

**NEW HAMPSHIRE BOARD OF PHARMACY**

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**PUBLIC MEETING MINUTES March 21, 2018**

The Board of Pharmacy Board Meeting opened at 8:30 a.m. with the following Commissioners present; Commissioner Merchant, Commissioner Fanaras, Commissioner Rochefort, and Commissioner Laliberte, Commissioner Genovese, Commissioner Pervanas, Commissioner Bouchard.

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Consent Agenda Review:

1. Move Cheshire Medical Center to 1A
2. Public Minutes moved to 1B
3. #16 fiscal meeting from Friday March 16 added.
4. #17 Discussion continuing education program added.
5. #18 FYI June Board of Pharmacy meeting to be held at MCPHS.
6. #19 SB581-FN passed the senate.
7. Non-Public Agenda items to add U, V, W, X
8. Items Tabled until April; Public Agenda - #5, Non-Public - O and Q
9. #20 Review of the Legislative Crossover from Commissioner Bouchard

New Business:

1. Consent Agenda on motion from Commissioner Genovese with a second from Commissioner Pervanas to accept the remaining items on consent agenda. Board Vote is 7-0-0.
- 1-a. Cheshire Medical Center PIC Change – Jeffrey Poirier and David Quigley, VP of Cheshire Medical Center. On motion from Commissioner Rochefort with a second from Commissioner Bouchard to approve the PIC change. Board Vote is 6-0-1 Commissioner Genovese and Commissioner Fanaras recused.
- 1-b. Correction to Public Minutes of February 21, 2018; Item 21 change DBIS sheet to VIS sheet. Commissioner Merchant notes that the Board was voting in the affirmative but the vote's show 6-0-0. Commissioner Merchant would like the votes to reflect all 7 members voting. The meeting minutes will be corrected and brought back to the Board for review and approval.
2. PIC Change Application for Rite Aid Pharmacy #1295 – David Ambrose, R.Ph. On motion from Commissioner Rochefort with a second from Commissioner Bouchard to approve the PIC change effective March 21, 2018. Board Vote is 7-0-0.

3. NH Hospital PIC change application – Mary Galatis, R.Ph and Rosemary Castanza Chief Nursing Officer, NH Hospital. On motion from Commissioner Rochefort with a second from Commissioner Fanaras to approve with an effective date of March 21, 2018. Board Vote is 7-0-0.
4. Genoa Pharmacy – no representation for the new pharmacy application. This will be tabled until April Board meeting.
5. Tabled until April Board meeting.
6. Hearing Council's Petition to accept the Voluntary Surrender of License for Samantha Sanborn, Pharmacy Technician. On motion from Commissioner Genovese with a second from Commissioner Rochefort to accept the Voluntary Surrender. Board Vote is 7-0-0.
7. Samuel Fiore – NH State Prison Pharmacy Proposal to change the process of filling prescriptions. Commissioner Merchant, are we possibly talking about going back to the floor stock days where we would have medications that are not patient specific but under some sort of lock and accessible by the nurse? Yes, we return about 8 boxes of medications that are about 2' x 2' x 2' with medications that need to be destroyed each month. There is a bar code system but it has not been put into place yet. We have about 20-25 medications that are most frequently used. I would ideally prefer to have a Pyxes or an Omnicell Machine but there are funding issues. The Board members understands the funding constraints, however the Board members ask that Mr. Fiore go back and put a dollar amount to the amount of waste then you would probably be able to pay for a Pyxes or Omnicell machine.
8. Pharmerica PIC Change – Mr. Emil Uliano, Jr and Mr. Stephen Gauthier, Director, Regional Manager both in attendance. Mr. Uliano sent in the application and it was returned for incompleteness then was returned to the Board's office. This was the reason for the delay in getting a PIC application to the Board on time and the lapse of pharmacist in charge. On motion from Commissioner Rochefort with a second from Commissioner Laliberte to accept the change of pharmacist in charge with an effective date of March 21, 2018. Board Vote is 7-0-0.
9. Ammonoosuc Community Pharmacy – request to keep records in the clinic and transfer as needed. The facility is shutting down their dispensing pharmacy and currently working through this process with the Board; however we are seeking guidance in regards to transferring the prescriptions that remain in the pharmacy after the closure date. We are not selling our prescriptions. We mailed a letter to all of our patients informing them of the closing and asking them to contact our pharmacy to transfer their prescriptions to a new pharmacy. We will have a pharmacist on staff to work with the patients even after we close. We have a phone number specific for patients to call and transfer their prescriptions. We hope everyone will call and will have transferred out, but we anticipate there will be a few people left over. We sent the letter out to over 2,000 households. We want to do the best thing for our patients and stay within the laws and rules. Administrator Bullek will send a letter of approval with a restriction that if the pharmacist leaves before one year, then the facility will come back to the Board with a contingency plan as to how they are going to maintain the records. And they must maintain the records for a minimum of 4 years from the date they close. On motion from Commissioner Fanaras to approve the above mentioned proposal with restrictions and a second from Commissioner Rochefort. Board Vote is 7-0-1 Commissioner Merchant recused.
10. Upper Connecticut Valley Hospital – Request to allow a Certified Pharmacy Technician into the pharmacy before opening. We are the tiniest hospital in New Hampshire, there is one pharmacist (me- Robert Gooch) and I have one Certified Pharmacy Technician. Because I am the only pharmacist, I would

like the technician to come in and clean the hood and get it up and running so when I come in I can get the infusion medication ready for the one person who wishes to come in and get it in the morning before she goes to work. One Board member has suggested the hiring of a pharmacist, so Mr. Gooch can be at all of these other events that are also just as important. The hood is in the pharmacy that has a keyed, alarmed pharmacy. The Pharmacy will not be open for business or dispensing when this person will be in there cleaning. One Commissioner stated; nobody is allowed to have key entry access except a pharmacist or security. You state that the Certified Pharmacy Technician texts you and go and process the prescriptions. At any time do you ever approve medications via text? Mr. Gooch replied in the negative, I always go and process the prescriptions myself. You state that you have a key fob. I would encourage you to limit the access to the pharmacy using the key fob and not allow access any other times, except what is allowed by the key fob. Ph709.06A only a pharmacist can open and close the pharmacy. At this time, when I am in meetings, my Certified Pharmacy Technician will text me and let me know there are orders, so I leave the meetings and go process the orders and then go back to my meetings after. The circumstances around this situation are very unique. We do not allow security in there at all. Security will call the pharmacist at night if there are any issues. We are working in Ph700's today and maybe we should go in there any define/word it so that this variance can be approved today. Ph709.06. There needs to be a variance because we do not define "absent" so in Ph700 and Ph800 and Ph1900 we need to define "absent" and also "security access" one recommendation is to make her access to the pharmacy limited to the time they are scheduled to be at work only and do this for the Nurse Supervisor as well. On motion from Commissioner Fanaras based upon Ph 709.06 Upper Connecticut Valley Hospital's request is granted with a second from Commissioner Rochefort. Board Vote is 7-1-0 Commissioner Pervanas votes in the negative. The Board of Pharmacy will review Ph700, Ph 800 and Ph1900 during this review we will look to; clarify, define, and review "absent and security access".

11. CVS request for a declaratory ruling on statute 318:38 (I) – The request is the same request as previously received with a different version of the rule. Again, Attorney Broderick and Administrator Bullek will discuss this request, and then you will have 60 days to answer their request. On motion from Commissioner Fanaras to accept the request for a declaratory judgement for CVS and further discuss and investigate the legislative intent of 318:38 and send off to Attorney Broderick with a second from Commissioner Rochefort. Board Vote is 7-0-0.
12. MPCHS University Pharmacy Lab floor plan change. They would like to change their floor plan, but this question brought up the question of why they were licensed at all. It was determined they do need a license because they are buying saline in order to practice making IV's. They are not a traditional pharmacy. We could issue a pharmacy permit with restrictions, but they would have a large amount of variances with this permit. We are currently working with this type of permit in rules right now and this would be a great time to put in a license type particularly for an Academic Facility permit. On motion from Commissioner Fanaras to accept their proposal as amended with a list of variances needed and a second from Commissioner Genovese. Administrator Bullek will create a list of variances and send it off to Cheryl they will review and sign, then mail it back to the Board's office to attach to their application. Board Vote is 7-0-0.
13. Rules Review; Ph300, Ph700, Ph1900 – Commissioner Merchant would like to speak to the Board members before reviewing the rules ready for final review before sending to the Legislative office for a Fiscal Impact Statement. He wonders if there should be a separate section just for definitions. He wonders if we are going down a wrong road, we do not have a clear chapter in the rules for definitions.

Commissioner Fanaras states that there are some definitions within the rules because it applies to the rule it is in. Commissioner Merchant would also like to go back and reformulate all of the chapters and rework all of the rules so that it reads more like a book with chapters. Our rules do not have just the practice of pharmacy, now we are into the Collaborative Practice and so much more. Commissioner Merchant feels that the permit holder should have clear definitions and they should provide a fit place to practice. The PIC really does not have any control over the facility, or fit place to practice, we do not define what that means. Commissioner Merchant is asking the Board members to go back and look at the way we are drafting the rules and designing the rules to the practice that we have today. Some Board members agree that sounds like a good idea, but that is a lot of work and something that would take many years to complete. Commissioner Merchant wants to rebuild the framework for the rules. Commissioner Laliberte agrees, that is what should be done, but we don't have the time to do it. And in the meantime, we have so much that is out of date, but what you want done is a couple of years in the making. Commissioner Merchant agrees, but if we can agree on a Table of Contents and a framework, then tackle the rules and put them into the framework. Commissioner Merchant wants the framework in place before we move the rules forward. Commissioner Merchant asks shouldn't we have rules in place that are more prescriptive, not descriptive.

14. Draft QRE and Self Inspection Reports – FYI. 15. This is all for retail, we need a separate one for Institutions. We have not had an Institution investigation in many years. We had the Lean people go out with two of our inspectors and it opened their eyes to what we really need and what our processes are. And we will hopefully get through this lean process. Part of the process now, if someone has to come to the Board for a PIC change, then they will have to do a self-inspection report. One question from the Board member, are we going to be able to take some of these data points and sort off of them? Administrator Bullek – yes. We are still a good 18 months away. We have multiple points to be added to our software list. Eventually when we go into the pharmacy, we will have everything broken out so we will have a list of pharmacists, technicians and so will be listed under the pharmacy. Once the rules are in place for the quality improvement, then the rest will follow. We will add in as we go. Both inspection rules and the violation rules will be in the 700's. The self-inspection report is pretty intense. And what we are after is to have the pharmacist in charge take a look at his/her operation. Anytime someone comes in front of the Board for a PIC change, the self-inspection will be part of their process; it is going to be all added in to the PIC change process. So once the PIC change is approved, then the new PIC will have a certain amount of time to complete the self-inspection. We would like to have them complete the self-inspection and a timeframe in order to have it back. Massachusetts already has this process in place, so when there is a PIC change, then they complete the "GAP Analysis/Self-Inspection" within a certain time frame to get it back to the Board. It is probably a good time to do it when they do the inventory report. And if there are deficiencies, then they have to go onto the Massachusetts website and submit a plan of correction to them. We put the plan of action or steps that we took to correct the deficiencies onto their website.
15. PeriNatal Substance Exposure task force. Administrator Bullek is asking one of the Board members to volunteer to sit on this task force. Commissioner Pervanas has offered.
16. Fiscal meeting held on Friday March 16<sup>th</sup>. Administrator Bullek provided the Board with an update. There were some positive outcomes from this meeting. We are going to separate the Compliance Audit and the PDMP Audit for the future. Commissioner Bouchard provided an update in regards to the Advisory Council and the strategic planning and the funding as well. We received the position for the data analyst as well. Commissioner Bouchard states that it appears the intent of the advisory council is

to bring all of the stake holders together to work and to make progress with the audit. There are new Advisory Council Board members and the new members are jumping right in and getting right to work on the tasks at hand. One of their questions was if they create policies and procedures, would they need to be approved by the Board. Commissioner Merchant agrees that any work that comes from the advisory council does need to be approved by the Board of Pharmacy.

17. Continuing Education program – The course is from the American College of Apothecary's. Commissioner Pervanas would like some more information regarding this course. Commissioner Merchant would like them to submit their syllabus and asks that Commissioner Pervanas look at the education piece and asks Commissioner Rochefort to look at the compounding piece of this program and then bring it back to the April Board meeting for review and approval. Administrator Bullek will send a letter out to Brenda Dillon and then bring it back to the April Board meeting.
18. The June Board of Pharmacy meeting will be hosted at the MCPHS University in Manchester, NH. The location of the meeting will be in the Brant Building in 118B beginning at 8:30 a.m.
19. SB581-FN passed the Senate. The Board and the stakeholders met in January and held a discussion and had formed an agreed upon wording for this issue. Everyone had agreed upon the wording and what passed the Senate is not the same wording that was agreed upon. **Here is the agreed upon wording in red:**

III-a. "Compounding" means the preparation, mixing, assembling, packaging or labeling of a drug or device as a result of a practitioner's prescription drug order or initiative based on the pharmacist-patient-prescriber relationship in the course of professional practice or, for the purpose of, or as an incident, to research, teaching, or chemical analysis, but not selling or dispensing. "Compounding" also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns. "Compounding" shall not include the reconstitution of powdered formulations before dispensing, the simple addition of flavoring, ~~or dilution the simple~~ **or the preparation of single drug or commercially manufactured sterile product for immediate administration to an individual patient, when done following aseptic techniques in strict accordance with the manufacturer's labeling and shall not be stored for later use. Any deviation in the preparation of a sterile product from the manufacturer labeling instructions is considered compounding.**

**RSA 318:14-a**

I. Products that are not commercially available may be compounded for hospital or office use but shall not be resold or dispensed. Nonprescription items may be compounded upon order by a practitioner for sale as long as the labeling complies with RSA 318:47-a and the product is not a copy of, or similar to, prescription or nonprescription products. **All compounding and preparation of a sterile product** shall be done in compliance with the United States Pharmacopeia as defined by board of pharmacy rules.

Commissioner Bouchard explained that the Board members should go to the General Court website and go to the Legislative Dashboard and put in the number and it will bring up the text of the bill itself and all the amendments. She also encourage all of the Board members to attend the hearing and express your concerns and provide the agreed upon language. On motion from Commissioner Rochefort and a second from Commissioner Fanaras that this is the wording that should be in the SB581-FN. Board Vote 7-0-0.

Administrator Bullek provided a list of the bills that are moving through the House and Senate process now and he was asking the Board, what they want to see for information regarding these bills. Commissioner Bouchard informed the Board members of the website and where they can go to look at the bills and the updates/crossovers in the bills. If the bill has passed, then they have crossed over.

HB-1822 FN- Contraceptive Bill – Mike is going to send out another email in support of this bill. On motion from Commissioner Pervanas and a second from Commissioner Bouchard to support this bill. Vote 7-1-0 Commissioner Fanaras opposed.

SB 350-A Biological Products should go through without any issues. There is an amendment that Administrator Bullek has not seen yet.

Commissioner Merchant asked about a Survey Monkey so we could send out a Survey Monkey to the Board members with all of these bills listed and the Board members could submit their response whether they oppose or support.

HB1418 –FN relative establishing a commission to study greater transparency in pharmaceutical costs and drug rebate programs

\*Motion from Commissioner Pervanas to move in to Non-Public Session with a second from Commissioner Genovese at 11:54. Roll Call – All Board Members in Attendance.