

Board of Pharmacy
Secretary of State, Office of Professional Regulation
National Life Building, North, Floor 2, Montpelier, VT 05620-3402
Approved Minutes
Meeting of December 1, 2010

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

Members present: Julie A. Eaton, R.Ph., Chair; Emma J. Pudvah; Judith Wernecke; Larry Labor, R.Ph.; Earl W. Pease, Pharm.D. and Steven M. Vincent, R.Ph.

Members absent: Jeffrey P. Firlik, R.Ph., Vice-Chair

OPR Personnel present: Christopher Winters, Director of OPR; Larry S. Novins, Board Counsel; Inspector Daniel Vincent; Amy Carlson, Chief Investigator; Peter Comart, Unit Administrator; Carla Preston, Case Manager and Kristy Kemp, Administrative Assistant.

Others present: Kerri Ryan with CVS Pharmacies; Susan DeLeo with Walgreens; Anthony Otis, representing the Vermont Community Retail Pharmacy Coalition; Mike Duteau, Vice President of Kinney Drugs; Amy Braun with Barton Pharmacy; Meika Zilberberg, VPMS Program Coordinator; Erika Edwards, VPMS Analyst.

2. The Chair called for approval of the Minutes of the October 27th meeting. Mr. Vincent made a motion, seconded by Ms. Pudvah, to approve the Minutes of the October 27, 2010 meeting as written. Motion passed unanimously.

3. **Guests:**

- a. Christopher Winters, Director of OPR, attended the meeting to inform the Board of his and Mr. Comart's discussion with the National Association of Boards of Pharmacy (NABP).

At the Board's last meeting in October, Director Winters had submitted a proposal from the John Snow Research and Training Institute (JSI). The proposal was to conduct a review and assessment of the essential services and staffing needs of the Vermont Board of Pharmacy. The Chair had suggested that Mr. Winters and Mr. Comart should speak with the NABP as one of its primary roles is to support the State Boards of Pharmacy.

Director Winters spoke with Josh Bolin, NABP Government Affairs Director, as well as Carmen A. Catizone, NABP Executive Director/Secretary.

Director Winter's shared with the Board a letter that he received from Mr. Bolin. In the letter Mr. Bolin indicated that the NABP would be more than willing to assist in the Board's evaluation efforts and provide the Board with the support it needs. Director Winters explained that individuals from NABP would come on-site to perform an analysis. Some of the items that these individuals will discuss during their visit are listed below:

- 1) Vermont's current staffing model;
- 2) Services that NABP currently offers that may improve efficiencies or offset operational burden; and
- 3) Alternatives to hiring full-time professional staff, such as using NABP staff or a local contractor for handling inquiries requiring professional expertise.

Mr. Comart explained to the Board that he would like to work with a few members to develop a work plan to submit to the NABP. Mr. Vincent and Mr. Labor volunteered to assist Mr. Comart with this task. The Chair suggested that a Board Member also participate when the NABP performs its on-site analysis.

Following its visit, the NABP will make a more formal recommendation and proposal for the Board's consideration.

- b.** Mike Duteau, Vice President of Kinney Drugs and Amy Braun with Barton Pharmacy attended to discuss the possibility of a new pilot pharmacy site in Barton, Vermont.

Mr. Duteau explained that the current volume of prescription orders filled at Barton Pharmacy does not justify the need for a retail pharmacy in the area. Ms. Braun stated that the current volume is around 2,800 to 3,000 scripts per month, averaging around 120 to 130 a day. Ms. Braun explained that there was a significant drop in the number of prescriptions that Barton Pharmacy processed in 2009 which is very concerning to her as the business owner.

The Board agreed that the area meets the requirements as being a remote and underserved area. The Board noted that the closest pharmacy is located in Orleans which is 7 miles away. Its concern was if the pharmacy in Orleans had to close for some reason, the closest pharmacy would then be located in Newport which is 14 miles away. The Board asked Mr. Duteau to submit a more in depth proposal for the Board to consider at its next meeting.

- c.** Meika Zilberberg and Erika Edwards attended to speak with the Board about the Vermont Prescription Monitoring System (VPMS). Ms. Zilberberg and Ms. Edwards spoke with the Board about current issues with compliance and bad data.

Ms. Zilberberg asked the Board for assistance with enforcing compliance. Currently when a pharmacy is not reporting as required by statute, Ms. Zilberberg sends the licensee a letter informing them of the law. The Board agreed that it would be appropriate to copy the Board on the initial letters that Ms. Zilberberg mails to the licensees. Should compliance issues continue, Ms. Zilberberg will share appropriate information with OPR's Case Manager and Chief Investigator for further follow-up.

The Board also discussed the issue of bad data within the reports submitted to the VPMS. The Board asked Ms. Zilberberg to draft a notice regarding the common data issues for its next Newsletter in March of 2011.

4. Hearings/Stipulations *et al.*

(None)

5. Reports:

Mr. Pease reported on the NABP/AACP District I and II Meeting Which was held October 29th through October 31st in Cooperstown, NY. Some of the items that were discussed at the meeting included the following:

- Multistate Licensure.
- Collaborative Practice Agreements – The Massachusetts Board has a template available on its website.
- Inspections – Some states have a list of minor infractions. If a facility has three minor infractions there is an automatic monetary fine.
- Proper ID for picking up a controlled substance prescription.
- Electronic Processing for Schedule II Prescriptions – The DEA held a discussion.
- Medication Return Programs.
- Impaired Professional Programs – Some states have these programs in place so that an individual can voluntarily surrender their license and enter the program rather than having disciplinary action taken against their license.

The Board mentioned the NABP 107th Annual Meeting which will be held from May 21st through May 24th of 2011 in San Antonio, TX. The Board will discuss which members will attend at a later date.

6. Follow-up Cases

Carla Preston, Case Manager, provided updates on current and follow-up cases. Ms. Preston noted that there are currently 52 pending cases.

The Board reviewed Mr. Thomas F. DeFranco's request for the removal of conditions on his license. Mr. Vincent made a motion, seconded by Mr. Pease, to approve Mr. DeFranco's request. Motion passed unanimously.

7. Legislation/Rulemaking:

Attorney Novins prepared a letter to the House and Senate Committees on Government Operations, asking for a two year extension on the two year limit on the remote pharmacy trial. At this time, only one remote pharmacy is in operation in Plainfield, VT. The Board has recently received an application for a second remote pharmacy to operate in Hardwick, VT and has received an inquiry for a possible third remote pharmacy. The Board is hoping that the extra time will permit it to have more experience and gain better insight into what rules should be adopted.

8. Complaints/Reports of Concluded Investigations

(None)

9. **Applications for Licensure as Pharmacists:**

Mr. Labor made a motion, seconded by Ms. Pudvah, to approve the following applicant for licensure as a pharmacist. Motion passed unanimously.

Tamer E. Fandy, PharmD (Endorsement)

Mr. Vincent made a motion, seconded by Ms. Pudvah, to approve the following applicant for licensure as a pharmacist. Five approved and one opposed. Motion passes.

Stephen M. Otis, PharmD (Endorsement)

Applications for Registration of Out of State Telepharmacy Pharmacists:

Mr. Vincent made a motion, seconded by Mr. Labor, to approve the following applicants for registration as Registered Telepharmacy Pharmacists. Motion passed unanimously.

William L. Andrews
Lawrence A. Dailey, Jr.
Stacey A. Elliott
Anthony M. Gastaldo
Shannon A. Hendricks
Charles M. Jibotian
Julie A. Launsbach
Tamara L. Stapley
Patricia A. Warren

Curtis L. Avant
Thomas M. Deeds
Michael D. Francis
Salma M. Habeeb
Kathryn A. Hutchinson
Erich H. Kujas
Leanette N. Pennartz
Brian E. Steger

The Board agreed to allow OPR licensing staff the ability to issue registrations to out-of-state registered pharmacists as long as all of the statutory and rule requirements are met. The Board will still review and approve the applications for registrations that are not in compliance, such as those that have criminal convictions, previously disciplinary history, and so forth. The Board will be provided with a list, at each meeting, of the registrations that have been issued since its previous meeting.

10. **In-State Drug Outlets:**

The Board reviewed the following applications for in-state pharmacies and took action as indicated.

- a. Ludlow Pharmacy, Inc., d/b/a Ludlow Pharmacy, 57 Pond Street, Ludlow, VT, submitted a new retail pharmacy application. Further documentation and an initial inspection are required. The scaled drawing was reviewed by the Board.
- b. Pharmacy Network, LLC, **d/b/a Community Health Pharmacy**, 4 Slapp Hill, Hardwick, VT, submitted an application for a new remote location. Further documentation and an initial inspection are required. The scaled drawing was reviewed by the Board. An initial inspection will be scheduled pending receipt of required documentation.

- c. Smith & Peck Pharmacy Management Services, Inc., **d/b/a Pete's Pharmacy**, 242 River Street, Unit 9, Springfield, VT, submitted a new retail pharmacy application. A temp license has been issued and is set to expire on December 10, 2010. Passed final inspection on November 4, 2010. Mr. Vincent made a motion, seconded by Mr. Pease to approve the pharmacy for full licensure. Motion passed unanimously.

Mr. Vincent made a motion, seconded by Ms. Pudvah, to grant authority to the Chair to approve the extension of a pharmacy's temporary license, in the event that the temporary permit will expire prior to the next Board meeting, upon a satisfactory report by the Inspector. Motion passed unanimously.

11. **Change in Pharmacist Managers:**

Mr. Labor made a motion, seconded by Mr. Pease, to approve the following changes in pharmacist managers. The question was called and the motion passed unanimously.

- a. **Kinney Drugs, Inc. #69**, (038-3336), located at 600 Blair Park Road, Williston, Vermont, submitted an application for change in pharmacist manager from Leah R. Rosenthal to Cheryl Tuigere.
- b. **Rite Aid Pharmacy #2481**, (038-2709), located at 107 East Main Street, Wilmington, Vermont, submitted an application for change in pharmacist manager from Henry G. Doran to Richard H. Brueckner.

12. **Non-Resident Pharmacies:**

Several non-resident pharmacy applications with no record of prior disciplinary actions were approved for licensure since the last meeting based on their completed applications. The Board was provided with a list of these facilities and found no issues.

The Board reviewed the following applications with prior disciplinary action. Based on the information provided, Ms. Wernecke made a motion, seconded by Mr. Vincent, to approve the non-resident pharmacies for licensure. Motion passed unanimously.

- a. **Burklow Development, Inc., d/b/a American Pharmacy Solutions**, 5001 Commerce Park Circle, Pensacola, FL.
- b. **Home Care Pharmacy, LLC, d/b/a Cincinnati Clinical Intervention Center**, 9482 Meridian Way, West Chester, OH.
- c. **Specialty Veterinary Pharmacy**, 10400 Westoffice Drive, Houston, TX.
- d. **Pharmacy Consultants, Inc., d/b/a Omnicare Clinical Intervention Center – Spartanburg**, 348-A E Blackstock Road, Spartanburg, SC.

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

Several non-resident wholesale distributor applications with no record of prior disciplinary actions were approved since the last meeting based on their completed applications. The Board was provided with a list of these facilities and found no issues.

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

- a. The Board noted that Lyndonville Pharmacy located at 101 Depot Street, Lyndonville, VT, will be closing on December 9, 2010.

15. **Continuing Pharmacy Education Requests:**

Mr. Labor made a motion, seconded by Mr. Vincent, to approve the following continuing pharmacy education request as indicated. The question was called and the motion passed unanimously.

- a. **“Diabetes Update 2010: Diagnosis: Diabetes...Now What? Current Trends in Treatment”** submitted by James Marmar, R.Ph., requesting approval for six and one half (6.5) live (didactic) continuing pharmacy education credit. The program was held on November 9, 2010. The Board issued approval number CPE-034(L)-1210.

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

(None)

17. **Pharmacy Technicians:** Total number of Active Registered Technicians is **1, 511** (1,393 Resident, 118 Non-Resident).

18. **Newsletter Topics!**

Topics for the next Newsletter include the following: expiration dates of prescription drugs, signage requirements, tracking of intern hours and bad data in the VPMS. The plan is to have draft for the Board to review at its January meeting.

19. **Miscellaneous Correspondence**

- a. The Board reviewed the November 29, 2010 email from Jennifer Schneider regarding licensing requirements for drug distribution to clinical labs for use in clinical trials or other research purposes. The Board explained that if the trials are under Independent Review Board (IRB) Purview, licensure is not required. If they are not under IRB purview, they will need to register as a distributor with the Board.
- b. The Board reviewed the November 30, 2010 email from James S. Heal, R.Ph., regarding Administrative Rule 10.31. Mr. Heal's question was “who can identify a medication that was brought into the facility by a patient.” The Board explained that its rules do not specify. It further explained that it would prefer a pharmacist however it is up to the hospital to come up with a standard procedure.
- e. The Board reviewed the November 30, 2010 email from Ms. Alicia Mayer, RN, MS, regarding the licensure requirements for the clinic where she currently practices. Ms. Mayer asked if the clinic would require a pharmacy license if it wishes to dispense prescription medications such as epinephrine for emergency use, oxygen, Hepatitis B, and the tetanus vaccine. The Board

Board asked Ms. Mayer to further clarify whether the clinic truly wishes to “dispense” prescription medications, or if it wishes to “administer” prescription medications. The Board stated that if the clinic wishes to administer the prescriptions mentioned above under the direction of a doctor, licensure would not be required.

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

The Board reviewed various documents from the NABP.

21. **Public Comment**

22. **Other Business Introduced**

- a. The Board continued its discussion on the licensure requirements for manufacturers/distributors of prescription and non-prescription medical devices. The Board clarified that licensure is not required for manufacturers/distributors of prescription and non-prescription medical devices, unless they handle prescription drugs in addition to the devices. The Board will work on cleaning up its Statutes and Rules in order to prevent further confusion in the future.

- b. The Board requested that the following question be added to the Application for License to Conduct a Pharmacy:

For institutional pharmacies only: Do you use outside telepharmacy services? If yes, please indicate which one.

The application will be updated to include the question above.

- c. The Board asked that Ms. Kemp and Mr. Comart create template signs that pharmacists can print off of its website and post in their pharmacies to comply with the signage requirements. Mr. Comart indicated that this would not be a problem and that the signs would be available as soon as possible. The Board also asked that a direct link to its Newsletters be available on its webpage. Mr. Comart will work on getting this task taken care of within the next week.

23. The next meeting of the Board is scheduled for **Wednesday, January 26, 2011.**

Meeting dates for 2011 are as follows: February 23rd, March 23rd, April 27th, May 25th, June 22nd, July 27th, August 24th, September 28th, October 26th and December 7th.

24. There being no further business, the meeting was adjourned at 2:19 PM.

Respectfully submitted,

Kristy Kemp, Administrative Assistant
Office of Professional Regulation