

BOARD OF PHARMACY

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

UNAPPROVED MINUTES Meeting of May 28, 2008

1. The meeting was called to order at 9:06 AM.

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

OPR Personnel: Larry S. Novins, Board Counsel, Carla Preston, Unit Administrator, and Daniel Vincent, Inspector.

Others present: Sabri Ibrahim (Rite Aid Corporation); Anthony Otis, Esq., Kerri Ryan, Peter Holman, and Meika Zilberberg.

2. The Chair called for approval of the Minutes of the April 23rd meeting. On page two, the second paragraph under item number three was clarified to indicate that counseling to patients at the remote site would be provided via telepharmacy (video) during the hours in which the pharmacy is open. The fourth paragraph was amended to add the emphasis that any proposed rules would allow others to have automated dispensing units in remote locations. Mr. Vincent made a motion, seconded by Mr. Firlik, to approve the Minutes of the April 23, 2008 meeting as amended. The question was called and the motion passed unanimously.

3. **Guests:**

At 11:00 A.M., Peter Holman and Meika Zilberberg from the Vermont Department of Health attended the meeting to discuss the Department's Prescription Monitoring Program. Mr. Holman provided an overview of the 2006 law which gave the Vermont Department of Health (VDH) the authority to begin a prescription monitoring system. He said much of the funding for the program is federal. He said currently 28 states have some type of prescription monitoring program in place. There is a great deal of variety among the programs. All New England states except New Hampshire have a system in place. He explained that the earlier systems were affiliated with law enforcement with heavy state control (e.g., purchase prescriptions pads from the state). He said the emphasis now is educational with focus on the safety of the patient. He said Vermont's program is based on Maine's system.

Mr. Holman said the law permits VDH to obtain patient records regarding Schedule II through IV which would be stored on a database for a period of six years. He said they are communicating with their selected vendors to set up the database and communicate with pharmacies to report the data. The VDH would collect 12 items, including the patient's name, address, date-of-birth, drug dispensed, dosage, refills, patient's health care provider, and the name of pharmacy where the prescription was filled. He said anyone with a Drug Enforcement Administration (DEA) number could query the database. It is a tool for providers and pharmacists to have a picture of a patient's use of controlled substances. It would identify the number of providers and pharmacies a patient has utilized to obtain prescription drugs. He said the system would be available to professional licensing boards during an active investigation. He said the Commissioner of the Department of Health has the authority to take action if a situation suggests fraud or other illegal activity or an imminent threat to the public health. He indicated that a law enforcement has no direct access to the system.

Meika Zilberberg said they are negotiating a contract with a vendor out of Alabama noting that four other states currently use this vendor. She said meetings have taken place with the stakeholders and other interested parties. They will be sending notices to pharmacies about collecting the patient information for the program and hope to begin collecting data by July 1st. The vendor will assist pharmacies in setting up electronic reporting to save additional workload and time.

3. **Guests** - continued

Mr. Holman said the law covers retail pharmacies which would require that weekly reports be submitted to VDH. He verified that the law covers all pharmacies licensed in Vermont, in-state and out-of-state pharmacies that ship products to Vermont. He noted that there are gaps in the law but wanted to begin with the basics and then work forward. Providers who dispense directly to patients are exempt. In addition, there are no reporting requirements for hospitals and emergency room facilities. He said that there could be gaps in reporting requirements concerning Dartmouth Hitchcock since it is located in New Hampshire and with the Veteran's Administration. They have not yet addressed hospitals that dispense to employees. Mr. Holman said they wanted to begin with retail pharmacies. He said the prescriber must have a DEA number and must be licensed in the State of Vermont to access his system.

The Board noted that since there would be no way to indicate a patient's diagnosis in the system, it is very likely that some patients would be prescribed large amounts of controlled drugs. Concerns were also raised about confidentiality, identity theft, and HIPAA requirements. Prescribers may be overcautious since the records must be reported resulting in under-prescribing.

Mr. Holman noted that other states have faced those concerns as well but the steps toward reducing theft and diversion must be informed that this information is being collected. He said use of the database will assist with overall patient care. Patients utilize various physicians and pharmacies and there is no coordination among the prescribers as to what is being prescribed and dispensed. He said patients assume the drugs are acceptable since they were prescribed by their physician. This could prevent possible addiction, overdose, and other health risks.

Ms. Zilberberg said according to the contract the vendor must ensure that all requirements for security and confidentiality are met. The data received from the pharmacies cannot and would not be altered. If a error is found the reporting pharmacy must evaluate and make appropriate corrections. Alternatives for accessing the system would be available should the prescriber not have internet access.

The Board mentioned the importance that the right prescriber is of record and reported to the database. Members noted situations in which the name of the prescriber is not legible, the name of the hospital, clinic or another prescriber in charge may be listed so that the prescription may be filled. Since the patient's record will be tied directly to that prescriber it is important that pharmacists list the name of the prescriber. The Board will note the importance of listing the name of the patient's prescriber and not partners or the head of a department in its next Newsletter.

Mr. Holman and Ms. Zilberberg said an notice of the requirement and strategy for pharmacists to comply will be sent to all pharmacies licensed in Vermont. They noted that approximately 85 of the in-state pharmacies are part of chains and that the information would be reported from their home offices. They said they will work closely with the other 50 or so in-state pharmacies to get the information reported to VDH. The Department is required to prepare a semi-annual report; the June 2008 report would contain some information. They agreed to share that report with the Board. They indicated that they would like to return to the Board in about six months to provide a progress report.

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

a. The Board considered the Motion to Remove the Condition in the matter of Walgreens Pharmacy #01756, Docket Number RX81-0507. The pharmacy's license on a condition pertained to monitoring and reporting requirements of an employee who no longer works at the pharmacy. Based on the information presented, Ms. Eaton made a motion, seconded by Mr. Firlik, to grant the request to remove the conditions.

4. **Hearings/Stipulations et al** - continued
The question was called and the motion passed. Mr. Vincent, Investigating Member, did not participate in the vote.

b. The Board considered a request to Dismiss the Charges in the matter of Timothy J. Luneau, Docket Number RX69-0307. The Board voted to go into deliberative session at 9:29 AM and out at 9:38 AM. A written Order stating the Board's findings will be issued.

5. **Follow-Up Cases :**

6. **Reports:**

A. Ms. Eaton and Mr. Pease reported on their attendance at the national NABP meeting. Topics of discussion included internet pharmacies and the need for a patient/physician relationship, background checks on pharmacy technicians, increasing the number of externship/internship hours to 1740, and soon. Some of these ideas may be discussed further during rulemaking.

B. Four members of the Board attended OPR's Board Member/Advisor Training held on May 21, 2008 at the Stoweflake in Stowe.

C. Daniel Vincent, Inspector, said he verifies that pharmacies have technician manuals on site and no test the date of the publication. He said he is in the process of revising the inspection form. He asked the Board to consider requiring an alarm system during its rulemaking. He noted that most pharmacies have an alarm system but felt it would be best practice if specifically required. The Board agreed to include the requirement for an alarm system that would detect and report an unauthorized entry.

7. **Legislation/Rulemaking:**

Mr. Novins reported that the OPR has been signed by the Governor. New provisions will take effect on July 1, 2008.

Anthony Otis, Esq. reported on the end of session results pertaining to pharmacy. He agreed to share that report with the Board.

The Board will send notices to all pharmacies highlighting the changes. The Board will also notify the Board of Medical Practice regarding the new law concerning dates prescriptions are valid.

8. **COMPLAINTS :**

9. **The Board reviewed the following Applications for licensure as a Pharmacist.**

Ms. Eaton made a motion to approve the following applicants for licensure as pharmacists. Mr. Firlik seconded the motion and the motion passed unanimously.

Stephen G. Grant, R.Ph.

Marcie B. Jorgensen, Pharm D

10. **Drug Outlets:**

The Board reviewed the following in-stated drug outlets and took action as indicated.

10. **Drug Outlets** - continued

- a. **Extended Care Pharmacy, LLC**, (closed pharmacy—long term care), located at 207 North Street, Bennington, VT. An in-person inspection will be conducted prior to issuance of a full license. The Board voted to extend the Temporary license until June 30, 2008. Another inspection is required.
- b. **Kinney Drugs Inc. #94**, (038-0002470), located at 308 Shelburne Road, Burlington, VT (formerly located at 789 Pine Street, Burlington—July 7, 2008 anticipated opening date), submitted a new application regarding its relocation. An inspection of the new facility is required.
- c. NCS Health care of Vermont, Inc. d/b/a **Omnicare of Vermont** submitted an application for relocation and name change to 113 Acorn Lane, Colchester, VT (formerly located at 16 Gregory Drive, S. Burlington). An initial inspection was conducted on April 8, 2008. Based on a favorable follow-up inspection conducted on May 9, 2008, Mr. Vincent made a motion, seconded by Ms. Eaton, to approve this facility for full licensure. The question was called and the motion passed. Mr. Pease recused and did not participate in the vote.
- d. New England Home Therapies, Inc., c/o Critical Homecare Solutions, Inc. d/b/a **Wilcox Home Infusion**, located at 400 Cornerstone Drive, Suite 130, Willis ton, VT, submitted a new application to reflect a change in ownership. Inspection required.
- e. New England Home Therapies, Inc., c/o Critical Homecare Solutions, Inc. d/b/a **Wilcox Home Infusion**, located at 250 Stratton Road, Rutland, VT, submitted a new application to reflect a change in ownership. Inspection required.

11. **Applications for Changes in Pharmacist Manager:**

Ms. Eaton made a motion, seconded by Mr. Firlik, to approve the following applications for Changes in Pharmacist Managers. Motion passed unanimously.

- a. Jo-Mar Inc. d/b/a **Harry's Discount Pharmacy**, (038-1252), located at 921 US Route 302, Berlin, Vermont, changed pharmacist managers from Timothy Luneau to John Marchewicz.
- b. **Kinney Drugs, Inc. #58**, (038-3314), located at 55 Shattuck Hill road, Newport, Vermont, changed pharmacist managers from Jean Paul Fournier to Robert Ianni, Jr.
- c. **Rite Aid Pharmacy #10324**, (038-3374), located at Route 7 South, Milton, Vermont, changed pharmacist managers from Carolyn Bowman to Joseph Rampe.
- d. **Rite Aid Pharmacy #10330**, (038-3376), located at 1 Congress Street, Morrisville, Vermont, changed pharmacist managers from Robert Ianni, Jr. to Carolyn Bowman.
- e. **Rite Aid Pharmacy #10313**, (038-3384), located at 2 Chester Road, Springfield, Vermont, changed pharmacist managers from John M. Walter to Muralikrishna Narra.
- f. **Rite Aid Pharmacy #10312**, (038-3371), located at 213 Main Street, Ludlow, Vermont, changed pharmacist managers from William Morganto Jane Rebhan.
- g. **Walgreens Pharmacy # 01756**, (038-3345), located at 10 Woodstock Avenue, Rutland, Vermont, changed pharmacist managers from Laura Lee McAllister to Donald J. Maloy.

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

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

12. Non-Resident Drug Outlets - continued

- a. Master Pharm, LLC, Richmond Hill, NY.
- b. Medco Health Solutions of Scottsdale, Scottsdale, AZ.
- c. New England Life Care, Inc., Woburn, MA.
- d. Option Care Specialty Care Pharmacy, Miramar, FL.

13. Wholesale Drug Outlets:

Mr. Vincent made a motion, seconded by Mr. Firlik, to approve the following (a through d) wholesale drug outlets for licensure. Motion passed unanimously.

- a. Gulf Coast Pharmaceuticals, Inc., Ocean Springs, MS.
- b. Indevus Pharmaceuticals, Inc., Cranbury, NJ.
- c. Kuehne & L Nagle, Inc., Alsip, IL.
- d. AmeriCares Foundation, Inc.
- e. Randy S. Stoloff, MD, Colchester, VT. Inspector Daniel Vincent reported on his findings during the inspection conducted at Dr. Stoloff's proposed location for a wholesale facility. Based on numerous deficiencies and unanswered questions, Mr. Vincent made a motion, seconded by Mr. Labor, to preliminarily deny Dr. Stoloff's application for licensure as a wholesaler. Dr. Stoloff will be notified. The question was called and the motion passed unanimously.

The Board discussed the need for more information from all wholesaler distributors when products are purchased outside of the normal channel of distribution. Based on that conversation, the Board voted to require an applicant wholesaler distributor to submit its business model or an explanation of the intent (purchased from, sold to, etc.) as part of the application. That requirement will be added to the wholesaler distributor application.

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

- a. The Board reviewed and noted the May 15, 2008 letter from Kinney Drugs, Inc. #58, Newport, Vermont, indicating their plans for renovation.

15. Continuing Education Requests:

Ms. Eaton made a motion, seconded by Mr. Firlik, to approve the following continuing education programs as indicated. Motion passed unanimously.

- a. ***"Treatment of Poisoning, a Nephrocentric Approach,"*** submitted by Shawna Barito, with Fletcher Allen Health Care, was approved for one hour of (didactic) continuing education credit and issued number CE306(L)-0408.
- b. ***"Vermont DUR Board Meeting,"*** submitted by Andrew Miller for his attendance at the Vermont DUR Board meeting held on April 1, 2008, was approved for two hours of didactic credits and issued number CE307(L)-0508.
- c. ***"Clinical Pearls—Innovative Practices by Vermont Practitioners,"*** submitted by Clare Coppock for the Vermont SHP, was approved for one hour of (didactic) continuing education credit and issued number CE308(L)-0508.

16. Intern/Preceptor application(s)

Mr. Firlik made a motion, seconded by Mr. Vincent, to approve the following applications as indicated. Motion passed unanimously.

- a. Nicole C. Gordon—Application for Registration of Intern, Troy, NY.
- b. Kelli L. Rothenberger—Intern's Evaluation of Internship Period and Preceptor's Affidavit of Internship Hours for the 494 hours she earned during the period of December 21, 2006 through April 24, 2008.
- c. Lawrence J. Mango—Application as a Preceptor, Price Chopper Pharmacy #171, Bennington, VT.
- d. Brent P. DeLaBruere—Application for Registration of Intern, Newport Center, VT.

17. Pharmacy Technicians: Total number of Active Registered Technicians is ~ **1,835**.

18. Newsletter Topics!

Topics to be included in the September 2008 issue include: notice that the inspection form will be posted on the Website, updated resource list; information regarding OPR's new licensing system, formularies for other professions, and soon.

19. Miscellaneous Correspondence

- a. The Board reviewed the April 30, 2008 letter from ProPharmCare, Inc. to determine whether licensure is required. Since the dispensing would take place in the State of Vermont, the pharmacists providing the service must be licensed.
- b. The Board reviewed the April 21, 2008 email from Jagrutiben Patel to determine whether Michigan's requirements for pharmacist licensure are substantially equal to Vermont's requirements. Ms. Preston will research this matter further.

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

The Board reviewed and noted correspondence from the NABP.

21. Public Comment

22. Other Business Introduced

Mr. Firlik reported on the status of Albany College of Pharmacy's plan to offer a pharmacy program in Vermont. He said they are now planning on a September 2009 opening date.

23. The next meeting is scheduled for **Wednesday, June 25, 2008** at 9:00 AM. Future meetings for 2008 are scheduled as follows: July 23rd; August 27th; September 24th; October 22nd; and December 3rd.

24. There being no further business, the meeting was adjourned at 3:25 P.M.

Respectfully submitted,

Carla Preston, Unit Administrator
Office of Professional Regulation