



Board of Pharmacy Meeting - Public Minutes

Pharmacy Board

Sep 27, 2023 at 9:00 AM EDT

Attendance

Members: John Genovese, Chair (JG), Eric Lessard (EL), Karl Peicker (KP), Lindsey Laliberte (LL), David Rochefort (DR).

Staff: Michael Gianunzio, Board Administrator, Jeanne Webber, Board Administrator, Shane Goulet, Esq., Board Counsel

I. Call to Order at 9:15 am

A. Schedule

II. Officer Elections

A. President

Motion:

Upon a motion by JG, with a second by EL, the Board voted to confirm David Rochefort as Board President

B. Vice President

Motion:

Upon a motion by JG, with a second by EL, the Board voted to confirm Lindsey Laliberte as Vice President

C. Secretary

Motion:

Upon a motion by JG, with a second by EL, the Board voted to confirm Karl Peicker as Secretary

III. Public Appearances

A. Hearings

1. Melissa Ostrander - 9:30 AM

Temp Application

Motion:

Upon a motion by XX, with a second by XX, the Board voted to

2. Amy Acosta - 11:00 AM

Renewal Application

Motion:

Upon a motion by XX, with a second by XX, the Board voted to

B. Public Inquiry

1. Accelerated Academy

The Board requests they appear before the Board at the next scheduled meeting in October.

2. USP 795 Guidance

Refer them back to the rules and law surrounding sterile compounding.

IV. OPLC / Board Administrator Updates

A. 2023 Gold Certificate Confirmation

1. Anne M. Ottariano
2. Steven G. Ottariano
3. Richard Rochefort (2022)

Motion:

Upon a motion by JG, with a second by LL, the Board voted to accept the Gold certificate nominees.

B. NHPHP Update

C. 2024 Meeting Schedule

We need to consider choosing a different day of the week or week of the month due to scheduling conflicts within the office.

Tabled – it is in rule that the Board must meet on the 3rd Wednesday

D. Electronic Prescribing Report

Questions stemmed from memo dated 9/6/23, stating PDMP will begin enforcement of this requirement.

Leslie

- E. Communication from NH Board of Nursing - Title Question
- F. DOJ Request for Pharmacy

Motion:

Upon a motion by JG, with a second by EL, the Board voted to approve the request, unanimous

- G. Board Administrator Authority to Sign Documents on Behalf of the Board

Motion:

Upon a motion by JG with a second by LL, the Board voted to grant authority to the Board Administrator to sign documents on behalf of the Board.

- V. Consent Agenda Items: removed pic changes due to legislation passed on 9/25/23

JG / KP – accept the consent agenda, leaving off D4

- A. Approve Minutes - Approved
 - 1. August 16, 2023
 - 2. August 21, 2023
 - 3. August 28, 2023
- B. Automated System Registration
 - 1. New Freedom Academy, Londonderry - Confirm Receipt
- C. NABP - Confirm Receipt
 - 1. Exam Fee Increases
 - 2. MPJE Blueprint Update
 - 3. Webinar: "Regulatory Framework for Human Drug Compounding"
 - 4. EO Registration Reminder for EO-COLC Forum
 - 5. USP Virtual Meeting - Mitigating Cancer Drug Shortages
 - 6. FDA Home Study Webinars – Confirm Receipt
 - 7. NABP Universal Columns – Confirm Receipt
 - a. 795 v.11
 - b. 797 v.11
 - c. 800 v.11
 - 8. NABP State Report- Dist.1 August 2023
- D. NABP State Report - Dist.1 September 2023 - Confirm Receipt

VI. Rules Review and Other Legislative Topics

A. HB 308

Remote Participation

B. HB 321

Non Public Minutes Review

C. PH 404 - Initial Proposal

Very initial working draft, having this posted to the website. Welcoming comment and feedback from the public.

D. PH Various (PIC) - Initial Proposal

501.01 B – says “licensed pharmacist shall”, should this include others than just the Rph? Include Licensed Pharmacist, Advanced Pharmacy Techs, Intern, Certified Technician, or Permit Holder. Tina will review to make sure all types are included.

804.01 D – Should the ending be removed as far as the date? It seems like this should be as it is taken up in the PLC rules, the Board agrees.

809.01 A – shall expire 2 years form the date of licensure

809.01 D – Remove ending similar to 804.01 D. EL pointed out that 804.01A also has similar language that should be updated.

903.01 C(1) – OPLC has a core application, Tina recommends that we use the core app, then create an addendum for any additional items requested by the Board. DR points out that it is ok to use the Core app as long as we still gather the same information in an addendum that is currently collected.

2504.01 (m) strike this line as it is covered elsewhere in rule

Request that Tina take another look at the 700's to make sure that we aren't missing anything regarding removing PIC as some refer as PIC, “PIC”, P-I-C, or spelled out Pharmacist in Charge.

Will post the 400 draft immediately, wait on the PIC / Various until Tina makes the updates we talked about.

E. PH 1000 - Awaiting Initial Proposal

This should be available for the October meeting

VII. Licensure Approval

A. Covetrus North America

Requesting to add Non-Sterile and Non-Sterile Hazardous compounding

Motion:

Upon a motion by JG, with a second by EL, the Board voted to grant the request; unanimous.

B. Option Care

Initial Sterile Compounding App

Motion:

Upon a motion by EL, with a second by KP, the Board voted to approve the application; unanimous.

C. Zuhaib Jaffer Malik

Initial App

Motion:

Upon a motion by EL, with a second by JG, the Board voted to hold a show cause hearing; LL absent; motion passed.

Get clarification as to where he is living / in the US versus where he is currently licensed.

D. Medical Center Pharmacy

Request to add "sterile" to current license.

1. Sterile Compounding Technique
2. Use & Maintenance of Equipment SOPs
3. Quality Control SOPs
4. Cleaning & Maintenance of Compounding Area & Equipment SOPs

Motion:

Upon a motion by JG, with a second by KP, the Board voted to approve the request; unanimous

VIII. New Business

A. PDMP Board Appointment

The Board needs to vote to replace the vacant seat on the Board.

Tabled to October Meeting

B. 1 Year FDA Enforcement Discretion Regarding 2023 Requirements Under DSCSA

1. Presentation by Jay Queenan

- Drug Supply Chain Security Act – looking at trying to make sure that medications that got to the patients had a pedigree, that it came from the proper suppliers.
- Representatives from law enforcement and industry talked about how their shipments were hijacked or side tracked. These drugs can then make their way back into circulation with no way of knowing if they have been stored properly or have been adulterated in any way.
- 11/27/2023 – this is when mfr / distributor respond to electronic requests for pedigree / chain of custody of their drug within one day.
- Because meds have a 2 part barcode – has the NDC, the Product ID, lot and expiration date. Wholesalers have product on their shelves without 2 part barcode and can't be sold unless they have this.
- FDA has delayed enforcement of this for 1 year to allow the wholesalers to catch up.
- ATP = Authorized Trading Partners, must be authorized by the FDA. This is an effort to eliminate the gray or fly by night distributors. It does not include 503b outsourcing facilities, they will not be required to ID where their product goes.
- If an Rph feels there might be something wrong with the product, it's no longer a best practice, it's a legal obligation to verify the drug. ATP has created a system called PULSE. The Rph can log in, ID themselves, scan the product they are suspect of and there will be a pool of licensed providers, send the information to the wholesaler. The wholesaler has 1 day to get back to the pharmacy and tell them where they sent the product, lot, NDC and unit size (cartons or cases).
- GSI codes – all mfr / wholslr / distributor – they might say we sold to walgreens, but will not identify individual stores, unless the individual stores have their own GSI code.
- If the product was sold to a repackager, the Rph will the log back into pulse and contact the repackager, then follow the chain until they are able to verify. While this happens the drug must be quarantined.
- If a drug is returned, we will only be told the last sale made by the mfr. So if a drug was returned 3 times, you'll only know about the 4th person it was sold to.

- PULSE has been piloted, there is currently no cost. It needs to be able to talk to all mfr and wholesalers. As everyone has different software this has been a challenge to quick reporting.
- How does this affect the Board? We might have to look at putting in administrative rules to spell out when an rph needs to examine drugs for tampering and reporting requirements.
- There is a question as to if manufacturers, wholesalers and distributors are required to be licensed with the Federal Government, they might lobby or push back on individual state licensing requirements.
- The concern is this could create drug shortages if full implementation is pushed for November. This is why they have been granted time to work on getting set up with 2 bar codes to be in compliance.

IX. Public Comments

X. Non Public Session

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

Motion:

Upon a motion by JG, with a second by EL, the Board voted to enter non-public session at 12:00pm; unanimous roll call vote.

XI. Resume Public Session

Motion:

Upon a motion by JG, with a second by LL, the Board voted to resume public session at 1:46 pm; unanimous roll call vote.

XII. Seal the Minutes of the Non-Public Session

Motion:

Upon a motion by JG, with a second by LL, the Board voted to seal the minutes of the non public session; unanimous roll call vote.

XIII. Adjournment

Motion:

Upon a motion by JG, with a second by LL, the Board voted to adjourn at 1:52pm; unanimous.

FOR NEXT MEETING

LL:

Vaccine issue added to next agenda 318-16:B V

CPhT's are being told that they can't give vaccinations. Send email to licensees to make them aware. Will

1st P-NP

Motion to keep minutes of the non-public session confidential from public disclosure pursuant to RSA 91-A: 3, III on the grounds that public disclosure would be likely to affect adversely the reputation of a person other than a board member and/or to render the proposed action ineffective and/or is not subject to public disclosure pursuant to RSA 236-B: 38. However, forty-eight hours after the mailing of any order, its respective vote shall automatically become public in accordance with RSA 326-B: 38.

Upon motion of JG seconded by EL, the Board voted to commence the **1st non-public session** at 12:00 p.m. and ended at 1:46 a.m.

Motion to come out of non-public was made by JG, and seconded by LL, by unanimous roll call vote.

Upon the motion of JG, and the second of LL, the Board voted to keep minutes of the non-public session confidential from public disclosure. Each member recorded his or her vote on the motion, which passed by unanimous vote.