

Louisiana Board of Pharmacy

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Minutes

The **Regulation Revision Committee** of the Louisiana Board of Pharmacy convened a meeting on **Thursday, February 6, 2025** at the Louisiana Board of Pharmacy located at 3388 Brentwood Drive in Baton Rouge, Louisiana 70809. The meeting was held pursuant to public notice, each member received notice, and public notice was properly posted.

1. Call to Order

Dr. J. Robert Cloud, Committee Chairman, called the meeting to order at 9:32 a.m.

2. <u>Invocation and Pledge of Allegiance</u>

Dr. Cloud delivered the invocation and Ms. Chris Melancon led the group in the Pledge of Allegiance.

3. Quorum Call

<u>Committee Members Present:</u> David Darce, Jacqueline Hall, Richard Indovina, Chris Melancon, Troy Menard, Richard "Andy" Soileau, and Committee Chair J. Robert Cloud.

Committee Members Absent: None.

<u>Also Participating:</u> Marty McKay (Board President), Joe Fontenot (Executive Director), Carlos Finalet (General Counsel), Sarah Stevens (Licensing Analyst Director), and Becky Parker (Compliance Officer).

<u>Public Attendees:</u> Lauren Paul (CVS Health), Joe Lavina (CVS Health), Alina Mangiurea (CVS Health), Jeff Mesaros (Mesaros Group), Malcolm Broussard (Hygeia Solutions), Kim Boasso (PharmCare of LA), Shelly Dupre (LA Alliance for Retail Pharmacies), Charlie Corona (LIPA), Sarah Perkins (Breazeale, Sachse & Wilson), Jessica Elliott (LARP), and Paul Menasco (Ochsner).

4. Call for Additional Agenda Items & Adoption of Agenda

Dr. Cloud asked if there were any additional agenda items to be added; none were requested. Without objection, the members adopted the posted agenda dated January 23, 2025. There were no objections to Dr. Cloud's request for authority to re-order the agenda should the Chairman determine it appropriate to do so.

5. Consideration of Draft Minutes from Previous Meeting – October 17, 2024

Dr. Cloud reminded the members they had received the draft minutes from the previous committee meeting held on October 17, 2024. With no objections, he waived the reading of the draft minutes. With no requests for amendments or corrections, and with no objection,

Dr. Cloud declared the minutes were approved as presented.

6. Opportunity for Public Comment

No public comments were offered.

*At this point, Dr. Cloud re-ordered the agenda to accommodate guests.

7. Rule Amendment Request-Remote Processing Services

CVS is requesting the Board to add remote "final product verification" to its definition of "Remote Processing Services", among other things.

Lauren Paul, Alina Mangiurea, and Joe Lavino with CVS Health presented an overview of CVS Air Support. The CVS representatives indicated that 35 states allow shared product verification and noted that there is now a pilot program in Virginia.

The committee expressed their appreciation for the presentation and will consider a pilot program for the shared product verification feature of Air Support.

*At this point, Dr. Cloud declared a recess. It was noted the members recessed at 10:27 a.m. and reconvened at 10:40 a.m.

8. Legislative Proposal 2025-B ~ CDS Schedules Update -Draft #1

Mr. Fontenot explained that each year LBP collaborates with the State Police Crime Lab to update the state's list of controlled substances to mirror recent federal scheduling action so that the state's scheduling mirrors federal scheduling of controlled substances. This proposal updates the state's list.

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

9. Regulatory Project 2025-03 ~ Pharmacy Technician Certificate Qualifications – Draft #2

Mr. Fontenot explained that, after the Board approved Draft #1 of this regulatory project, staff identified additional language in the new law that needs to be addressed in regulation. Act 253 from the 2024 legislative session requires LBP to issue a pharmacy technician certificate to a pharmacy technician applicant who is licensed in another state if the other state required the applicant to pass an examination, or to meet education, training, or experience standards. This proposal adds language to the regulation to allow for licensing of a technician licensed in another state that meets either of those requirements.

The committee unanimously approved Draft #2 for submission to the Board for its consideration.

10. Regulatory Proposal 2025-B~ Nonresident Pharmacy – Draft #1

Mr. Fontenot explained that this proposal for PICs of nonresident pharmacies reflects the Chapter 11 change in the experience requirement for a PIC, from two years of active practice to one year, which is presently being promulgated. Additionally, this proposal repeals Section

2301.A, which was identified by staff as possibly confusing and unnecessary when compared with current language in Section 2309.

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

11. Regulatory Proposal 2025-C ~ Practitioner CDS License - Draft #1

Mr. Fontenot explained that the proposal is pursuant to Act 444 of the 2022 Regular Session that amended the medical marijuana law to expand the authority to issue recommendations for medical marijuana to "authorized clinicians", then defined that term to include physicians, advanced practice registered nurses with prescriptive authority, and medical psychologists.

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

12. Regulatory Proposal 2024-K ~ Centralized Prescription Dispensing – Draft #2

Mr. Fontenot explained that during the last meeting, the committee directed staff to prepare Draft #2, considering suggestions made by the committee. Mr. Fontenot noted that Federal regulations require remote dispenser pharmacies to return prescriptions of CDS to the onsite pharmacy; sending the CDS prescriptions directly to the patient is not allowed.

The committee discussed whether the requirement for a remote dispenser to return non-CDS prescriptions to the on-site pharmacy is necessary. The members agreed that it is not.

Jeff Mesaros (The Mesaros Group, current president of NABP) spoke about different models that he has seen for remote dispensers. Mr. Mesaros will provide to Mr. Fontenot more information regarding those models.

*At this point, Dr. Cloud declared a recess for lunch. It was noted the members recessed at 11:37 a.m. and then reconvened at 12:11 p.m.

Discussion continued. Considering the proposed language restricting returns to the remote dispenser for reuse, members discussed whether delivery by contracted carriers should be considered to be outside the physical possession and environmental control of a pharmacy, which has historically been the Board's interpretation. Members discussed that a contracted courier with which a pharmacy can control the delivery conditions and a common carrier (like FedEx, USPS) whose conditions a pharmacy cannot control should probably be considered differently.

Members agreed that the regulation should address environmental control for proper storage of medication. There was some discussion regarding tamper-evident packaging for deliveries.

The committee instructed staff to compose Draft #3 for consideration at its next meeting.

13. Regulatory Proposal 2025-A ~ Prescription Drug Delivery – Draft #1

Mr. Fontenot explained that the issue of prescription drug delivery requirements was discussed during the revision of regulations addressing drug product storage requirements. The definition of "dispense" or "dispensing" in law includes the delivery of a drugs or device to a patient or patient's agent. Therefore, "dispense" necessarily includes the transfer of possession of a drug or device to the patient or patient's agent. Release of the prepared prescription to a delivery agent does not complete the dispensing process. The pharmacy is responsible for product integrity until the patient takes possession. Mr. Fontenot explained that the proposal reflects the Board's interpretation that has been in place for years.

Discussion of this proposal overlapped with that of Proposal 2024-K. Members considered pharmacy control, contracted carriers, and tracking environmental conditions. Their discussion included methods for patients receiving deliveries to determine whether the medication has been stored outside of the temperature range and time allowed for excursion. Members noted that environmental conditions are shipment specific, not just a universal standard, as medications can have different requirements and excursion allowances.

The committee directed staff to compose Draft #2 for consideration at its next meeting.

See attached for public comments submitted for consideration.

14. Rule Review – LAC 46:LIII.101-525

Mr. Fontenot explained that Act 192 of the 2024 legislative session adds a requirement for each agency to "review a sufficient number of the rules adopted by the agency so that all of the rules of the agency have been reviewed within a 5-year period and shall submit a report to the appropriate legislative oversight committee."

Mr. Fontenot and Mr. Finalet reviewed Sections 101 through 525 and determined that the rules are necessary and align with both applicable law and the Board's mission. They further concluded that the probable benefits of the rules outweigh any associated burdens or costs imposed on those regulated by the Board. Mr. Fontenot recommended no changes to these sections.

The committee unanimously approved the acceptance of Mr. Fontenot's recommendation.

- 15. <u>New Agenda Items Added During Meeting</u> No new agenda items were added.
- 16. Adjourn Having completed the tasks itemized on the posted agenda, with no further business pending before the committee and without objection, Dr. Cloud adjourned the meeting at 1:45 p.m.

Minutes approved by the Committee at subsequent meeting on June 18, 2025.