Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ E-mail: info@pharmacy.la.gov

REGULATION REVISION COMMITTEE MEETING
January 18, 2023

M I N U T E S

The Regulation Revision Committee of the Louisiana Board of Pharmacy met at 10:30am on January 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 – October 11, 2022
6. Opportunity for Public Comment
7. Old Business
    a. Regulatory Proposal 2021-A ~ Collaborative Practice – Draft #1
    b. Regulatory Proposal 2022-K ~ Pharmacy Change of Ownership Procedures – Draft #3
    c. Regulatory Proposal 2022-M ~ Staffing Ratios – Draft #3
    d. Regulatory Proposal 2022-O ~ Marijuana Pharmacy – Draft #2
8. New Business
    a. Legislative Proposal 2023-A ~ CDS Schedule Update
    b. Legislative Proposal 2023-B ~ PMP Advisory Council Meetings
    c. Legislative Proposal 2023-C ~ Immunizations
    d. Maintaining Product Integrity During Storage, Delivery, and Shipping
        i. Oklahoma proposes landmark rule to keep mailed medications safe from extreme temperatures (nbcnews.com)
        ii. Oklahoma BOP – Proposed Rule – 535 2023_Chapter 15
    e. Automated Medication Systems (AMS) Stocking & Restocking - Electronic Product Verification & Human Intervention - LAC 46:1217
    f. Consideration of Nonresident Pharmacy Use of Remote Technicians
    g. Discussion - Distribution & Dispensing of Naloxone
9. New Agenda Items Added During Meeting
10. Adjourn

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

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

Public attendees were:
Malcolm Broussard; Jeff Mesaros & Mark Johnston (CVS), Reggie Dillard (Gladstone), Peter Provost (LATA), Sarah Perkins, Shelly Dupre & Jessica Elliott (LA Alliance for Retail Pharmacies), Randal Johnson (LIPA), Heather Machurin & Myra Thomas (Ochsner), Mariah Boden & Lauren Bailey (LA Medical Society), Berkley Durbin (Medicine Louisiana), Mary Beth Wilkinson (Adams

& Reese), Ben Sims (Brookshire's), Tram Nguyen (Walgreens), Jessica Adams (Cardinal), Matt Chambliss & Lena Nguyen (CRx Specialty Solutions), and Jassoni Martin.

Call for Additional Agenda Items & Adoption of Agenda
The topic of *Data Waiver Registration Elimination* added to the agenda by unanimous vote of the Committee.

Opportunity for Public Comment
None were made.

Consideration of Draft Minutes from Previous Meeting – October 11, 2022
The Committee approved the minutes by consensus.

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

Mr. Fontenot explained that, while the proposal has already been approved by the Board, Dr. Culotta, LSBME's Executive Director, has not provided comments on the language.

The Committee discussed collaborative practice protocols, including a procedure requiring any changes made by the pharmacist to be reported to the provider.

Mariah Bowen with the LA Medical Society stated she is hesitant to support the proposal's arrangement/protocol language.

Myra Thomas with Ochsner is in support of proposal, stating the need to have more accessibility to healthcare.

The Committee deferred further promulgation of the proposal. Board representatives will meet with interested parties to address any concerns.

Legislative Proposal 2023-C ~ Immunizations

Mr. Fontenot explained this proposal is a result of 2022 Regular Legislative Session.

The proposal lowers a qualifying patient's age from 17 to 7 years of age.

Mariah Bowen with the LA Medical Society is opposed to the proposal. She stated pediatricians giving immunizations use that opportunity to conduct a full review of a child's overall health.

The Committee deferred further promulgation on the language. Board representatives will meet with interested parties to address any concerns.

Regulatory Proposal 2022-K ~ Pharmacy Change of Ownership Procedures – Draft #3

Mr. Fontenot explained the history leading up to the proposal.

Malcolm Broussard expressed concerns that the proposal is contrary to the Board's statutory mandate to determine a proposed owner's fitness to own a pharmacy.

After discussion, Draft #3 was approved for submission to the Board for its consideration.

Regulatory Proposal 2022-M ~ Staffing Ratios – Draft #3

After discussion, Draft #3 was approved for submission to the Board for its consideration.

Legislative Proposal 2023-A ~ CDS Schedule Update

The Louisiana Department of Health is the agency with the statutory mandate to make changes and updates to the Controlled Dangerous Substances statutes. Mr. Fontenot is in discussions with its leadership to arrange for the Department's assuming this duty in lieu of the Board.

Legislative Proposal 2023-B ~ PMP Advisory Council Meetings

The proposal comes recommended by the Prescription Monitoring Program's Advisory Committee.

It changes the frequency the Advisory Council must meet from quarterly per year to a minimum of once per year. The proposal also authorizes the Advisory Council to meet electronically.

After discussion, proposal was approved for submission to the Board for its consideration.

Automated Medication Systems (AMS) Stocking & Restocking - Electronic Product Verification & Human Intervention - LAC 46:1217

At issue is Subsection B(1) of the regulation which states:

> *B. When the pharmacy employs electronic product verification procedures as described within this Section, the stocking and restocking of medications and devices within an automated medication system may be performed by other licensed personnel approved by the pharmacist-in-charge without the necessity of direct pharmacist supervision.*
> ***1. A bar code verification, electronic verification, or similar verification process which prohibits any human intervention following pharmacist verification of the product may be utilized to assure the correct selection of drugs to be placed into an automated medication system.***
> *2. The use of a bar code, electronic verification, or similar verification process shall require an initial quality assurance validation followed by ongoing quality assurance reviews at intervals no greater than 90 days since the previous review, all conducted by a pharmacist.*

The Committee discussed what it considers 'human intervention' and proper pharmacist supervision of the process.

Myra Thomas with Ochsner explained that all barcoded medications have a double check: that the medication package is correct and that the medications in the package are correct. Afterwards, when the cubie is at AMS, everything is scanned again the AMS site to reconfirm accuracy.

The Committee directed Board staff to prepare a draft for Committee's review at its next meeting.

Regulatory Proposal 2022-O ~ Marijuana Pharmacy – Draft #2

After reviewing the proposal as Draft #2, the Committee agreed to the following:

Line 142 - change the word 'reviewed' to 'verified'.
Line 290 - change the word 'obtain' to 'have access to'.

Lines 133-142 & Line 296: leave ‘pharmaceutical grade’ and its definition.
Line 177 - change the wording ‘distributed to’ to ‘received by’.
Line 191 - change the wording ‘batch of marijuana used in a’ to ‘final product’.
Line 306 - remove ‘bulk raw product’.
Line 411 - change the wording ‘shall undergo’ to ‘be subject to disciplinary review.’.
Line 412 - remove entire line.
Line 513-514 - remove both lines.
Line1024 - change the reference to ‘R.S. 40:1046.4’ to “R.S. 40:1064.1’
Line 1024 - add a ‘subsection b’ stating the pharmacist’s authority to dispense the product.

After discussion, the proposal was approved as Draft #3 for submission to the Board for its consideration.

Discussion - Distribution & Dispensing of Naloxone

Chair Indovina asked if hospital in-patient pharmacies can dispense Naloxone to patients going home from the hospital. Mr. Fontenot explained that the Board’s regulations do allow for that practice but the federal Robinson-Patman Act should be reviewed to determine its applicability.

Data Waiver Registration Elimination – Draft #1

The federal government no longer issues “DEA-X” credentials to practitioners prescribing, administering or providing a narcotic for use in maintenance or detoxification treatment to a narcotic-dependent person.

Accordingly, the Committee made the following changes to LAC Title 46: LIII Section 2745:

Lines 10-12 - removed
Line 56-58 - removed
Line 24 - modified to the correct citation: 21 CFR Section 1301.23.

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

Maintaining Product Integrity During Storage, Delivery, and Shipping - Oklahoma BOP Proposed Rule

Mr. Fontenot explained that the Board’s current regulations in Chapters 12, 15 and 24 have product storage language but Chapters 11, 23 and 25 do not.

The Committee directed staff to make those changes as well as develop proposed language to address the integrity of patient-specific prescription medications during shipment and delivery. Staff will reference US Pharmacopeia and manufacturers guidelines in doing so.

Consideration of Nonresident Pharmacy Use of Remote Technicians

An Ohio non-resident pharmacy is employing pharmacy technicians in Louisiana for the remote processing of prescriptions for the pharmacy. The technicians are monitored remotely by a pharmacist in Ohio.

Current Louisiana regulations do not allow technicians to work from home.

Mr. Indovina stated concerns with security of healthcare information and patient privacy concerns in such a scenario. He also stated concerns with distractions in this setting that may jeopardize patient safety.

Ms. Hall has concerns that not allowing for this practice could isolate Louisiana for another avenue of patient care nationally. She suggested looking at the checks and balances of the operation.

Committee determined the Board should decide whether such practice by a technician in under the 'direct and immediate' supervision of pharmacist as required by statute.

Mark Johnston with CVS stated 25 states now allow for technicians to work from home.

Reggie Dillard suggested the Committee review Tennessee's policy on restrictions to such a practice.

Staff was directed to further research the practice for the Committee's consideration at its next meeting.

Having completed its consideration of the posted agenda, the Committee adjourned at 3:32pm.

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.

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Carlos Finalet, General Counsel