

## Louisiana Board of Pharmacy

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## REGULATION REVISION COMMITTEE MEETING January 24, 2024

### MINUTES

The Regulation Revision Committee of the Louisiana Board of Pharmacy met at 9:30 am on January 24, 2024, at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809. The following agenda was considered and discussed:

- 1. Call to Order
- 2. Invocation & Pledge of Allegiance
- 3. Quorum Call
- 4. Call for Additional Agenda Items & Adoption of Agenda
- 5. Consideration of Draft Minutes from Previous Meeting July 18, 2023
- 6. Opportunity for Public Comment
- 7. Regulatory Project 2023-09 ~ Product Integrity
- 8. Regulatory Proposal 2023-C ~ Automated Medication Systems (AMS)
- 9. Regulatory Proposal 2024-A ~ Pharmacy Technicians
- 10. Regulatory Proposal 2024-B ~ Controlled Dangerous Substances (CDS) Licensing
- 11. Regulatory Proposal 2024-C ~ Durable Medical Equipment (DME) Permit Change of Ownership
- 12. Regulatory Proposal 2024-D ~ Open Meetings via Electronic Means
- 13. Regulatory Proposal 2024-E ~ PMP Advisory Council Open Meetings via Electronic Means
- 14. Legislative Proposal 2024-A ~ Transfer of CDS Prescriptions
- 15. Legislative Proposal 2024-B ~ CDS Schedule Update
- 16. Discussion Shared Pharmacy Services
- 17. New Agenda Items Added During Meeting
- 18. Adjourn

**Committee members participating were:** Robert Cloud, David Darce, Jennifer Dupree, Jacqueline Hall, Chris Melancon, Troy Menard and Committee Chair Ricky Indovina.

**Also participating were:** Marty McKay (Board President), Joe Fontenot (Executive Director), Carlos Finalet (General Counsel), Sarah Stevens (Licensing Analyst Director), Becky Parker (Compliance Officer) and Cary Aron (Compliance Officer).

#### Public attendees were:

Mark Johnston (CVS Health), Jeff Mesaros (Mesaros Group), Rich Palombo (Cigna/Express Scripts), David Chauvin (Lil Dave's Pharmacy), Jeenu Philip (Walgreens), Shelly Dupre (LA Alliance for Retail Pharmacies), Malcolm Broussard (Hygeia Solutions), Paul Menasco (Ochsner), Charlie Corona (Louisiana Independent Pharmacies Association), Dale Masten (Genoa), Minh Nguyen (Willow Bark Pharmacy), and Sarah Perkins (Breazeale, Sachse & Wilson LLP).

## Call for Additional Agenda Items & Adoption of Agenda

There were no calls for additional agenda items, and the agenda was adopted.

#### Consideration of Draft Minutes from Previous Meeting – July 18, 2023

The Committee approved the minutes by consensus.

## **Opportunity for Public Comment**

None were made.

## Regulatory Project 2023-09 ~ Product Integrity - Draft #2

Draft #1 was approved by the Board for promulgation at its August 16, 2023 meeting. The *Notice of Intent* was published in the November 20, 2023 edition of the *Louisiana Register*. The *Public Hearing* was held on December 28, 2023. Mr. Fontenot provided the comments received pursuant to the Public Hearing to the members for their review and he addressed those comments. In response to the comments received, staff prepared Draft #2 removing the controversial component of "delivery" and focusing only on "storage."

Following discussion of the importance of regulations regarding product integrity, the Committee approved Draft #2 for submission to the Board for its consideration.

#### Regulatory Proposal 2023-C ~ Automated Medication Systems (AMS)- Draft #4

Mr. Fontenot explained the history of this regulation, including the Notice of Intent from May 20, 2015 and subsequent amendments which led to confusion and misunderstanding.

After reviewing the proposal as Draft #4, the Committee agreed to the following:

- Line 12- Strike "without the necessity of direct pharmacist supervision."
- Line 13- Change to read "A bar code verification or other electronic verification"
- Line 13- Strike "or similar verification process"
- Line 14- Change "may" to "shall"
- Line 16- Change to read "The use of a bar code or other electronic verification"
- Line 16- Strike "or similar verification process"

The Committee instructed staff to prepare Draft #5 with these changes, along with direction to clearly differentiate between AMS with and without electronic verification capabilities, for consideration at its next meeting.

## Regulatory Proposal 2024-A ~ Pharmacy Technicians - Draft #1

Mr. Fontenot explained that the Board had received many requests for an option for pharmacists to be able to provide training for pharmacy technician candidates, as an alternative to enrolling in a nationally accredited, board approved training program. Ms. Stevens explained that PTCB and NHA now require hours of experience prior to sitting for the examinations that the Board requires for technician licensure. This change makes Option B (proof of successful completion of a board-approved pharmacy technician certification examination and successful completion of high school or GED) only useful for technicians who transfer from another state. Mr. Fontenot also explained that during previous committee discussion, lowering the minimum age for a technician candidate to 16 in order to include high school students in Work Force Development had been suggested.

The committee discussed requirements for training programs for those applicants under the age of 18, whether adding the option for candidate training by a pharmacist should affect staffing ratios, and if allowing candidates under the age of 18 would lead to increased incidents of diversion.

Public comments expressed gratitude for pursuing the option to allow pharmacists to train technician candidates.

The committee agreed to the following changes: Line 23- strike the word "a" prior to "technician" Line 38- add "and enrollment in a Louisiana Department of Education Pharmacy Technician training program." after "Labor".

After Line 47- add Clause

"iii. If under 18 years of age, verification of enrollment in a Louisiana Department of Education Pharmacy Technician training program."

Line 48- Change "d." to "e."

Line 111- add "and the Louisiana Department of Education Pharmacy Technician training program."

The committee asked staff to compose Draft #2, with instructions to redefine Pharmacy Technician Educator in Line 22 to include the Department of Education Pharmacy Technician training program, and incorporate "no later than 10 days" in the notification requirement in Lines 85-87.

The committee also discussed a need to work on clarifying language to indicate that a person may not hold more than one active primary credential (pharmacist, pharmacy intern, pharmacy technician, pharmacy technician candidate).

# Regulatory Proposal 2024-B ~ Controlled Dangerous Substances (CDS) Licensing – Draft #1

Mr. Fontenot explained that the amendments to the change of ownership procedures reflect recent changes in regulations addressing pharmacy change of ownership.

After discussion the Committee agreed to the following changes:

Lines 20-21- Change to read: "2. An application for the reinstatement of an expired credential which has been terminated may be approved when the applicant's primary credential is in an acceptable practice status with the issuing agency."

Line 29- Change "by board staff, if" to "when"

Line 37- Strike "at R.S. 37:1184."; add "in Section 115 of this Part."

Line 72- Change "shall" to "may"; remove "upon termination of this activity"

Line 75- Change "decides" to "agrees"

Line 76- Remove "by the board"

Line 78- Remove "by the board"

After discussion, the proposal was approved as Draft #2 for submission to the Board for its consideration.

## Regulatory Proposal 2024-C ~ Durable Medical Equipment (DME) Permit Change of Ownership – Draft #1

Mr. Fontenot shared with the Committee a letter from Cardinal Health regarding the proposal.

The Committee instructed staff to contact Cardinal Health for more information and then to composed Draft #2.

## Regulatory Proposal 2024-D ~ Open Meetings via Electronic Means – Draft #1

Mr. Fontenot explained the proposed regulations, in response to legislative mandate.

Following discussion, the Committee agreed to the following change:

Line 7- Remove "Policy"

The amended proposal was accepted as Draft #2 for submission to the Board for its consideration.

## Regulatory Proposal 2024-E ~ PMP Advisory Council Open Meetings via Electronic Means – Draft #1

Mr. Fontenot explained the proposed regulations, in response to legislative mandate.

The proposal was approved as Draft #1 for submission to the Board for its consideration.

### <u>Legislative Proposal 2024-A ~ Transfer of CDS Prescriptions – Draft #1</u>

Mr. Fontenot explained that this proposal was written in a manner so that any future federal changes regarding transfers of CDS prescriptions will be automatically reflected at the state level.

The Committee approved Draft #1 for submission to the Board for its consideration.

## <u>Legislative Proposal 2024-B ~ CDS Schedule Update – Draft #1</u>

Mr. Fontenot explained that he had discussed the proposed update with the Louisiana State Police Crime Lab.

The proposal was approved by the Committee as Draft #1 for submission to the Board for its consideration.

#### **Discussion-Shared Services**

Due to the time, it was decided that this item would be discussed at the next Committee meeting.

Having completed its consideration of the posted agenda, the Committee adjourned at 2:36 pm.

I certify that the foregoing are true and accurate minutes of a meeting of the Regulations Revision Committee of the Louisiana Board of Pharmacy, held on the above noted date.

Minutes prepared by Compliance Officers Becky Parker and Cary Aaron. Minutes approved by the Committee at subsequent meeting on April 25, 2024