

# NEW HAMPSHIRE BOARD OF PHARMACY

121 South Fruit Street, Ste 401

Concord, New Hampshire 03301-2412

603-271-2350



## PUBLIC MEETING MINUTES November 14, 2018

Board of Pharmacy Meeting convened at 9:35 a.m. with the following Commissioners present; Commissioner Merchant, Commissioner Rochefort, Commissioner Genovese, Commissioner Laliberte, Commissioner Pervanas, Commissioner Bouchard, Commissioner Harrington.

Absent:

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Roll Call verifies a quorum.

### 1. Consent Agenda Review:

Move Off: G - PDMP Monthly Review

Add On:

- a. - FDA MOU most recent update
- b. - Congratulations to the NH Board of Pharmacy Chair, Gary Merchant for being Elected to the House of Representatives.

On motion from Commissioner Genovese with a second from Commissioner Pervanas to approve the remaining items on the Consent Agenda, with a Board Vote of 7-0-0.

Remaining Items:

- 1-a Public Minutes of 10-17-18
- 1-b PIC Change - Bernard Provencher, RPh - Northeast Pharmacy Services, Concord.
- 1-c PIC Change - Falon Kaspszak, RPh - Bedford Pharmacy
- 1-d PIC Change - Emilie White, RPh - New London Hospital
- 1-e PIC Change - Courtney Turgeon, RPh - Hannaford #8317 Rochester
- 1-f PIC Change - Erica Sievert, RPh - New England LifeCare Concord

2-a Adoption of Ph 800 Pharmacy Technician Rules. On motion from Commissioner Pervanas to approve with a second from Commissioner Rochefort and a Board Vote of 7-0-0.

2-b Adoption of Ph 1600 Intern Rules. On motion from Commissioner Pervanas to approve with a second from Commissioner Rochefort and a Board Vote of 7-0-0.

3. PDMP Strategic Plan - Opening statement from Commissioner Merchant, We have a proposed plan before us. The discussion is about the plan itself. The plan as it is proposed is not what was discussed at the 2 day strategic plan meeting in June. At the two day meeting there were 5 overarching goals and I do not see these in the plan itself, where it addresses those goals or half

measures in order to achieve those goals. What I do see within the plan is how to deal with the audit, which appears to be more of an operational plan and not a strategic plan, in my opinion. Commissioner Bouchard - I have concerns with the language on the bottom of page 9 and the top of page 10 the discussion during the strategic planning process identified stakeholders that could benefit from the PDMP data. I do not agree with opening this up to other users. Commissioner Pervanas - There are some items listed that do not have strategies listed underneath it, almost like there is missing information, I understand that this is a work in progress. I have worked on strategic plans in my work experience and a strategic plan does not happen in two days, they take a very long time, to organize and put together. I feel that this is a good starting point, but I think it is something that we need to work on and improve. Commissioner Laliberte and Commissioner Genovese support and agree with the previous Commissioners comments. Commissioner Rochefort - One of the things we have talked about over several months is the inability to receive reports, reporting issues and the software shortcomings. This strategic plan should include these. Commissioner Harrington-I agree with Commissioner Pervanas that we need to identify short term and long term strategies to be able to accomplish all our goals here. Being able to create short term strategies will allow us to get results sooner, while some of the long term strategies will account for some of the challenges that we've had with getting the data to be able to move things forward. Also as I look at some of the performance measures and the tactics that would need to be in place to be able to support that, I am not sure that we have access to the information that we need to be able to get that information. What I don't want to do is to over promise for what we can't deliver on. Commissioner Merchant - in hearing this discussion, I would say fundamentally the Board is in favor of the intent of the plan, but we don't favor the content or the fundamental plan itself as written today. That we need to go back and review the audit and get some clarification from it. Commissioner Harrington - I feel that maybe some of it is the structure, the fundamentals that are embedded in the plan I think are good, I think it is just rolling it back up under those 5 overarching goals and showing that each of the strategies we have in place will support those goals. As I try to do that, there may be goals, that don't have strategies to be able to support it. So I think just laying it out differently, taking those fundamentals that Michelle has come up with and through strategic planning sessions and rolling it up under those goals might help. Commissioner Merchant - So what's before us is a vote in favor of the draft, or vote not in favor of the draft. So we need a motion, which way do people want to go? Commissioner Bouchard asks can we vote to amend the letter. Yes.

We need to amend the draft letter to read:

1. The Board is in favor of the plan, but not all of the content of the plan.
2. We need to outline the 5 goals given, but also stress the problems related to the software program and that we really cannot achieve anything until we have a software program that fits our ability to reach those goals.
3. We need to delete the language on the bottom of page 9 and the top of page 10 related to opening up the program to other stakeholders.
4. The draft letter needs to come back to the Board for review. It will come back to the Board in December.

On motion from Commissioner Bouchard with a second from Commissioner Harrington to amend the letter as defined above with a Board Vote of 7-0-0.

Administrator/Chief of Compliance Bullek - asks the Board, how are they going to move forward with this. The Board needs to move forward along the timeline with the Strategic Plan, which means the Board will need to hold another meeting to decide what their next steps will be and how they are going to frame what you just discussed. You have to have something moving forward with this. The next deadline is you need to have something for December's Fiscal by the last Friday in

November. You have a two-three week window ahead of time that you have to have your plan accepted.

Commissioner Merchant is calling upon Commissioner Harrington, at the next advisory council meeting, which is scheduled for November 19, 2018, to ask them to build upon that frame that we just framed. Commissioner Merchant will be glad to help if they need help editing along the way. Just let him know. The Advisory Council should be made aware of the deadline, if they do not know about it.

4. Ph 500 Ethics Rules - First Draft. Our previous Intern Gizelle Gepigon helped us gather information from other states along with our current ethics rules. The Attorney General's office has stated we have the statutory authority to write and enforce ethics rules. Pharmacy Ethics is a big topic nationally and we want a lot of comment on these, we do not want to overstep our boundaries, but we want to be sure we are protecting the public the best way we can. Commissioner Bouchard would like to put this onto our December meeting for discussion. This is a Board discussion, not a general discussion. Commissioner Merchant would like to be certain we include 'fit place to practice' which Commissioner Laliberte is working on these rules in Ph 700. We also want to be certain the permit holder is providing a fit place to practice. 501.02 'civil immunity' Administrator/Chief of Compliance Bullek will refer this to Board Council. 502.01 Definitions will be needed here, including criminal acts, are we talking about misdemeanors, felonies, and is it in our purview to defined those acts. Some states are taking a very hard line to 'sufficient personnel' so if we go in this direction; we need to work through this carefully. One request/comment was to have a Vaccine Registry available for all practitioners; this would eliminate the issue with duplicate vaccines. Someone would have to send a letter to DHHS asking for their Vaccine Registry to be available. Ph 318:20, there is a typo, it should say 'party' not parties. The Board will review and send comments back to Administrator/Chief of Compliance Bullek with any comments **no later than November 30<sup>th</sup>**. Discussion Item.
5. Statute Changes - Clean-up bill. On motion from Commissioner Genovese with a second from Commissioner Pervanas to approve these items, with a Board Vote of 7-0-0.
6. New Pharmacy Application - Genoa Healthcare, Keene - Kelly Cook, RPh and Kevin O'Connell in attendance. This facility will be working in coordination with Monadnock Family Services; it is essentially a Closed, Long Term Care Pharmacy. There is a floater list of people who would cover if needed and they will have a driver to deliver. The service will include mailing. They are both aware that the driver will need to be a registered technician in order to deliver the medications. On motion from Commissioner Rochefort with a second from Commissioner Pervanas to approve the New Pharmacy Application with a Board Vote of 7-0-0.
7. New Pharmacy Application - Genoa Healthcare, Claremont - Priya Patel, RPh and Kevin O'Connell in attendance. This facility is a Behavioral Health, Full Service Pharmacy. A PRN pharmacist will cover her absence. Ms. Patel is aware that she is responsible for the pharmacy while she is away. On motion from Commissioner Rochefort with a second from Commissioner Pervanas to approve this application with a Board Vote of 7-0-0.
8. Ph 2100 Inspection Rules - Final Review to send for Fiscal Impact Statement. The only forms you have not seen before is the Practitioner Inspection rules. This packet includes all of the forms, including self-inspections, and some secondary forms that we need to use. Hopefully we will only be using these for a year or year and a half until we get our new tablet/iPad and software that will work with our My License Office software. Once we have our new package in place, we will be able to

have the 106 drug loss forms and all documentation for that pharmacy available at the beginning of an inspection. Currently we put these into the database, but have a paper document for the inspectors. The price tag of that software package is \$97,000,000.00 a lot more than originally anticipated, but once we have it, the Inspectors will have everything they need in order to complete an inspection right at their fingertips. Even when they go up to Berlin, they will have hotspot access that they need in order to complete an inspection, review the database, etc. In regards to the Compliance Audit all compliance forms are in this packet and are just about completed. The compliance audit requirements are about 90% completed. We are sitting down and updating just monthly all the forms, procedures, processes, etc. This set of rules is on our website in case anyone wants to take a look at them. Commissioner Rochefort has a lot of questions regarding these inspection rules; In the audit, they pointed out we do not have a mechanism in place to inspect Non-Resident pharmacies; yet, on the same side we do have the mechanism to do in-state pharmacy inspections. The audit states we need to do 'Risk Based Inspections'. Will the inspection frequencies be included in these rules? I would like to have the in-state pharmacies and out of state pharmacies all inspected with the same guidelines, including Non-Resident Pharmacies. I don't want to see our standards in New Hampshire become so erroneous in the State of New Hampshire that our residents have to go outside of New Hampshire in order to have Sterile Compounding. The wording in these rules state they could be inspected 'up to twice a year'. Commissioner Rochefort would like to have an out of State pharmacy inspection process put into these rules. Ph 2103.01 (c). Sterile & Non-Sterile "outsourced" is not required. We should ask the companies to "have the documents available upon request" and not required to send in to the board every time they have an inspection. We need to 'group' the risk levels together. Anyone doing Sterile Compounding should be in their own category. 2105.01(3) B-1 High Risk Facilities shall include; 795 into that section and we will have to add the revisions when completed 797 and 800. Administrator/Chief of Compliance Bullek, is asking all Board members to review and submit comments back to Mr. Bullek **no later than November 30<sup>th</sup>**. Discussion Item.

9. Ph 2200 Investigation/Violation rules - Final Review to send for Fiscal Impact (Audit Requirement) The Board would like to see the fines put into our policy and procedures. We can put that into policy. There are 3 documents; Statutes, Regulations, Guidance Documents I would like to start using the guidance documents so that we do not have submit those documents to JLCAR. Administrator Bullek explained to Commissioner Merchant that if you reference this in the rules then it will have to be put into the rules. And he also spoke with the Board's Attorney, and also Director Walsh states, if you want to incorporate any document at all, if you reference it, then it has to be part of the JLCAR process, even though it is not considered part of the rule. Commissioner Merchant states he was thinking of the Declaratory Ruling. Direct Walsh states that the Declaratory Ruling might not be the correct avenue for what he is trying to accomplish. Administrator/Chief of Compliance Bullek, is asking all Board members to review these rules submit all comments back to Mr. Bullek **no later than November 30<sup>th</sup>**. Discussion Item.
10. Ph 2400 Contraceptive Rules & Protocol - First Read of Draft Rules. Commissioner Pervanas asks Ph 2403 B should be ACPE or Board approved program. Ph 2406.02 The way it is written sounds like the pharmacist has to drop everything to assist the patient. Commissioner Pervanas states this came out of Oregon and the pharmacist stated that a patient came in and wanted to talk about this and the pharmacist asked if they could come back in a few minutes, and the patient was fine with it. Administrator Bullek will put 'or' in there. At least give the patient the option to come back in a ½ hour and this is part of the workflow for a pharmacist because the pharmacist has ½ hour worth of prescriptions to be filled and then they meet with the patient, it is part of the workflow.

Administrator/Chief of Compliance Bullek is asking all Board members to review and submit comments back to him **no later than November 30<sup>th</sup>**. Discussion Items.

11. FYI - Attorney General's Office response to definition of 'Standing Order' - Administrator Bullek will file.
12. FDA, Memorandum of Understanding (MOU) - Commissioner Rochefort explained all of the different reasons why not to enter into this MOU with the FDA. The letter goes on to urge the FDA to revisit the quantity vs quality and to work with NABP and possibly come back with different parameters. On motion from Commissioner Pervanas with a second from Commissioner Laliberte to accept this response and to send it out with a Board Vote of 7-0-0.
13. Draft LSR regarding "Licensed Pharmacist Assistant" Commissioner Merchant has provided an outline on how the Board would like this license type to be licensed with our office. Type on the first line to read "Pharmacist Assistant" On motion from Commissioner Bouchard to accept the LSR as amended with this discussion with a Board Vote of 6-1-0, Commissioner Pervanas opposed.
14. New Pharmacy Application - Premier Pharmacy removed, not reviewed by the Board - Incomplete application.
15. Request for clarification of Ph 807.03 (h) concerning CPhT stocking of medication in an ADM (Automatic Dispensing Machine). The non-certified technician can pull the medications and be checked by a Certified Pharmacy Technician and then restock can be completed by a certified technician. In the new rules approved at this Board meeting Ph 807.02 (c) it clearly defines and is correct in the rules. Discussion Item.

FYI - Projects with each Board Member:

**Commissioner Bouchard** - is monitoring the NH General Court's website and the LSR's coming and she does not see anything for the PDMP or the BOP. Search by key words came up with Opioid, relative to a study the effect of the Opioid crisis and domestic violence in New Hampshire children. Relative to treatment in the Opioid crisis with cannabis. And also adding Opioid addiction through qualifying medical conditions. Another LSR speaks about individuals on Boards and the penalty for failing to file a Financial Disclosure Form. Statutory Commissions to study costs & drugs and loss. In January the Board will vote to outline the stance of the Board for any LSR's in progress. Whether we support, oppose, or negate the LSR & Statutory Commissions so everyone will know where the Board stands on each topic.

**Commissioner Harrington** - regarding the advisory council. We reviewed some reports in October of drug overdoses and it does appear that this has leveled out a bit. The council hopes to share some de-identified data in the near future and at their next meeting now, they will be looking at the Strategic Plan.

**Commissioner Rochefort** - I have been reviewing the revisions to chapter USP 795, 797, and 800. USP 800 will have a Final Release scheduled for 12/2019 along with 797. Chapter 795 and 797 are not final. Chapter 800 is final. Because our statute has the USP as law, we are going to have to redo our sterile compounding rules all over again. I have a group of stakeholders that I am gathering together to work on this project and we are still looking for a hospital stakeholder to add to this group before we begin this project.

**Commissioner Pervanas** - Previous Board Commissioners voted to self-report their ce's every year to the CEAC Audit. The CEAC committee will be meeting soon to review all Certified Technician Audit and get that process completed.

**Commissioner Genovese** - I am putting together a stakeholders meeting with Cathy from the Hospital Association to review the Institutional rules and provide updates. The date is to be determined.

**Commissioner Laliberte** - Ph 700 there will be a meeting in December/January to review and go through these rules. If anyone is interested, please email me and I can give you the date and place we plan to meet.

**Commissioner Merchant** - I am working on the CQI rules and the LSR for Licensed Pharmacy Assistants we talked about today. We are trying to come up with a revision to the draft that includes some of the comments from the last meeting. I plan to have a conference call to include past Board member Bob Stout.

16. PDMP report - Commissioner Rochefort has a question about page 59 Vendor Management and clinical alerts when will these reports be presented to the Board? Administrator Bullek states, when the data is not corrupt, it will be brought before the Board. We cannot get the data in a proper format that is presentable. Commissioner Merchant asks - where are these public reports located? NH PDMP public report is on the PDMP website. #2 shows PDMP 'audit report declined' I am concerned because the Board did not "decline" the report. I opposed it, but the Board did not. This report is on Michelle's website and she will make the corrections. On Motion from Commissioner Merchant to approve once the wording shows the report is "under review" with the Board and she removes "Decline(d)" with a second from Commissioner Pervanas and a Board Vote of 7-0-0.

On motion from Commissioner Rochefort with a second from Commissioner Pervanas to adjourn the public meeting at 12:20 p.m. with a Board Vote of 7-0-0.

\*Roll Call to move into Non-Public validated a full Board was in attendance.

*\*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.*

Chair Signature of Approval \_\_\_\_\_ Date \_\_\_\_\_