

Louisiana Board of Pharmacy

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REGULATION REVISION COMMITTEE MEETING July 18, 2023

<u>MINUTES</u>

The Regulation Revision Committee of the Louisiana Board of Pharmacy met at 10:30am on July 18, 2023, 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 January 18, 2023
- 6. Opportunity for Public Comment
- 7. Old Business
 - a. Regulatory Proposal 2021-A ~ Collaborative Practice Draft #1
- 8. New Business
 - a. Reconsideration of Regulatory Project 2023-02~Temporary Closure of Pharmacy
 - b. Regulatory Proposal 2023-B ~ Product Integrity
 - c. Regulatory Proposal 2023-C ~ Automated Medication Systems (AMS)
 - d. Regulatory Proposal 2023-D ~ Prescription Monitoring Program (PMP)
 - e. Regulatory Proposal 2023-E ~ Pharmacists Application
 - f. Discussions
 - i. Centralized Prescription Dispensing
 - ii. Pharmacy Technician Credentialing Process
- 9. New Agenda Items Added During Meeting
- 10. Adjourn

Committee members participating were: Robert Cloud, David Darce, Jennifer Dupree, Jackie 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), Becky Parker (Compliance Officer), Cary Aaron (Compliance Officer) and Sarah Stevens (Licensing Analyst Director).

Public attendees were:

Steven Trahan (Institutional Pharmacies of LA), Jeff Mesaros (Mesaros Group), William Kirchain (Xavier University College of Pharmacy), John Michael Houeye (Xavier University College of Pharmacy), Maria Bowen (Louisiana State Medical Society), Berkley Durbin (Medicine Louisiana), Malcolm Broussard (Hygeia Solutions), Karleisha Austin (Xavier University College of Pharmacy), Shelly Dupre (LA Alliance for Retail Pharmacies), Matthew Cross (LIPA), Carl Menesco (Ochsner), Paul Menasco (Ochsner) and Sarah Perkins.

Call for Additional Agenda Items & Adoption of Agenda

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

Opportunity for Public Comment

None were made.

Consideration of Draft Minutes from Previous Meeting - January 18, 2023

The Committee approved the minutes by consensus.

Regulatory Proposal 2021-A ~ Collaborative Practice – Draft #1

Mr. Fontenot stated that Dr. Culotta, Executive Director for the Louisiana State Board of Medical Examiners (LSBME), was provided the draft document but has not provided comment.

Maria Bowen with the Louisiana State Medical Society (LSMS) discussed that LSBME has no authority to approve protocols in their rules, and that current Collaborative Drug Therapy Management (CDTM) regulations would allow protocol-based collaboration. She also expressed concern that the proposed rule does not include language prohibiting the unauthorized practice of medicine.

Chair Indovina stated that some protocols are needed for patient care, and that there is nothing in the proposed rule to allow a pharmacist to independently practice.

Lauren Bailey with the LSMS stated she does not believe the proposed version could be approved with changes, and does not want to see a completely rewritten rule.

Several Committee members stated there is a need to help patients.

Dr. William Kirchain with Xavier University College of Pharmacy stated that the Louisiana Society of Health System Pharmacists (LSHP) are not in support of the majority of the current CDTM regulations. Dr. Kirchain indicated that LSHP will go straight to the legislature if there is no progress on the proposal.

After further discussion among committee members and public attendees regarding physician registration, agreements and protocols, the committee deferred further action regarding the proposal. Ms. Bowen will attempt to arrange a conference call between Board and LSBME representatives to gain clarity.

Reconsideration of Regulatory Project 2023-02 ~ Temporary Closure of Pharmacy

Chair Indovina explained that the proposal is a result of patients being unable to obtain filled prescriptions that were in pharmacies that closed due to hurricanes, COVID, etc. During promulgation, the proposal was returned to the Committee after public comments objecting to the language allowing access to filled prescriptions without a pharmacist present subsequent to a pharmacist-in-charge temporarily closing a pharmacy without a declaration of emergency.

Matthew Cross with the Louisiana Independent Pharmacies Association (LIPA) stated he has an issue with proposed language allowing the pharmacist-in-charge to determine it necessary to close in the absence of an emergency, and is concerned with the potential lack of counseling by a pharmacist.

After a public discussion with Mr. Cross and others present, the Committee agreed to the following:

Rewrite the sentence in (E)(1) as 'When the governor issues or renews a state of emergency pursuant to the Emergency Assistance and Disaster Act of 1993, R.S. 29:721 et seq., or a state of public health emergency pursuant to the Louisiana Health Emergency Powers Act, R.S. 29:760 et seq., or when the pharmacist-in-charge determines it necessary to close the

pharmacy for a temporary period of time during an emergency and/or Act of God, the following provisions shall apply'.

Change title (E) to 'Temporary Closure of Pharmacy in an Emergency'.

The Committee approved the amended project for submission to the Board for its consideration.

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

CO Parker introduced the proposal, which removed the phrase "which prohibits any human intervention," added procedures that must be followed if restocking without direct pharmacist supervision, and differentiated between stocking and restocking. The option of removing "other licensed personnel" from those individuals authorized to restock the AMS was discussed.

Stephen Trahan with Institutional Pharmacies of Louisiana is in favor of restocking without direct pharmacist supervision when an electronic verification method is utilized.

The committee discussed persons allowed to restock an AMS under current rule.

After reviewing the proposal as Draft #1, the Committee agreed to the following:

Lines 24-25: remove "or other licensed personnel approved by the pharmacist-in-charge" and add "or" between "certified pharmacy technician" and "pharmacy technician candidate"

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

Regulatory Proposal 2023-B ~ Product Integrity

Mr. Fontenot discussed the proposed changes to the rules.

Mr. Broussard asked if the language in Line 14 reading 'All areas where drugs are stored or located...' is sufficiently specific.

After discussion, Draft #1 was approved for submission to the Board for its consideration.

Regulatory Proposal 2023-D ~ Prescription Monitoring Program (PMP)

Mr. Fontenot explained the requirement to report Naloxone prescriptions to the PMP will be unnecessary when it is available over-the-counter, and the word 'butalbital' on Line 14 is sufficient.

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

Regulatory Proposal 2023-E ~ Pharmacists Application

Mr. Fontenot explained that an NABP service evaluates eligibility to sit for examination and the 30-day time period is no longer applicable to the Board.

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

Discussion- Centralized Prescription Dispensing

President McKay explained that the Centralized Prescription Dispensing regulations were written in 2007. Pharmacy practice has changed considerably since that time. President McKay suggested a review of the regulations to determine if any changes are needed. Labeling requirements were discussed.

The Committee directed Board staff to examine rules from other states and place on the agenda for the next Regulation Revision meeting.

Discussion- Pharmacy Technician Credentialing Process

Chair Indovina stated that people under the age of 18 may be viable technician candidates; for example, those in high school Workforce Development Programs.

Discussion among the Committee members included salary issues and the seemingly lack of hirable candidates from many accredited programs.

The Committee deferred in favor of a serious need to determine necessary rule changes.

Having completed its consideration of the posted agenda, the Committee adjourned at 3:04pm.

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 Cary Aaron and Becky Parker. Minutes approved by the Committee at subsequent meeting on January 24, 2024