

Board of Pharmacy
Secretary of State, Office of Professional Regulation
National Life Building, North, Floor 2, Montpelier, VT 05620-3402
Unapproved Minutes
Meeting of March 25, 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.; Jeffrey P. Firlik, R.Ph. and Emma J. Pudvah.
Absent: Ann Overton, Secretary.

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

Others present: Crystal Bousquet, Anthony Otis, Esq., Matt Byrne, Esq., Michele Kartschoke, R.Ph., and Audrey McGregor-Reardon.

2. The Chair called for approval of the Minutes of the February 25th meeting. Mr. Pease made a motion, seconded by Mr. Labor, to approve the Minutes of the February 25, 2009 meeting as submitted. Motion passed unanimously.

3. **Guests:**

Matthew B. Byrne, Esq. with Graveland Shea and Audrey McGregor-Reardon owner of McGregor's Medicine-On-Time Pharmacy (MOT) attended the meeting to discuss amending the rules to better describe their long term care pharmacy operations. Their powerpoint presentation included suggested amendments to the Board's Administrative Rules to recognize the practice of long term care pharmacies. They distributed copies of their presentation, federal regulations and other states' statutes or regulations concerning definitions of long term care pharmacies. Their proposed changes included the composition of the Board to include pharmacy technicians and recognition for certified pharmacy technicians. They also referred to the National Association of Boards of Pharmacy's definition and model language on these topics.

Ms. McGregor-Reardon and Mr. Byrne said they would like to see the definition of institutional pharmacy amended to fit MOT's operation. They explained that their operation differs from most home care services in the way the medications are delivered. Medicine-On-Time is a long term care, closed-door pharmacy providing complete regimen review management. They work closely with Vermont institutions and prescribers that supervise their patients in monitored medication plans. Patients may start in long term care facilities, correctional facilities or other institutional facilities. Patients served by MOT are able to continue on their treatment plan in the community, after release from an institution. The patient, physician (prescriber) and pharmacy have a similar relationship as do other home care services but with more active management and communication among them with very tight control about how the medications are shipped to the patient. All directives come from the prescriber. It is a unit dosing system in which the unit doses are sent to the patient under a very specific regimen but with instructions for the patient to take their medication on their own. Medicine-On-Time receives the unused medications back so they can determine if the regimen is working. They said the difference from other home care services is how they work with the pharmacist, physician to get the medication to the patients so they can take them on their own. They explained that they have contracts with several institutions regarding these services. Patients may include current residents of an institution or those patients recently released from an institution but those who need the prepackaged medications. Ms. McGregor-Reardon said the ratio is about 50/50 for patients who receive the medication at their homes.

3. **Guests** - continued

Ms. McGregor-Reardon and Mr. Byrne mentioned choices for Care Medicaid Waiver Regulations which were implemented in October of 2005. They propose a similar waiver process. Physicians enter their patients by confirming the medical necessity of the program for the safety of the patient which allows patients no longer residents of a facility to be eligible for the services they provide. Once started in the program patients can only be discontinued via physician, facility or by death. Medicine-On-Time strives for adherence and treats all aspects of patient care. The waiver from the physician would allow more patients to stay on the program without the need for a court order. They said there is a process in place and patients have to meet certain criteria to be eligible for such a waiver. It is not granted just for convenience.

The Board explained that an institutional pharmacy (i.e., hospital, nursing home) dispenses to the nurses and the nurses administer the medication to the patients. The Board recognizes that the service MOT provides is valuable. Most pharmacies do not provide a separate unit for medications due to the extra time involved and little difference in reimbursement for providing that service.

Ms. McGregor-Reardon and Mr. Byrne said that in their model, patients receive the drugs and self-administer or are administered by licensed or unlicensed persons in the patient's home. They are funded by Medicaid Part D. There would be no difference in being licensed as a long-term care pharmacy or an institutional pharmacy with regard to the services provided. Therapeutic drug monitoring is offered to home-based people who are presented with prepackaged medications. Being considered an institutional pharmacy takes away regulatory uncertainty and is easier to communicate about services provided. They said it also helps recognize that pharmacy practice is moving in this direction and provides services for a certain population. It allows MOT to serve clients at home versus in an institution and be compensated for it. There are different reimbursements based on circumstances.

The Board indicated that its proposed amendment to the definition of institutional pharmacy would qualify pharmacies that serve patients who reside in an institution, such as a hospital pharmacy. The proposed definition of long-term care pharmacy recognizes services to patients who reside outside of an institution. It is clear that MOT's operation is not an institution even if not physically part of the pharmacy.

Ms. McGregor-Reardon and Mr. Byrne wanted to depart from the definitions because their operation is a hybrid of both types and have proposed a separate definition to fit their hybrid operation. Reimbursement is the issue. Their reimbursement rate is greater for an institution providing long-term care services. The third-party payers pay at a higher rate.

Ms. McGregor-Reardon said she has hired a nurse and then the nurse performs more services such as take photos of the pharmacist. She said her operation does not fit the definition of a retail pharmacy which is currently licensed and would like to see this issue addressed.

Ms. McGregor-Reardon and Mr. Byrne proposed tiered levels of pharmacy technicians, those with certification and those without and to broaden the scope of practice for certified technicians. They referred to the NABP model rule for more information. They also suggested having pharmacy technicians be members of the Board. Ms. McGregor-Reardon renewed her invitation to members of the Board to visit the facility and observe the operation. She said Inspector Daniel Vincent visited her site and acknowledged that it was very different.

3. **Guests** - continued

In summary, Ms. McGregor-Reardon and Mr. Byrne indicated that long term care pharmacies fill a gap in services between institutional pharmacy and retail pharmacy. Recognition is consistent with Vermont's policy as set forth in the Choices for Care Waiver. They asked the Board of Pharmacy to recognize the value to the community of long term care pharmacy and to create a language that would better address this important service.

The Board noted that their proposed definition might fit their operation but might not fit another applicant's. The Board is cautious about creating a definition that would prohibit other pharmacies from similar activities. The Board recognizes the benefit of having pharmacy technicians on the Board and indicated that changing the composition of the Board would require legislation. Amending the requirements or definition of pharmacy technicians would also require statutory changes.

Chairman Vincent said the Board would be discussing proposed rule changes later in the day in hopes of finalizing the draft so they can be submitted to the legislative committees. Attorney Novins explained that the Board has nearly completed the proposed changes but has set out reserved sections for areas that need further review but would allow the other sections to move forward.

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

a. At 10:00 AM the Board considered a Stipulation and Consent Order in the matter of **Cynthia Koch**, Docket Numbers RX06-0807, RX35-0108 and RX03-0808. The Respondent was not present. Larry S. Novins presided for the Board. Gregg Meyer was presented for the State. Chairman Vincent made a motion, seconded by Ms. Pudvah, to accept the Stipulation and Consent Order as presented. The Board voted to go into deliberative session at 10:08 AM and out at 10:43 AM. The matter was discussed further. The Board voted to go into deliberative session at 10:46 AM and out at 10:50 AM. Based on Attorney Meyer's explanation and additional information provided, the Board voted to accept the Stipulation and Consent Order as presented. Ms. Eaton, Investigating Member, did not participate in the vote.

The Board asked that in the future more information be provided in the Orders so that the Board understands why a particular agreement may differ from previous cases.

b. At about 10:55 AM the Board considered a Stipulation and Consent Order in the matter of **Lawrence J. Mango**, Docket Number RX66-0408. The Respondent was not present. Larry S. Novins presided for the Board. Gregg Meyer was present for the State. Mr. Labor made a motion, seconded by Ms. Eaton, to accept the Stipulation and Consent Order as presented. The question was called and the motion passed unanimously. Ms. Pudvah, Investigating Member, did not participate in the vote.

c. At about 11:00 AM the Board considered a Stipulation and Consent Order in the matter of **Price Chopper Pharmacy #171**, Docket Number RX67-0408. The Respondent was not present. Larry S. Novins presided for the Board. Gregg Meyer was presented for the State. Mr. Firlik made a motion, seconded by Mr. Labor, to accept the Stipulation and Consent Order as presented. The question was called and the motion passed unanimously. Ms. Pudvah, Investigating Member, did not participate in the vote.

5. **Follow-up Cases**

No action to report.

6. **Reports:**

Mr. Firlik reported on his participation in the initial kick-off meeting held on March 12, 2009 re the E- Prescribing Advantage. He provided two handouts titled, "The E-Prescribing Advantage" by Tom Groom and "Vermont e-Prescribing Program," by Point-of-Care Partners, Health Information Technology. Topics covered included an overview, e Prescribing Components & Value, e Prescribing Value Proposition, SureScripts' Services, Feasibility Study Findings, Payer Member Records, Benefits, Prescription Routing, Medication History for Hospital and more. He noted that there are financial incentives to do e-prescribing which is primarily via facsimile. He said the level of e-prescribing will increase in the coming months. He noted that it will be additional work for the pharmacist in the beginning but would increase monetary savings in the end.

7. **Legislation/Rulemaking:**

The Board discussed public comments submitted regarding the proposed changes to its Administrative Rules. The Board agreed to try to put all signage requirements in the same area. The latest draft was reviewed and a few minor changes were made. In addition, the Board discussed the issues raised earlier regarding definitions for different types of pharmacies and their functions. There is a significant distinction between a long term care (or home care) pharmacy which serves only residents of an institution from a long term care pharmacy which may serve both residents and former residents. In the end the Board proposed the following language.

Part 18 Long Term Care Pharmacies

- 1) **18.1 Community Based Long Term Care Pharmacies:** Community based long term care pharmacies are those pharmacies that only provide services to patients who do not reside in institutional settings, but who require a higher level of service than that typically provided by retail pharmacies. These would include unit dose or multi dose packaging promoting compliance with drug treatment regimens, and higher levels of medication therapy management.
- 2) **18.2 Applicable Rules:** Community Based Long Term Care Pharmacies shall comply with Part 9 Pharmacy Practice Rules.
- 3) **18.3 Community based long term care pharmacies** are distinguished from Institutional Long Term Care Pharmacies which are addressed in 10.2(b) of these Rules.

This information will be included under Section 18 of the draft rules. The changes will be made and updated copies of the proposed rules will be sent to members and posted on the Web Site. Currently licensed pharmacies offering closed door, home care services will be notified. This specific language will also be mentioned in the Board's June 2009 New letter.

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

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

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

Marquette, Michael J. (Endorsement)

Smith, Kate S. (Endorsement)

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). Temporary License is set to expire on April 30, 2009.
- b. Pharmacy Health Services, Inc. d/b/a/ **Marble Works Pharmacy** (038-3398), 99 Maple Street, Middlebury, VT submitted a new application to reflect a change in ownership. The latest inspection was conducted on March 11, 2009. Based on the results of the inspections, Mr. Firlik made a motion, seconded by Ms. Eaton, to approve this facility for full licensure. The question was called and the motion passed unanimously.
- c. 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. Temporary License is set to expire March 31, 2009. Mr. Firlik made a motion, seconded by Ms. Eaton, to extend the Temporary License to April 30, 2009. The question was called and the motion passed unanimously.
- d. Pharmacy Health Services, Inc. d/b/a/ **New England Mail Order Pharmacy** (038-3400), 111 Maple Street, Middlebury, VT submitted a new application to reflect a change in ownership. The latest inspection was conducted on March 11, 2009. Based on the results of the inspections, Mr. Firlik made a motion, seconded by Ms. Eaton, to approve this facility for full licensure. The question was called and the motion passed unanimously.
- e. 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). Temporary License is set to expire April 30, 2009.

Instate Manufacturer/Wholesaler:

- a. **Equinox Compounding Pharmacy LLC**, 34 Ways Lane, Manchester Center, VT, submitted an application for an in-state manufacturer/wholesale distributor. The Board reviewed the March 19th E-mail in response to the Board's questions from Cindy Harrington and Philip O'Neill and concluded that in addition to the retail services offered both manufacturing and wholesale distribution are also involved in the process as described. This one facility offers retail, manufacturing and wholesale services. The Board agreed to accept the most recent application submitted for both additional activities (manufacturing and wholesaling) however the facility and its operation would require multiple licenses. In addition to the retail license previously issued, an in-state manufacturing license is needed for compounding over-the-counter products and since these products would be sold to veterinarians and others, a wholesaler license is also needed.

Based on the information provided, Ms. Eaton made a motion, seconded by Mr. Pease, to issue 90-day Temporary Licenses as a manufacturer (124) and wholesaler (039). Since the facility was very recently inspected, no follow-up inspection is required to add these additional services. Approval for full licensure is subject to receipt of a copy of their approval from the Food & Drug Administration (FDA).

11. **Change in Pharmacist Manager:**

Mr. Laborn made a motion, seconded by Mr. Firlik, to approve the changes in pharmacist managers for completed applications as indicated below. Incomplete applications were tabled to the next meeting. Motion passed unanimously.

11. Change in Pharmacist Manager - continued
- a. **Copley Hospital Pharmacy**, (037-1531), located at 528 Washington Highway, Morrisville, Vermont, changed pharmacist managers from Mila Lishkato Dan iel Lewis.
 - b. **Rite Aid Pharmacy #10320**, (038-3364), located at 1 Prince Lane, Bristol, Vermont, submitted an application for change in pharmacist manager from Patricia Bardsharto Theresa L. Shangraw. The application is incomplete; additional signatures are needed—tabled.
 - c. **Oscopharmacy #7530**, (038-3320), located at 64 Equinox Terrace, Manchester Center, Vermont, changed pharmacist managers from Harry William to Sylvia Lio.
 - d. **Rite Aid Pharmacy #10310**, (038-3386), located at 52 Main Street, Windsor, Vermont, changed pharmacist managers from Cynthia J. Koch to Patricia A. Smith.
 - e. **Rite Aid Pharmacy #10308**, (038-3361), located at 1823 Vermont Route 107 #2, Bethel, Vermont, changed pharmacist managers from Patricia A. Smith to Kristin Cronin.
 - f. **Costco Pharmacy #314**, (038-3117), located at 218 Lower Mountainview Drive, Colchester, Vermont, submitted an application for change in pharmacist manager from Thomas Drougasto Marcie Jorgensen. The application is incomplete; copy of inventory needed—tabled.

12. **Non-Resident Pharmacies:**

Mr. Firlik made a motion, seconded by Ms. Pudvah, to approve for licensure the following non-resident pharmacies shipping medication to patients residing in Vermont. Motion passed unanimously.

- a. **Senior Med LLC**, 4015 Crescent Park Drive, Riverview, FL.
- b. **Morabito's Pharmacy**, 21 North 20th Street, Kenilworth, NJ.

13. **Wholesale Drug Outlets:**

Mr. Laborn 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.

- a. **APP Pharmaceuticals, LLC**, 600 Supreme Drive, Bensenville, IL.
- b. **Bound Tree Medical, LLC**, 129 Centerville Road, Henniker, NH.
- c. **Bound Tree Medical, LLC**, 481 Airport Industrial Drive, Southaven, MS.
- d. **Integrated Commercialization Solutions Inc.**, 345 International Boulevard, Suite 400, Brooks, KY.
- e. **Pharmacy Buying Association**, 1825 NW Vivion Road, Riverside, MO.
- f. **Smith Medical Partners, LLC**, 950 Lively Boulevard, Wood Dale, IL.
- g. **Sunbelt Medical/Emergi-Source**, 20 Capital Drive, Hilton Head Island, SC.
- h. **Merck & Co.**, Westpoint, PA.

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

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.

15. Continuing Professional Education Requests - continued

- a. **“Management of Pulmonary Embolism”** submitted by Shawna Barito, was approved for one hour of live (didactic) continuing professional education credit which was offered on March 17, 2009. The approval number issued was CE332(L)-0309.
- b. **“AMA Category I”** (three day seminar) submitted by, was approved for 24 hours of live (didactic) continuing professional education credit which was offered on, 2009. The Board acknowledged that approval of AMA Category I courses is not required. The approval number issued is CE(L)-0209.

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

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

- a. **Stephanie A. Austin**— submitted an Application for Registration of Intern and was approved.
- b. **Katherine S. Frank**— submitted an Application for Registration of Intern and was approved.
- c. **Kathleen Sawtelle**— submitted an Application for Registration of Intern and was approved.
- d. **Elisa A. Winterbottom**— submitted an Application for Registration of Intern and was approved.
- e. **Janeen W. Sanborn**— submitted an Application as a Preceptor and was approved.

17. **Pharmacy Technicians:** Total Number of Active Registered Technicians is **1,512** (1268 Resident, 244 Non-Resident).

18. **Newsletter Topics!**

Topics for the next issue of the Newsletter will include the DEA's updated requirements for reporting the theft or loss of controlled substances which requires registrants to include the National Drug Code (NDC). 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 drafted an article regarding wireless alarm systems. Ms. Eaton drafted reminders about registration requirements for technicians and interns. A reminder about renewals will be included in the newsletter noting additional information the Board will be seeking (reapplication for preceptor and place of employment). In addition, the Board will be requesting the type of pharmacy being licensed (i.e., compounding, mail order, retail, etc.) for in-state pharmacies so that a description (subcategory) may be added to OPR's system and that license as an endorsement. The Board's decision regarding long term care pharmacies will also be included in the newsletter.

19. **Miscellaneous Correspondence**

- a. The Board reviewed and discussed the March 16, 2009 letter from Bob Frenier regarding Price Chopper Pharmacy in West Lebanon, NH and its ability to deliver drug to the Chelsea Health Center in Vermont. They proposed a type of mail box system for patients to pick up their medications. The Minutes of the October 25, 2006 meeting were also reviewed in which this matter had been previously addressed. The Board will invite Mr. Frenier and otherstoits next meeting to discuss this matter further.
- b. The Board reviewed the information regarding Critical Point/Web Based Training Program for USP 797. Larry Labor will participate and report back to the Board. Inspector Daniel Vincent, Investigative Coordinator, Gregory Kelly, and Chief Investigator, Amy Carlson also plan to participate in this training.

- a. The Board reviewed the information regarding the Pharmaceutical and Chemical Diversion. Mr. Firlik hopes to attend.
- b. The Board reviewed the information from the Pharmpr 18th DEANational Conference on concerning the proposed rules.

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

- a. The Board reviewed the information regarding the Florida on May 16 to 19, 2009. Chairman Vincent is of budgetary constraints but hopes to send at least allow others to attend this important conference.
- b. The Board reviewed and noted other miscellaneous NABP correspondence.

21. **Public Comment**

Comments from guests were addressed above.

22. **Other Business Introduced**

The Board had follow-up questions and concerns regarding Pharmacy Network LLC d/b/a/ **Community Health Pharmacy—Pilot Project**, 157 Towne Avenue, Plainfield, Vermont. Concerns were raised about the technician who is employed by the Plainfield Health Center but supervised by the pharmacist. Is it a contract issue? It was the Board's understanding that the pharmacy technician would be an employee of the pharmacy. The Board had requested but has not yet received a copy of the job description for the pharmacy technician at the remote location. Since a nurse is to be the backup person for the technician in case of absence, the Board concluded that the nurse must also be registered as a pharmacy technician since she would be serving in that role. The Board indicated that the roles of the physicians, nurses, pharmacy technicians and the pharmacy must be clear for this operation. Different settings may permit other duties that would not be allowed in this scenario (i.e., nurse permitted to restock cabinet in hospital setting but not in pharmacy setting).

23. The next meeting is scheduled for **Wednesday, April 22, 2009** at 9:00 AM.

Meetings in 2009 are scheduled as follows: **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 3:55 PM.

Respectfully submitted,

Carla Preston, Unit Administrator
Office of Professional Regulation