

## NEW HAMPSHIRE BOARD OF PHARMACY

121 South Fruit Street, Ste 401

Concord, New Hampshire 03301-2412

603-271-2350



### PUBLIC MEETING MINUTES January 17, 2018

The Board of Pharmacy meeting convened at 8:44 a.m. with the following Commissioners present; Commissioner Merchant, Commissioner Pervanas, Commissioner Fanaras, Commissioner Bouchard, Commissioner Rochefort, Commissioner Laliberte.

Commissioner Genovese –Absent

---

*\*At the end of the Public Agenda, the Board will go into a Non-Public meeting under RSA 91-A:3, II(c) Matters which, if discussed in public, would likely affect adversely the reputation of any person, other than a member of this board, unless such person requests an open meeting. This exemption shall extend to include any application for assistance or tax abatement or waiver of a fee, fine or other levy, if based on inability to pay or poverty of the applicant.*

#### Agenda Review:

##### Items to move off the agenda:

- Ph1500 – Prescription Drug Monitoring Program administrative rules – Moved to #14
- Ph1100 – Collaborative Practice administrative rules moved to #15
- Walgreens – Exeter 1F will moved to #16
- All Genoa Name Change Applications 1-m through 1-q will move to items #17, 18, 19, 20, 21
- All Care Pharmacy PIC changes 1-r, 1-s, 1-t will move to items #22, 23, 24
- Move Public minutes of 12/11/17 off of the agenda to item #25

##### Items to Add to the Agenda:

- Add Compliance report to Item #26

##### Items to Move to Non-Public

- \* Item 4 Walgreens #10410 – Littleton – Incomplete application, operating without a PIC.
- \* Item 5 CVS #16862 – Nashua – Incomplete application, operating without a PIC.
- \* Unfinished Business ROI 435-17 Rite Aid #04144.
- \* Item 13 moved to Non-public (same as above-but listed on the agenda twice (unfinished business & #13))

- 1 Consent Agenda: Motion to approve the remaining items on the Consent agenda from Commissioner Pervanas and a second from Commissioner Laliberte. Vote 6-0-0.
- 2 PDMP update on audit response to fiscal committee. Michelle Ricco-Jonas presented a draft response. This format will be used as monthly updates to the fiscal committee. It will go to Administrative Services January 25,

2018, then to Fiscal Committee February 16, 2018 then Board will receive an update at the February meeting. Once approved by the Fiscal Committee, it will be a public document. This format and the timeline are approved by Board members. Motion from Commissioner Bouchard to approve with a second from Commissioner Pervanas. Vote 6-0-0.

\*Thank you to Commissioner Bouchard for accepting the position on the PDMP Advisory Council for the Board of Pharmacy.

- 3 6 Change in Ownership applications for Rite Aid containing a Walgreens Pharmacy (on the prescription label it will have both names). In attendance; Susan DeLeo, Healthcare Supervisor with Walgreens and Kabrina Hudson, Pharmacy Transition Lead with Walgreens. Inventory will be completed within 3 days of the date of change. The effective date of change is January 25, 2018.
  - a. Veronica Lewis, R.Ph PIC – Ossipee. Motion to approve from Commissioner Rochefort and Second from Commissioner Fanaras. Vote 6-0-0.
  - b. Sarah Connelly, R.Ph PIC – Wolfeboro. Motion to approve from Commissioner Rochefort and Second from Commissioner Fanaras. Vote 6-0-0.
  - c. Sejal Patel, R.Ph PIC – Center Conway. The application needs to be updated with additional pharmacist and who has access. Application was corrected at this meeting. Motion from Commissioner Rochefort and a Second from Commissioner Laliberte. Vote 6-0-0.
  - d. Jennifer Keazer, R.Ph PIC – Colebrook. Motion to approve from Commissioner Rochefort and Second from Commissioner Laliberte. Vote 6-0-0.
  - e. Todd Lukaszewski, R.Ph PIC – Berlin. Motion to approve from Commissioner Rochefort with a Second from Commissioner Pervanas. Vote 6-0-0.
  - f. Bryan Rossitto, R.Ph PIC – Lancaster. Motion from Commissioner Rochefort with a Second from Commissioner Pervanas. Vote 6-0-0.
- 4 Walgreens #10410 Littleton- PIC change application. In attendance; William Spencer, R.Ph PIC and Joel Parr, District Manager. An inventory count was completed when the PIC took over and will do another one when the PIC change is approved by the Board. The application was incomplete and tabled in December; we were required to submit a new application and now is being brought back before Board. We had a 60 day permit granted on the November 13, 2017 valid until December 31, 2017. We essentially lost the 30 days. The store did not have a PIC for 17 days. Motion to approve the pharmacist in charge application from Commissioner Rochefort and a Second from Commissioner Pervanas. Vote of 6-0-0.
- 5 CVS Pharmacy #16862 Nashua –PIC change application. In attendance; Philip Dangelo, R.Ph PIC and Josiane Abou-Jaoude, District Manager. Motion to approve the pharmacist in charge application by Commissioner Rochefort and a Second from Commissioner Pervanas with an effective date of January 17, 2018. Vote 6-0-0.
- 6 DHMC at Centerra, new facility. This is the only 24 hour facility within a 70 mile radius. There will be a set time to have a rest break each day. This pharmacy will also be doing central fill for other pharmacies in the area. At this time there is only one pharmacist listed, but we are hiring and we are looking to open March 1, 2018. When Compliance completes the Initial Inspection, the facility will provide a complete list of employee's that will be employed there. Motion from Commissioner Rochefort for a 60 day permit with a Second from Commissioner Laliberte. Vote 6-0-0.
- 7 Rule change request to begin rule writing for PDMP funding proposal – Motion from Commissioner Bouchard with a Second from Commissioner Laliberte. Vote 5-1-0 Commissioner Fanaras opposed.
- 8 Draft sterile compounding application –FYI to the Board and to review wording. One suggestion is to add 'Route of Delivery' ie; IV, IM, Intra fecal, Ophthalmic, Sub Q, Epidural to assess the risk for safety issues. One suggestion is to have training listed. One suggestion is to list the last inspection and if Sterile Compounding. One suggestion is to have Consultant Pharmacist listed. One suggestion is to title it "Non-Pharmacy" Application.

- 9 Return Logistics International Corp. Brian Stenz – conference call to discuss if his company is required to get a license. They are a disposal company and they never step foot into New Hampshire, the companies ship their disposed medications to his company and they put it in an incinerator and convert it into electricity. In our definitions RSA 318:1, 29 it details reverse distributor and the necessity for licensure.
- 10 Performix request to approve their Technician Training Program –This is a very basic program. We would like to see it more practice specific. The questions are very general. It also states there is an attachment 3, but that was not included and that would have been valuable to assess this program. New Hampshire has some nuances to our rules. We would have liked to have seen a more robust program. Administrator/Chief of Compliance has offered to send them the checklist again. Vote called to approve - not answered. Vote called to deny 6-0-0. Program Denied.
- 11 State Prison Proposal – Sam Fiore, R. Ph PIC. The Board would like to ask him to come in and meet with the Board in February to discuss his ideas.
- 12 Sterile Compounding Hearing – Commissioner Merchant wanted people to come in and speak to the Board to hear their concerns. On Tuesday January 23, 2018 at 9:00 a.m. there is a meeting with the stake holders, sub-committee; Commissioner Genovese, Commissioner Merchant and Commissioner Rochefort to collectively find language that will work. Ultimately, public health and protection for the patient is most important.
- a. Rick Fredette – Dave Hutton, Practice Manager for Atlantic Digestive Specialists, and Dawn Houghton is a consultant that is helping to address this issue. I also represent a couple of the clients that have been sited; Dr. Mitz in Littleton who is owner, provider physician, North Country Gastroenterology and Convenient MD with multiple locations. I have been asked to be the spokesperson today so that we do not overlap. The Coalition favors the proposed amendment to RSA 318's definition of compounding and the coalition hopes to work with the Board as it relates to rules that will then be promulgated. Stated right up front the objective of the coalition is to have safe, access by patients to services/treatments that they have been enjoying for the past 15 years. The coalition, my clients as well, view the Board's actions, recently in November and December, of fines and violations recently received as something that needs to be rescinded as a show of good faith and a desire to have this situation dealt with responsibly and professionally. The providers that have been caught up in this new enforcement effort would be disadvantaged and treated unfairly if that were not the case. The third point is to ensure the 'status quo' the interpretation of the law and the enforcement of the law as of October/November 2017 remain as 'status quo' and so essentially that they can continue to provide services to patients, that they have been providing, for many years, without interruption of services. That 'Status quo' remain until such time as rules are adopted by the Board and by this collaborative process that we envision with the stakeholders meetings and such and no further actions until we have clarity from the Board of pharmacy as to the concerns that they are seeking to address and the direction that they are going to be taking in the future.
- b. Dawn Holcolm, Consultant, I run the State Oncology Association in Connecticut. I urge to rescind and reset. There are several key issues to be reviewed. There is no state of emergency. What happened with NE Compounding Center was a criminal activity of a pharmacy that was acting as a manufacturer. What we are talking about here are medical practices that have been functioning under their medical license and they have been compliant with what they are supposed to do. I caution that USP 797 and USP 800 will not be completed until at least 2019 so I hope the Board does not hang its hat on those standards.
- c. Christopher Czek, R.Ph representing Bioscrip Infusion Services in Bedford, NH and Ryan Tannigan, R.Ph representing Option Care Bedford in Bedford New Hampshire. We have been supplying biologics and home infusion to patients safely for decades. We have stringent policies and procedures in place for our employees. I, (Chris Czek) testified in front of the Senate and submitted data showing that we have safe techniques in place. Our nurses cannot even administer until they have been trained for 90 days and have been approved by their preceptor. Mr. Tannigan; our companies are competitors in day to day life, but in this circumstance, we are on the same page. Our nursing model is very similar to Chris' all of our

nurses are registered nurses and most of them have gone on to get the registered nurse infusionist certification, there is continuing education requirements, the certification needs to be renewed every 3 years, our organization has drafted some ideas for legislation. Our organization is also in favor of the rescind and reset of the violations and we look forward to working in a collaborative practice in the future.

- d. New England Life Care – Keith Tommisett, R.Ph our organization is a not for profit home infusion company. We work as an extension to our hospitals. Brett Snow, Regional Director for New England Life Care has sterile compounding experience dating back to 1989 when they used to do sterile compounding bare-handed. Erika Sievert – New England Life Care in Concord office. We are in agreement with all of the statements as stated, we want to commend the Board for willing to come together as partners and work collaboratively for the union of the best practice for our patients. Thanking the Board for their willingness and eagerness to come together and work together for the patient care and to make sure it is paramount in the process moving forward.
- e. Anthem Blue Cross Blue Shield - Paula Rogers there are different numbers when looking at Remicade there were several hundred that needed to be re-directed and when broadening our view, there was about 1,000 that needed to be re-directed for treatment. This company favors a statutory amendment and encourages clarification and definitions.
- f. Vice President NH Hospital Association - Cathy Rizzaro-Thumburg, the hospital agrees with the direction that the Board was taking and with regards to keeping the patient safety. The hospital wants to ensure that all practice settings has the same set of standards. The hospitals have been working very diligently to meet the standards of USP 797 and those standards have not come easy and the hospitals want to ensure no matter what setting and no matter what the standards are that everyone meet those same standards. The hospitals want the Board know that we will be an active participant in these discussions.

Comments from the Board: The Board is asking participants attending January 23, 2018 meeting to bring any data that you think would be helpful as we work through this process. Another request is to demonstrate how they can provide a safe environment in the home. Chris Czek would be happy to bring a nurse and some dummy vials to do a demonstration.

- g. Jennifer Sharon – NHIA would caution that we should be determining what the ruling needs to be before we determine exactly what the process needs to be. I am fearful that if we start bringing people in here it could have an issue with how we affect the ruling. I would suggest that we focus on the ruling at the stakeholders meeting and then focus on training components and how we want the process to work before we start looking at a process. I applaud the Board for working together with the stakeholders and there is a bit of a gap here between what you feel is happening in the patients home and what we feel is happening in the patient's home and the training component associated with that. First we need to focus on;
  - 1. Patient Safety
  - 2. Common Standard in all practice settings
  - 3. Evidence based, decisions based on the data

At this time, we would like to close the conversation and move on with the agenda.

On Motion from Commissioner Rochefort and a Second from Commissioner Pervanas to delay enforcement action further until June 1, 2018. Vote 6-0-0.

The Board has imposed discipline that includes; Nashua Rheumatology, North Country Gastroenterology and Atlantic Digestive at its November/December 2017 meeting. On Motion from Commissioner Merchant and a Second from Commissioner Pervanas to vacate the disciplines imposed. Vote 6-0-0.

14. Ph1100 Collaborative Practice – On Motion from Commissioner Fanaras and a Second from Commissioner Bouchard to approve. Vote 6-0-0.
15. Ph 1500 PDMP rules – On Motion from Commissioner Bouchard and a Second from Commissioner Fanaras to approve. Vote 6-0-0.
16. 1-f Exeter – Walgreens, PIC change on Motion by Commissioner Rochefort to approve effective 1/17/2018 with a second from Commissioner Fanaras. Vote 6-0-0.
17. 1-m Name Change for the Genoa facilities – no representatives in attendance. The Board is frustrated with all of the issues with the applications and not being complete. There were duplicates and some not signed. The Board requests that the original application be all together and then the subsequent documents submitted to the back of those applications.
- \* Per the discussion: all of the PIC changes, name changes, and so on, received in office, if they are NOT COMPLETE in ALL manner the application **will be returned to the address on the application itself.**
  - \* Per the discussion: In the rules is the form able to be corrected without changing all of the rules? Chapter 300's are currently being worked on and Traci will review the rules and the application and come to the February meeting with suggestions and ideas on how to streamline this process.
  - \* Per the discussion: Fix the form, create a checklist, put a timeline on them, and start on the rules and with all these three things it should assist in streamlining this process.
- On Motion from Commissioner Rochefort to approve the name change applications for Genoa QoL Healthcare Rochester, Nashua, Manchester, Laconia, Derry contingent upon receipt of the signature page with a Second from Commissioner Pervanas. The above Motion and Second Withdrawn.
- On Motion from Commissioner Rochefort to approve the name change application from Genoa a QoL Healthcare Company, LLC to Genoa Healthcare, LLC for the facilities of;
17. 1-m Rochester,  
 18. 1-n Nashua,  
 19. 1-o Manchester,  
 20. 1-p Laconia,  
 21. 1-q Derry
- And are approved contingent upon receipt of the signature page; with a Second from Commissioner Pervanas. Vote 6-0-0.
22. Care Pharmacy Epsom – Justin Couture, R.Ph moved from 1-r. PIC change application. On motion from Commissioner Rochefort and a second from Commissioner Pervanas to approve the PIC change. Vote 6-0-0.
23. Care Pharmacy Rochester – Francis Cassidy, R.Ph moved from 1-s. PIC change application. On motion from Commissioner Rochefort and a second from Commissioner Pervanas to approve the PIC change. Vote 6-0-0.
24. Care Pharmacy Wolfeboro Falls – Alexander Pelkey, R.Ph moved from 1-t. PIC change application. On motion from Commissioner Rochefort and a second from Commissioner Pervanas to approve the PIC change. Vote 6-0-0.
25. 1-a Public Meeting Minutes dated 12/11/17 moved to item 25. Item 25 moved to Non-Public.
26. Compliance Report – Administrator/Chief of Compliance asked the Board to consider moving licensing to Biennial renewals. The Board has requested that the inspection forms be placed on our website under Compliance. Commissioner Pervanas has a task force meeting coming up and will share the rules with the task force if the Board is ok with it. Rules to revisit in February: 300, 700, 1800. Ph800 went off to fiscal impact and they have not come back yet. Ph800 and Ph1800 could be combined. The Board needs to have a Policy &

Procedure manual strictly for the Board for chain of command and organizational procedure, elections every year and so on. We can just add to the current book that we have.

Motion from Commissioner Merchant and seconded by Commissioner Fanaras to move in to Non-Public meeting pursuant to RSA 91-A: 3, II (c) *Matters which, if discussed in public, would likely affect adversely the reputation of any person, **other than a member of this board**, unless such person requests an open meeting. This exemption shall extend to include any application for assistance or tax abatement or waiver of a fee, fine or other levy, if based on inability to pay or poverty of the application.*

**Roll Call:** Commissioner Merchant, Commissioner Genovese, Commissioner Pervanas, Commissioner Fanaras, Commissioner Bouchard, Commissioner Rochefort all in attendance. Commissioner Genovese absent.

Motion to adjourn the public session from Commissioner Fanaras and seconded by Commissioner Bouchard at 12:00.

DRAFT