

## NEW HAMPSHIRE BOARD OF PHARMACY

121 South Fruit Street, Ste 401

Concord, New Hampshire 03301-2412

603-271-2350



### PUBLIC MEETING MINUTES November 15, 2017

The Board of Pharmacy meeting convened at 8:30 a.m. with the following Commissioners present; Commissioner Merchant, Commissioner Pervanas, Commissioner Fanaras, Commissioner Genovese, Commissioner Bouchard, Commissioner Rochefort, Commissioner Laliberte, all in attendance.

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Agenda Review: Move the following items to New Business as assigned: Change of Ownership for John Tracy –Item #12. Ph1800 rules will be Item 13. Ph 800 will move to Item 14.

Adding to Consent Agenda: **Item 1A** Compliance report. **Item 1B** PDMP meetings minutes from October. **Item 9A** Memo from Attorney Broderick and Attorney Lamberti. **Item 10** Discussion on Sterile Compounding. **Item 11** Eastern States Compounding-approval request. **Item 12** Change of Ownership - Pharmerica. Item 13 Ph 1800 rules. Item 14 Ph 800 rules.

Adding to Non-Public Items: 1) Extension of one of the items to be discussed. 2) Item U the person scheduled to attend will not be attending.

#### Public Announcement:

1. The meeting in December will be December 11, 2017 and it will be held at the New Hampshire Hospital Association at 125 Airport Road, Concord, New Hampshire 03301.
2. The non-public meeting will be held directly after this public meeting today.

Consent Agenda: Motion to approve the consent agenda as amended, as stated above, by Commissioner Genovese with a second by Commissioner Pervanas 6-0-0.

#### New Business:

- 1A** Compliance Report: Motion to accept from Commissioner Pervanas with a second from Commissioner Genovese 6-0-0.
- 1B** Advisory Council minutes/discussion with Dr. Strang – FYI.
- 2** Genoa change in location. Motion to approve the amended application to include the 2 pharmacy technicians not currently listed on the application itself. Motion made by Commissioner Rochefort and a second from Commissioner Pervanas 6-0-0.
- 3** Colonial Pharmacy – Not moving until the end of December. The corrected address is 82 Newport Road. The town made a correction to the address. Motion to approve from Commissioner Rochefort and a second from Commissioner Genovese 6-0-0.
- 4** Pipeline Rx – Kevin Jones, VP of Pharmacy Operations. Our organization is a medication processing organization which provides tele-pharmacy services to hospitals, and medication review. We are not involved with direct

handling or dispensing of medications. We are primarily involved in the acute care setting, but we have been approached by PillPack, Inc. to assist with medication order review of some of their outpatient orders this would free up the pharmacists to have more patient discussions and order entry. I am here to discuss with you what type of licensure would be required for our pharmacy to get licensed with your office and get set up to help this organization. We also would like to know if our company is a remote medication order check we have people working out of their homes with a HIPPA compliance computer system that is private and secure for all of our patients information. We do not keep any information in our pharmacists' homes; it is all kept in our pharmacy. We are currently practicing in 35 states and have 3 active pharmacies in Illinois, Nevada, and South Carolina we have a little over 100 pharmacists that work with us primarily from their home offices. CVS is asking for the specific rules to be developed and what the tele-pharmacy will actually bring to New Hampshire. And if there are errors made, we have no recourse at this time. It is a fairly common practice for hospitals in New Hampshire, correct. Yes. The Pharmacists are licensed in New Hampshire. This is only data processing and DUR. This has to be married to Central Fill Processing and we do not have this in our rules right now. And CVS is asking for quite a bit more than what this company is asking for. This is a unique model in itself. The pharmacist would be reviewing these from their homes and the medication will still be dispensed from the PillPack pharmacy itself. This would help with the initial review and order entry. They already run 24 hour and our pharmacist would be involved, but in their own homes. We do think we would be able to comply with the Central Fill Processing, except we are not currently licensed in New Hampshire, so typically we would get a Non-resident pharmacy license. At the present time we are not providing the IV Compounding, in other states we are providing that video review for compounding for nurses in other states, but not New Hampshire at this time. Commissioner Merchant we would recommend that you apply for a Non-resident Pharmacy license and comply with the Central Fill Processing Model and contract with the PillPack, Inc. A question, Is our model having a pharmacist working from their home, is that acceptable. I believe that is being done now, and as long as they are licensed in New Hampshire. The only issue is making sure that the pharmacist is licensed in New Hampshire. We need clarification from the Board as we move forward, because Pipeline is not the only request we have received within the last few weeks. Board Administrator suggests we put Ph 1200 into the schedule to be reviewed and updated.

- 5 Melissa Drye – open hearing at 8:59 a.m. Ms. Drye received a Violation Notice from Inspector Elder on September 23, 2017 for not completing a biennial inventory report as required by the Laws and Rules of the Board of Pharmacy. Ms. Drye wanted to have an open dialog as to why she did not do the biennial inventory report. She was wondering if the Biennial Inventory requirement could be taken out of the rules/laws because we have a Perpetual Inventory and it is a running inventory. She was taught in pharmacy school to always go with the more stringent. In retail you are always reminded of what needs to be completed. In independent practice, there are no reminders. Commissioner Rochefort the perpetual inventory is not as comprehensive as a biennial inventory. Ms. Drye - It does not account for what is on the floor. Commissioner Rochefort the law is the law and we cannot strike laws here. Commissioner Fanaras if you were to do a biennial inventory would you physically count the items on the floors?" Ms. Drye "I would probably not count the items on the floor. I feel pretty strongly that the counts would be the same". Commissioner Laliberti – Perpetual inventory only contains a schedule II drug, do you have any lorazepam or anything on your floors? Ms. Drye our perpetual includes all of our controls all of our controls live in our CII safe, the only lorazepam that lives outside of the safe is what is in the refrigerator because we do not have a refrigerator in the safe. Commissioner Pervanas you took on that responsibility as being the pharmacist in charge, and that comes with a huge responsibility, when the pics come in front of us and they are taking on that responsibility, we let them know it is a big responsibility and that is why you have to follow the laws and rules. In order to avoid diversion and discrepancies, we have to abide by them and our job is to protect the public and that is why we have those laws in place to protect the public and you really need to take the law book and abide by it. Commissioner Merchant when you do a perpetual inventory, it does not include stock in other areas of the facility. It counts what is in the automated system and because the license is all encompassing and the biennial inventory has to be done as a whole institution not just the automated system. So even though they are redundant, one is a comprehensive inventory and the other is perpetual of what is in the automated system. On motion by Commissioner Pervanas to deny the appeal of the

violation, with a second from Commissioner Fanaras. Hearing closed at 9:20 A.M with a vote of 5-1-0  
Commissioner Genovese abstains.

6 Igor Sereda – I came from Kasistan, and the reason I am here is to get a license as a wholesale pharmacy. With Mr. Sereda is Krista M. Speidel, CPhT-08798. Commissioner Pervanas - Do you have a license to practice pharmacy in any other states. Why New Hampshire? Mr. Sereda stated no, cause I come from another country and I got some family business there, my family had a pharmacy wholesale business in Kasistan selling drugs and pharmacy equipment and stuff, so I got some experience there. I talked to my dad and he says I should try to open a pharmacy business here because there is a lot of space to grow. I did some research and I found out it is a good place to get a license here. It is a reasonable to sell it here, because expenses are low here. Commissioner Pervanas – what type of medications do you plan to sell. Mr. Sereda – it is going to generic prescription drugs only. Commissioner Pervanas - All generic prescription drugs right now and then I will try to get a license in other states later on; we will see how it starts. Commissioner Pervanas – what is your education, or background? Mr. Sereda – I have education in my country, I have a Business Education from university in my country, Kasistan. I am just investing money, my family gave me money to open new business and I have some experience there. I actually have my own small business in my own country as a travel agency and I am working on visas and flights, tickets, other stuff. Commissioner Genovese – so you are not a pharmacist. Mr. Sereda – no. Commissioner Genovese – do you intent to import generic medications, or buy from this country only? Mr. Sereda – no, just from this country, it is just the drugs that people use mostly every day. I did some research and what makes the highest profit and on generic prescriptions is the highest profit, and it is just the drugs that people use every day. Commissioner Laliberti – You say you are the investor, who will be running the organization? Mr. Sereda - We got 3 or 4 people, do you mean like who’s gonna work? I have Laura and I have some other people and I am going to do some delivery first by myself, and so people will buy from me because I can do fast delivery in the state by myself. Commissioner Laliberti – do you have any legal counsel working with you to make sure the supply chain is correct? He consults with Ms. Speidel, CPhT, and Mr. Sereda - ya, ya, I got them. Commissioner Rochefort – Where do you plan on buying your drugs from, what companies? Mr. Sereda - Big wholesalers, some manufacturers. Commissioner Rochefort - do you have contacts right now? Mr. Sereda – yes almost, I am in contact with them I am going to sell to nursing houses and small pharmacies, hospitals, but they keep asking for the license. I am just going to resell it, but I am going to do it with small portions and fast deliveries, so this is the reason people will buy from me. Commissioner Rochefort - What steps have you taken, what plan do you have to be in compliance with the Drug Supply Chain Security Act? It is a Federal Law that makes certain the supply chain of drugs that actually reaches the consumer. So there is a consistent traceable line of drugs to the consumer, which requires policies, or quarantining of drugs so the manufacturers can identify. It is something moving forward that you will have to address that. It is the DSCSA your customers will ask you for that. And we as a Board will want to be sure that you have that in place. Mr. Sereda – I will just hire someone to deal with that, because I am not a pharmacist. Commissioner Rochefort - The facility on the application, is that the facility where you will house your drugs? Mr. Sereda – yes, that is our office, we have had the inspection already and it is all done and that is where we have our office. We have 3 rooms it’s around 700 square feet because it was the requirements for getting an inspection. Commissioner Rochefort – Will you be storing your drugs here at the address on your application? I have some storage room and package room. Like are your drugs that you are going to be selling, are they going to be stored there? I am not sure right now, because I have like I am going to refill it every time. Commissioner Fanaras – I am listening and I am hearing that you are going to buy from wholesalers and sell to pharmacies. I own pharmacies and I don’t see hospitals buying because they buy from wholesalers. It seems like there is a lot that you do not understand. It seems like you want to get the license, and then figure it out. We are charged with protecting the public, and I am concerned about that. As a business owner, I would think you would want to have all the questions nailed down before you go for a license. There seems to be a lot of questions left unanswered and there seems to be a lot of questions about the business that you do not understand. We are charged with protecting the public safety and it seems that you do not have the answers to a lot of the questions that we ask you. It is a nice business plan and that is good, but it looks like the cart is before the horse and the industry and what it takes to be successful. Mr. Sereda – I will try. Commissioner Fanaras – I know you will. Commissioner Merchant – do you have plans in the business plan about the controls and alarms and you mentioned again you are buying from a wholesaler and then selling it again. We commend you for wanting to become an entrapneur, it is great but I am trying to

embark upon you some of the practicality that we all have living in this space. And do you have a physical location that is going to be compliant with USP standards and Federal Standards, and some documentation showing the temperature and humidity and the alarm documentation. How the facility is going to be maintained within the guidelines of the law. On motion from Commissioner Pervanas with a second from Commissioner Fanaras a vote to deny the application 6-0-0.

- 7 Mackenzie Dacre - open hearing at 10:05 A.M. Hearing will be held in abstencia, Mr. Dacre not in attendance. Attorney Mavrogeorge would like to address an issue, and Mr. Bullek can attest to this, when the Notice of Hearing was issued, it was inadvertently mailed to Mr. Dacre's old address that he had on file. He had updated his new address with the Board. Based on our belief in exhibit 8 that will be submitted, Mr. Dacre submitted an address change to the Board and also had his mailed forwarded to his new address in California. He did in fact pick up his Notice of Hearing at the post office in California and signed for it, and then he proceeded to make an argument that he never got it. However, the receipt was signed for by Mr. Dacre showing he did in fact receive proper notice as spelled out in Exhibit 8. We ask that the Board proceed. We ask that the Board find that Mr. Dacre did in fact receive proper notice. Exhibit 8 does show multiple communications between Mr. Dacre and Mr. Bullek, and myself. On motion from Commissioner Genovese to accept Exhibit 8 and find that Mr. Dacre did receive proper notification with a second from Commissioner Pervanas. One of the witnesses supposed to attend today's hearing, Richard Meinking, had a family emergency and could not attend, he has submitted an affidavit, signed and notarized. Exhibit 7 was submitted and accepted on motion from Commissioner Genovese with a second from Commissioner Pervanas. Closing statement from council states Ph 204.16 B – Failure to Appear. Because Mr. Dacre has failed to appear for this hearing he admits to all of the facts that were alleged and consents to whatever judgement you decide to hand down on him. After testimony from 7 different witnesses, the hearing closed at 11:25. On motion from Commissioner Rochefort and a second from Commissioner Fanaras to revoke Mr. Dacre's license with a vote of 5-1-0 Commissioner Pervanas abstain.
8. Ryan Croasdale – I am requesting reinstatement of my pharmacist license. The attorney general's office took my license away over two years ago. Commissioner Rochefort – I commend you for coming back here, Thank you. You mentioned that you are a support for others in your situation. Do you have a support network that you can rely on? Now you are sober, but I want you to have a network that you can rely on. Mr. Croasdale – I have identified certain things that lead to my stress. Commissioner Rochefort – Where will you work if you get your license back? Mr. Croasdale – I am not sure, but I do understand that community pharmacy is not a great place for me to work. Commissioner Fanaras – in reviewing this would you feel uncomfortable with practice restrictions? Mr. Croasdale – you people would know best, but no, I would not. I know that I have put myself in this difficult situation and it will be difficult for me to even get a job. So probably a hospital setting or a long term care facility. The Board commends you Mr. Croasdale for going through this program and coming back here today and facing the music so to speak and we wish you well in your future. With a motion from Commissioner Fanaras and a second from Commissioner Bouchard to allow license reinstatement with restrictions;
- 1) He is not allowed to be a Pharmacist in Charge for 2 years from the date he gets his license back.
  - 2) Continue with the Impaired Pharmacist Program until being released from the program itself, entirely.
  - 3) The Board needs to receive annual letters from the Impaired Pharmacist Program.
  - 4) He has to take and pass the MPJE exam.
- 9A Memo from Attorney Broderick and Attorney Lamberti. CVS needs to include the statutory authority for its proposed changes, as required under Ph 207.01 (b) (5). Therefore by rule it is deemed insufficient/incomplete, so by November 19<sup>th</sup> I have to submit a letter to you stating what the statutory requirement is and then you can resubmit for discussion at the December meeting. As you can see there is a lot of discussion and involvement from others in here as well.
- 10 IV Sterile Compounding – The question before the Board today is an issue about sterile compounding. I just want to make the public aware of it today and to let the public know we will be discussing it. It will not be solved today. Two fundamental issues, who can do the compounding and where the compounding can be done. RSA 318:42 does say that a Registered Nurse can make an IV add mixture provided it is done with prepared sterile adequacy. There is sterile compounding being done in people's homes and in doctor's offices but not being done

according to the USP 797 standards. USP 797 is considered the law of the land according to the Board. At this time the Board collectively will look at this and discuss it.

- 11 Eastern States Compounding – My name is David Rochefort and I own Eastern States Compounding and I recuse myself from deliberating on this topic with the Board. I would like Program Approval by the Board for Sterile Compounding Technicians. We devised a training program for our data entry technicians. We want to formalize our program. Just because a technician is certified does not make them a good compounding technician. We comply with the rules and we have our technicians get approved by the National program. We sent them away to get the 2/3 day training, and they get the certification that satisfies the Board requirements, but we want them to be doing quality compounding. The program is 6 weeks. They work directly with the pharmacists, and we teach an in-depth training and product verification and sterile compounding, and all of the different ingredients and what this means clinically. Then they have an exit interview and testing throughout the process. We track their progress and it is stored in their training file. We do not sell this program to other companies, we use this primarily for our company to help us retain staff and be certain our staff are creating quality products. On motion from Commissioner Bouchard with a second from Commissioner Fanaras to approve the Eastern States Compounding Sterility Training Program. Vote 6-0-0.
- 12 Change of ownership for Pharmerica – The total number of hours is incorrect for the staff listed there. The hours should be 66, not 56. Administrator Bullek will contact John Tracy, Pharmacist in Charge to get clarification on the hours. On motion by Commissioner Laliberti to approve the change of ownership with the noted changes with a second from Commissioner Pervanas. Vote 6-0-0. Rescinded the other two motions because not completed in the correct format which was an addition error in hours of operation. Commissioner Rochefort made a motion to approve the change of ownership of Pharmerica with a second from Commissioner Pervanas. Vote 6-0-0.
- \* As a side note, the Board indicated on the application the company is an LLC, but we do not have any place on our application to select LLC. The application needs to be corrected.
- 13 Ph 1800 Tabled to fix the rules to be exactly what we want them to be.
- 14 Ph 800 Two changes need to be made:
1. (6) *A technician in training program to achieve certification must complete the program and attain certification status within one year of the date **of the beginning of the program**.*
  2. Ph 807.01 (d) needs to be kept in the rules. ***The pharmacist on duty or the supervising pharmacist may further limit the duties of a pharmacy technician.***

On motion from Commissioner Laliberti to approve Ph 800 rules with the changes as stated above and move forward in the process and second from Commissioner Pervanas vote 6-0-0.

Board President Merchant stated:

Compounding Discussion to the Public in Public Session – The question before the board is an issue about sterile compounding. We do not want to solve it today, but we want to make the public aware of what the issue is. There are two fundamental issues we see; ‘who can actually compound’ and ‘where does the compounding occur’ and what we are basically trying to understand is; who can compound. If you look at RSA 318:42 it does allow a Registered Nurse to make an IV admixture provided it is done with ‘prepared sterile adequacy’ what we are trying to get to is what does that mean ‘prepared sterile adequacy’. The other component is with USP 797. There is a requirement in our rules that in order to have compounding activity, you are supposed to have a permit. The Board has not defined what kind of permit that is, but it is saying that we need to come to some sort of decision by the Board about what’s allowed, where. There are sterile compounding products that are being made in patient’s homes and being made within physician’s offices but they are not being made under the USP 797 standards. And the Board basically says the USP 797 standards are the Law of the Land within the State of New Hampshire. So we are trying to, at this point in time as a Board, collectively look at what that means and how to interpret that. So I am making it more of an omnium to you folks to let you know what is happening, what

is going on, for full transparency. This is not a question to be deliberated today but to let you folks know what is happening, what is going on for full transparency.

Motion from Commissioner Genovese to close the Public meeting pursuant to RSA 91-A: 3, II(c) and seconded by Commissioner Pervanas. Roll Call: All Board members in attendance 12:55 P.M.

Motion from Commissioner Genovese to move into Non-Public meeting pursuant to RSA 91-A: 2 and seconded by Commissioner Fanaras. Roll Call: All Board members in attendance 12:57 P.M.