conducted and Temporary License is set to expire February 28, 2009. A follow-up inspection is required.
- c. JMS Pharmacy Management Inc. d/b/a/ **Castleton Health Center Pharmacy**, 275 Route 30 North, Bomoseen, VT submitted a new application. Based on the Final inspection conducted on November 12, 2008 and Inspector Vincent's report, the Board approved this pharmacy for full licensure.
- d. Pharmacy Health Services, Inc. d/b/a/ **Marble Works Pharmacy**, 99 Maple Street, Middlebury, VT submitted a new application to reflect a change in ownership. The Board approved this pharmacy for a Temporary License set to expire February 28, 2009. A favorable inspection is required for full licensure.
- e. Pharmacy Health Services, Inc. d/b/a/ **Marble Works Pharmacy (Vergennes)**, 187 Main Street, Vergennes, VT submitted a new application to reflect a change in ownership. The Board approved this pharmacy for a Temporary License set to expire February 28, 2009. A favorable inspection is required for full licensure.
- f. Pharmacy Health Services, Inc. d/b/a/ **New England Mail Order Pharmacy**, 111 Maple Street, Middlebury, VT submitted a new application to reflect a change in ownership. The Board approved this pharmacy for a Temporary License set to expire February 28, 2009. A favorable inspection is required for full licensure.

11. **Change in Pharmacist Manager:**

Ms. Overton made a motion, seconded by Ms. Eaton, to approve the changes in pharmacist managers as indicated below. Motion passed unanimously.

- a. **The Medicine Shoppe**, (038-3352), located at 20 South Main Street, Barre, Vermont, changed pharmacist managers from Deborah Sleep to Barbara Corkery.
- b. **Rite Aid Pharmacy #10329**, (038-3358), located at 355 North Main Street, Barre, Vermont, changed pharmacist managers from Barbara Corkery to Stephanie Ibey.
- c. **Rite Aid Pharmacy #10324**, (038-3374), located at Route 7 South, Milton, Vermont, changed pharmacist managers from Joseph Rampeto Carolyn Bowman.
- d. **Rite Aid Pharmacy #10330**, (038-3376), located at 1 Congress Street, Morrisville, Vermont, changed pharmacist managers from Carolyn Bowman to Chris Hazzuda.

12. **Non-Resident Drug Outlets:**

Ms. Eaton made a motion, seconded by Mr. Pease, to approve the following non-resident drug outlets for licensure. Motion passed unanimously.

- a. BioScrip Pharmacy, Inc., 21-23 Stanhope Street, Boston, MA.
- b. Embrace Pharmacy, a division of All-American Allergy Alternatives, LLC, 842 N. Westhill Blvd., Appleton, WI.
- c. Matrix Pharmacy LLC dba My Matrix Pharmacy, 5706 Benjamin Center Drive, Tampa, FL.
- d. Orchard Pharmaceutical Services, Inc., 7835 Freedom Avenue, NW, North Canton, OH.
- e. PMSI, Inc., Tampa, FL
- f. Factor Support Network Pharmacy Inc., Camarillo, CA/
- g. USMed, Inc., Miami, FL

13. **Wholesale Drug Outlets:**

Ms. Eaton made a motion, seconded by Ms. Pudvah, to approve the following wholesale distributors for licensure. Motion passed unanimously.

- a. International Pharma Packaging & Distribution, 1300 Altura Road, Fort Mill, SC.
- b. Kowa Pharmaceuticals America, Inc., 530 Industrial Park Blvd., Montgomery, AL.
- c. Ceva Logistics U.S. Inc., Arlington, TX.
- d. Foundation Care, LLC, Earth City, MO.
- e. INO Therapeutics, LLC, Somerset, NJ.
- f. Pharmedium Services, LLC, Memphis, TN.

14. **Drug Outlet remodeling, changes in Officers/Directors, hours of operation, etc.:**

- a. The Board reviewed and noted the notice from Prasco, LLC stating that it is no longer distributing products to Vermont from its Cincinnati, OH location.

15. **Continuing Professional Education Requests:**

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

- a. **“Endocarditis Prophylaxis: Who, What and When?”** submitted by Fletcher Allen Health Care, was approved for one hour of live (didactic) continuing professional education credit offered on November 18, 2008. The approval number issued is CPE320(L)-1208.

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

Ms. Overton made a motion, seconded by Ms. Pudvah, to approve the following applications as indicated. Motion passed unanimously.

- a. **Michelle Somaini, R.Ph.** – Application as a Preceptor – Approved subject to signature of owner.
- b. **Stephen J. Lyons** – submitted Intern’s Evaluation of Internship Period and Preceptor’s Affidavit of Internship Hours and was approved for the 697 hours she earned during the period of June 9, 2008 through October 10, 2008 while working at Rite Aid Pharmacy, West Rutland, Vermont.
- c. **Jeffrey A. Endicott** – submitted an Application for Registration of Intern – Approved.

17. **Pharmacy Technicians:** Total number of Active Registered Technicians is **1,431** (1199 Resident and 232 Non-Resident).

18. **Newsletter Topics!**

Topics for the March 2009 issue of the Newsletter (deadline February 1st) will include the DEA’s updated requirements for reporting Theft or Loss of Controlled Substances which requires registrants to include the National Drug Code (NDC). The paper version of the DEA Form 106 became obsolete as of October 28, 2008. The Board will also provide an update as to the statutes of the proposed rules and anticipated timeline. An update regarding the Department of Health’s prescription monitoring plan may be included as well. Mr. Pease agreed to draft an article regarding wireless alarm systems.

19. **Miscellaneous Correspondence**

- a. Mr. Novins reported on recent communication from Melika Zilberberg, MS, Program Coordinator of the Vermont Prescription Monitoring Program System administered by the Vermont Department of Health. The Department of Health has no legal authority to delegate responsibilities to the Board. Concerns were raised about language requiring the Board to determine the frequency of reports and to consider requests for waivers. Mr. Novins documented the reasons discussed. The Board continues to monitor this issue.
- b. The Board reviewed and discussed the October 24, 2008 email from Robert Hamilton with the Albany College of Pharmacy concerning the Vermont campus. The pharmacy practice labs will need to be licensed. They will be provided with a copy of the inspection forms (Temporary and regular) for informational purposes. It was noted that Channel 3 News highlighted the school’s plans and the number of applicants who had already applied.
- c. The Board reviewed and approved the updated “initial” inspection form which was presented by Inspector Vincent.

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

- a. The Board reviewed and noted the first quarter National Pharmacy Compliance News.
- b. The next meeting will be held in Miami, Florida a. The Board hopes to have a strong showing at the national meeting.

21. **Public Comment**

22. **Other Business Introduced**

The Board worked with Attorney Novins to draft the Report to the Legislature (House and Senate Committees on Government Operations) regarding its findings with regard to pilot experiments initiated in the previous calendar years (Title 26 V.S.A. § 2032(d)(2)(f)).

23. The next meeting is scheduled for **Wednesday, January 28, 2009** at 9:00 AM.

Meetings in 2009 are scheduled as follows: **February 25th; March 25th; April 22nd; May 27th; June 24th; July 22nd; August 26th; September 23rd; October 28th; and December 2nd.**

24. There being no further business, the meeting was adjourned at 4:02 PM.

Respectfully submitted,

Carla Preston, Unit Administrator
Office of Professional Regulation