

NEW HAMPSHIRE BOARD OF PHARMACY

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PUBLIC MEETING MINUTES October 18, 2017

The Board of Pharmacy meeting convened at 8:35 a.m. with the following Commissioners present; Commissioner Merchant, Commissioner Pervanas, Commissioner Fanaras, Commissioner Genovese, Commissioner Bouchard, Commissioner Laliberte. The Board of Pharmacy Adjourned at 1:15 P.M.

Absent: Commissioner Rochefort

Agenda Review: no additional items added to the public agenda. Ph 1800 moved to new business #24 on the agenda. The CVS hearing has been re-scheduled to the November 15th meeting. We will not have a PDMP non-public report today.

Consent Agenda: Motion to accept the consent agenda items from Commissioner Bouchard and a second from Commissioner Pervanas. 6-0-0

Unfinished Business:

Ph 800 for review. 803.01 D 4 – “A technician in a training program to achieve certification must complete the program and attain certification status within one year of the date of hire”. Administrator Bullek; “I discussed this topic with the hospital pharmacy group a couple of weeks ago and this does not pertain to them because they are only hiring Certified Pharmacy Technicians now and other facilities have a specific training program that they are required to complete before they are even put out into the pharmacy. The committee feels that we would be limiting the technicians by including this requirement. So the question to the Board is: Do you want a time frame for the technician training and also how do we want to document this with our inspections since we also have the inspection rules to look through today. Commissioner Laliberte is proposing to remove it. Looking at #4 this would not need to be in there because if they are nationally certified then you do not need the additional training because almost all of the companies are requiring that they are New Hampshire certified by the next renewal. They usually have about 250 hours between the online training and then inter-mingling them into the practice. We are moving towards having only Certified Pharmacy Technicians doing data entry training unless they are in a training program. So this deals with the data entry which makes sense, but what do we do with the other training beyond the data entry training, that is also required. A lot of what we heard is that they want to have a separate license for the people that only do cashier and pulling insurance information and such. This does move in conjunction with the Advanced Pharmacy Technician so there will be 3 levels of technician practice; The New Hampshire Registered Pharmacy Technician, the New Hampshire Certified Pharmacy Technician and then the Advanced Practice Technician. Commissioner Fanaras states this rule is mainly for the Registered Pharmacy Technician who is currently in the program. He is also proposing to move it to a New Hampshire Certified Technician. The new inspection reports are going to have this in the inspection reports, so when the inspectors go in to inspect, they will be looking for this documentation to see if the technicians are currently in or have completed the additional education. Question; is this a necessary line to even have in there? The Administrator will move it back to “C” with the other technicians. And we will have those 3 labeled as such. Then to decide if 80 hours is enough.

Maybe add a definition adding a New Hampshire Registered Technician that would be someone who is registered with the Board. Then the National Certification will be a different type. It should be the pharmacist in charge that should sign off. A couple of weeks for the Pyxis (automated dispensing cabinet) fill, then the compounding, etc. For consistency we should keep the minimum of 80hrs and so it should be up to the facility and the PIC to decide as long as they have had a minimum of 80 hours. As far as the rules are concerned, it should be a minimum of 80 hours and the decision will be up to the PIC and the facility.

Ok going to the last section and look at 807.02 and 807.03; this was hospital driven, these should be all set. One of the things is a certified technician being able to dictate what a certified tech where it says certified technician, it should say New Hampshire certified technician throughout all the rules. We need to define each of the license types in our definitions. Mike to go in and fix all of these to read New Hampshire Certified Pharmacy Technician.

What about robotics? Bar coding thing, the way this is written, this does not apply. It will have to effect Long Term Care, but everyone feels the first line covers it. Adding in "or" would take care of it. Ph 807.03 is fine. For taking phone orders off an answering machine, and we decided it had to be deleted by a pharmacist.

Mike will make the changes and the Board will have them to vote and move forward to fiscal impact in November.

New

Inspection forms: We have Interns that will be completing a rotation and we will have them labeling and correlating with the Laws and Rules and hopefully we will have these all numbered and ready for review in December to begin using January 1st.

Key Compounding – Hearing: Early January of this year we agreed to stop shipping sterile compounded medications into New Hampshire. It was a voluntary agreement and we went through an FDA inspection; we had very limited recalls which we completed successfully with FDA and have FDA approval for the pharmacy to continue on with Sterile and Non-Sterile practice going on. And so we felt this was the right time to come before the Board and ask for the practice restrictions to be lifted. And so we sent the request to Mr. Bullek and so now we are here. We sent a binder to all of you, 7 copies (marked as exhibit A). No additional documents submitted at this time. Questions from the Board members; Commissioner Pervanas; can you talk about the recent sterility testing because obviously the reason why we had practice restrictions is because you had some issues with the fungal growth and the improvements you have made and what you have done to guarantee that the products being sent from your facility to our patients in New Hampshire are safe. Key Compounding; Tab 7 has a detailed record of what we have done. It also contains the room certification which we have done twice, once in January and then we did again in May and both were favorable results and then we have another one signed for the end of this month. We are doing daily testing under the guidance of a microbiologist and that has all been in compliance with the guidelines. The fungal growth was very unusual because we have never had it, and we have no record of the fungus and since then we have not record of the fungus. So we have hired another microbiologist which has more experience, to look at the root cause analysis, and we also needed to do the USP 800 remodeling and so we want to cover all aspects of where we are continuing on to ensure the safety and the control of the environment and that this never happens again. We had a voluntary recall and about 50 % of the recalls came back to us from about 90. There were no adverse events with any of the patients and we followed all of the guidelines of the FDA and their guidance with the recalls. FDA has specific protocols that we have to follow and how we share the testing information with our patients. So if a patient calls and request information, we share that with them. We test every single batch of sterile compound products that we make. Commissioner Fanaras; Can you talk about Eagle Analytical and how that went when you brought in that company. Key Compounding; It seems like they are a consultant. We did contact Eagle Analytical; as soon as we realized we had a problem we contacted them, and they have a service to help manage a controlled environment and we told them what happened and we talked over the phone at first, then he came out to the pharmacy for about 3 days and he worked with us, going over the process of the cleaning, and the validations, he also recommended on how to do the samplings, and even though the USP requires every 6 months, that doesn't give you a good amount of trending and so we decided to do it daily so we can get to the root cause analysis. Commissioner Merchant, you mentioned the testing of the batches themselves, what kinds of testing is done. Key Compounding; We do both in house and send out a batch and we quarantine our product and then we send it out and

also we have developed in house testing. What are you testing for in house; we are testing endotoxin, sterility, potency testing, we also use ARL for potency testing and for our product. Now the results of the testing either in house or send out, is that available to the public on your website. No, they are not available on our website, but if they call us, then we do share that information, upon request.

Commissioner Genovese, What was the cause of the fungus? Key Compounding; That was the part that was puzzling; we could not get a good answer and so I was recommended by PCAP to contact Ola Venz, I hired her and we are in the process of really getting into that, and the preliminary guidance I received from her is more testing, deeper level, and longer time. Her estimation so far she gave us about 6 different possibilities. One is how the structure of the facility the return of the air flow of the facility, perhaps is too much, USP recommends 60 but our facility has 120, we thought that was a good thing, but her suggestion is that maybe it is not, so if we lower it down to 60. She also recommends maybe our pass through needs to be further from the water, maybe another suggestion is TSS the outside facility when they come in, perhaps they did not do a good job of cleaning their products before they come in, so we have upgraded and revamped our SOP's and so they have to follow our very strict guidelines and even washing the hands and equipment and gowning, so they would have to follow our strict guidelines. The forward thinking is the prevention. We do not have an exact idea of why it happened. But her thoughts are prevention and increased testing and so if something happens, it will be very clear as to why and when it happens. Commissioner Genovese, do you still have practice restrictions in other states; Key Compounding; no, our own board inspected us and we are cleared to practice. As far as I know we are free to practice from the FDA. The communication with the FDA is a little different that with other states. And so I did ask if we were all clear, but the response was no answer. We did respond to the 483 and they did bring microbiologists and collected samples. Commissioner Merchant; moving forward would the pharmacy be willing to provide periodic testing results to the Board? Key Compounding; Yes we would. I would just like to say, this has been a learning experience and thank you. Hearing closed at 9:25 a.m.

Following deliberations in Non-Public session, pursuant to RSA 91-A: 2 the Board returned to Public Session and Voted as follows: Key Compounding: On motion from Commissioner Fanaras to remove practice restrictions and submit quarterly reports for 1 year with a second vote from Commissioner Genovese. Vote 6-0-0

Item 20 - USP 800 Compounding rules postponed – FYI

Item 22 – IS Wholesale Inc – Mr. Igor Sereda – Tabled until the November 15, 2017 Board meeting.

Item 23 – Eastern States Compounding request from David Rochefort, Tabled until November 15, 2017 Board meeting.

Item 24 – Ph 1800 Advanced Practice Technicians Rules –review of Office of Legislative Services (OLS) Recommendations

The proposed Ph 1800 rules were reviewed and approved at the August 31st board meeting. However, comments from OLS were provided to board members at the meeting just prior to the vote. Commissioner Merchant wanted to ensure that members of the board reviewed and understood a specific OLS comment; that the board lacked statutory authority to create a 'new' category of technician, aka, Advanced Pharmacy Practice Technician.

A key element of the Advanced Pharmacy Practice Technician rules is that the rules hold the Permit Holder accountable, responsible, and liable for actions of such individuals. In order to accomplish this, this category of registrant required its own set of rules separate from the 800 rules governing registered and certified technicians.

By incorporating eligible duties allowed by an Advanced Pharmacy Practice Technician, specifically product verification within the 800 rules, it would require a pharmacist to be accountable and responsible for the actions of the Advanced Pharmacy Practice Technician, and not the Permit Holder.

Significant work has been done to create these rules, and with the holiday season fast approaching; there is insufficient time and resources available to make revisions to the rules in order to meet the JCLAR time requirements. In the event JCLAR does not approve the rules, that board can revisit incorporating the duties into PH 800s.

Commissioner Fanaras made a motion to accept all the changes to the rules and send them to JLCAR for review and approval. Motion was seconded by Commissioner Laliberti. Vote was 6-1-0 with Commissioner Pervanas voting No.

Item 18 –10:00 a.m. Michelle McMaster Disciplinary Hearing Pursuant to an Emergency Suspension that was issued on September 21, 2017. Attorney Heaton to admit exhibit 1, in which Ms. McMaster has written and signed a statement in which she admits to taking Tylenol #3 Alprazolam and Hydrocodone on multiple occasions starting in April 2017. Michelle McMaster is absent and Attorney Heaton asks the Board to find Ms. McMaster in default and pursuant to Administrative Rule Ph 204.16 part B she has waived her right to an adjudicatory hearing inter a default judgement. In addition, I have also prepared a Proposed Final Decision and Order to assist the Board. In addition to this I ask the Board to revoke her Pharmacy Technician Registration and assess a fine of \$500.00 for cost of investigation and prosecution. No questions for Attorney Heaton and hearing closed at 10:08 a.m.

Following deliberations in Non-Public session, pursuant to RSA 91-A: 2 the Board returned to Public Session and Voted as follows: Ms. Michelle McMaster: On motion from Commissioner Pervanas and a second by Commissioner Genovese to revoke her Pharmacy Technician Registration # PhT 06596 and issue a \$500.00 fine for cost of investigation and prosecution. Vote 6-0-0.

Motion from Commissioner Fanaras to close the Public meeting pursuant to RSA 91-A: 2 and seconded by Commissioner Pervanas. Meeting closed at 10:10 A.M. **Roll Call: Attending:** Commissioner Laliberte, Commissioner Fanaras, Commissioner Pervanas, Commissioner Merchant, Commissioner Genovese, Commissioner Bouchard.
Absent: Commissioner Rochefort

Motion from Commissioner Pervanas to move into Non-Public meeting pursuant to RSA 91-A: 2 and seconded by Commissioner Fanaras. **Roll Call: Attending:** Commissioner Laliberte, Commissioner Fanaras, Commissioner Pervanas, Commissioner Merchant, Commissioner Genovese, Commissioner Bouchard.
Absent: Commissioner Rochefort

Motion to Seal the Non-Public Minutes from Commissioner Genovese and a second from Commissioner Pervanas per 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. Roll Call Vote all Board members in attendance.