Louisiana Board of Pharmacy

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

October 9, 2025

Senator Cameron Henry
President, Louisiana Senate
Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2025-08 – Centralized Prescription Dispensing

Dear Senator Henry:

The Board of Pharmacy seeks to amend Section 1141 of its rules related to Centralized Prescription Dispensing. The proposed rule changes clarify the existing requirements related to prescription labeling and the maintenance of audit trail information. It further establishes standards for the delivery of prepared prescriptions between a remote dispenser and an on-site pharmacy. Additionally, the proposed rule changes specify that centralized prescription dispensing of controlled substances must comply with all applicable provisions of federal regulations set forth in 21 CFR Parts 1300 through 1399.

In connection with this regulatory project, the following items are appended:

- Notice of Intent
- Fiscal & Economic Impact Statement

As indicated in the solicitation, we will convene a public hearing at 9:00 a.m. on Wednesday, November 26, 2025 to receive public comments and testimony on this proposed rule changes. We will summarize those comments and our responses thereto in our next report to you. In the event you have any questions or need additional information about this project, please contact me directly at jfontenot@pharmacy.la.gov or 225.925.6481.

For the Board:

M. Joseph Fontenot, Jr. Digitally signed by M. Joseph Fontenot, Jr.
Date: 2025.10.09 13:57:19 -05'00'

M. Joseph Fontenot Jr.
Executive Director

cc: Chair, Senate Health & Welfare Committee
Via Email: APA.S-H&W@legis.la.gov
Speaker, House of Representatives
Via Email: APA.HouseSpeaker@legis.la.gov
Chair, House Health & Welfare Committee
Via Email: APA.H-HW@legis.la.gov
Editor, *Louisiana Register*
Via Email: Reg.Submission@la.gov
Reference File

NOTICE OF INTENT

Department of Health

Board of Pharmacy

Centralized Prescription Dispensing (LAC 46:LIII.1141)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Board of Pharmacy hereby gives notice of its intent to amend Section 1141 of its rules relative to Centralized Prescription Dispensing. The proposed Rule changes clarify the existing requirements related to prescription labeling and the maintenance of audit trail information. They further establish standards for the delivery of prepared prescriptions between a remote dispenser and an on-site pharmacy. Specifically, the proposed changes require that delivery be conducted in a manner that ensures the integrity of the medication by adhering to nationally recognized standards, and address packaging and temperature control. The proposed Rule changes also address possession and control of prescription drugs during delivery, whether by a common carrier, contract carrier, or pharmacy employee, and prohibit the dispensing of any prescription drug compromised in transit. When prescriptions are not dispensed to patients, the proposed Rule changes require that they be returned to the remote dispenser pharmacy in situations where the remote dispenser and the on-site pharmacy operate under different ownership. Finally, the proposed Rule changes specify that the centralized prescription dispensing of controlled substances must comply with all applicable provisions of federal regulations set forth in 21 CFR Parts 1300 through 1399.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII. Pharmacists

Chapter 11. Pharmacies

Subchapter D. Off-Site Services

§1141. Centralized Prescription Dispensing

A. – A.1.b.… …

2. Labeling. The remote dispenser shall label the container in compliance with Section 2527 of this Part, using the on-site pharmacy's information. The label shall also include the remote dispenser's name indicating that the prescription was filled at the remote dispenser. ~~All drugs dispensed to a patient that have been dispensed by a remote dispenser shall bear a label containing an identifiable code that provides a complete audit trail of the dispensing of the drug and pharmacy primary care activities.~~

3. Audit Trail Information. The remote dispenser and on-site pharmacy shall maintain a complete audit trail identifying pharmacy personnel involved in the dispensing process.

4. Delivery Between Remote Dispenser and On-Site Pharmacy. Delivery of prepared prescriptions between the remote dispenser and the on-site pharmacy is permissible using a common carrier, contract carrier, or pharmacy employee. Proper safeguards shall be in place to ensure the integrity of the medication — preserving its safety, identity, strength, quality, and purity throughout the delivery process.

a. Standards. The pharmacy shall ensure that all prescription drugs are delivered in compliance with nationally recognized standards, including those established by the manufacturer or the United States Pharmacopeia (USP).

b. Packaging. Prescription drugs delivered by a common or contract carrier shall be enclosed in tamper-evident packaging.

c. Temperature Control. Throughout the delivery process, prescription drugs shall be maintained within the temperature range specified by the United States Pharmacopeia (USP) or as recommended by the manufacturer, with allowances for permitted excursions.

d. Possession and Control. When a pharmacy relinquishes physical possession and control of a prescription drug during delivery, the drug shall not be returned to the pharmacy for reuse.

i. Common or Contract Carrier. If there is no formal agreement in place with a common or contract carrier that ensures delivery integrity standards and grants the pharmacy control during transit, prescription drugs shall not be returned to the pharmacy for reuse.

ii. Pharmacy Employee. When a pharmacy employee delivers a prescription drug, the pharmacy retains physical possession and control of the medication throughout the delivery process.

e. Compromised Product. If it is determined a prescription drug is in any way compromised during delivery, it shall not be dispensed.

5. The on-site pharmacy shall return to the remote dispenser prepared prescriptions not dispensed to the patient, if the pharmacies do not have the same owner.

6. Centralized prescription dispensing of controlled substances shall comply with all applicable provisions of 21 CFR Parts 1300 - 1399.

B. – B.2.e. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1131 (June 2007), amended LR

Family Impact Statement

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the Rule proposed for adoption, repeal, or amendment. The following statements will be published in the *Louisiana Register* with the proposed agency Rule.

1. The Effect on the Stability of the Family. The proposed rule changes will have no effect on the stability of the family.

2. The Effect on the Authority and Rights of Parents Regarding the Education and Supervision of their Children. The proposed rule changes will have no effect on the authority and rights of parents regarding the education and supervision of their children.

3. The Effect on the Functioning of the Family. The proposed rule changes will have no effect on the functioning of the family.

4. The Effect on Family Earnings and Family Budget. The proposed rule changes will have no effect on family earnings and family budget.

5. The Effect on the Behavior and Personal Responsibility of Children. The proposed rule changes will have no effect on the behavior and personal responsibility of children.

6. The Ability of the Family or a Local Government to Perform the Function as Contained in the Proposed Rule. The proposed changes will have no effect on the ability of the family or a local government to perform the activity as contained in the proposed rule.

Poverty Impact Statement

In accordance with Section 973 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a poverty impact statement on the Rule proposed for adoption, repeal, or amendment.

1. The Effect on Household Income, Assets, and Financial Security. The proposed rule changes will have no effect on household income, assets, or financial security.

2. The Effect on Early Childhood Development and Preschool through Postsecondary Education Development. The proposed rule changes will have no effect on early childhood development or preschool through postsecondary education development.

3. The Effect on Employment and Workforce Development. The proposed rule changes will have no effect on employment and workforce development.

4. The Effect on Taxes and Tax Credits. The proposed rule changes will have no effect on taxes or tax credits.

5. The Effect on Child and Dependent Care, Housing, Health Care, Nutrition, Transportation, and Utilities Assistance. The proposed rule changes will have no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

Small Business Analysis

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed Rule on small businesses:

1. The Establishment of Less Stringent Compliance or Reporting Requirements for Small Businesses. The proposed rule changes will have no effect on reporting requirements for small business.

2. The Establishment of Less Stringent Schedules or Deadlines for Compliance or Reporting Requirements for Small Businesses. The proposed rule changes will have no effect on schedules or deadlines for compliance or reporting requirements for small business.

3. The Consolidation or Simplification of Compliance or Reporting Requirements for Small Businesses. The proposed rule changes will have no effect on consolidation or simplification of compliance or reporting requirements for small business.

4. The Establishment of Performance Standards for Small Businesses to Replace Design or Operational Standards Required in the Proposed Rule. The proposed rule changes will have no effect on establishment of performance standards for small businesses to replace design or operational standards for small business.

5. The Exemption of Small Businesses from All or Any Part of the Requirements Contained in the Proposed Rule. There are no exemptions for small businesses in the proposed rule changes.

Provider Impact Statement

In accordance with House Concurrent Resolution No. 170 of the Regular Session of the 2014 Legislature, there is hereby submitted a provider impact statement on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, the following effects on the providers of services to individuals with developmental disabilities:

1. The effect on the staffing level requirements or qualifications required to provide the same level of service. The proposed rule changes will have no effect on the staffing level requirements or qualifications required to provide the same level of service.

2. The Total Direct and Indirect Effect on the Cost to the Provider to Provide the Same Level of Service. The proposed rule changes may increase the cost to the provider to provide the same level of service if the provider is currently engaged in centralized prescription dispensing and is delivering prescription medication to the on-site pharmacy without proper safeguards in place to ensure the integrity of the medication. The amount of this increase is variable and indeterminate.

3. The Overall Effect on the Ability of the Provider to Provide the Same Level of service. The proposed rule changes will have no impact on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments, via United States Postal Service or other, or in the alternative by personal delivery to M. Joseph Fontenot Jr., Executive Director, at the office of the Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-1700. He is responsible for responding to inquiries regarding the proposed Rule changes. The deadline for the receipt of all written comments is 12 p.m. on Wednesday, November 26, 2025.

Public Hearing

A public hearing to solicit comments and testimony on the proposed Rule changes is scheduled for Wednesday, November 26, 2025 at 9 a.m. at the Board office. During the hearing, all interested persons will be afforded an opportunity to submit comments and testimony, either verbally or in writing. The deadline for the receipt of all comments and testimony is 12 p.m. that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

M. Joseph Fontenot Jr.

Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

RULE TITLE: Centralized Prescription Dispensing

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

Other than the cost of rulemaking, there are no estimated implementation costs or savings for state or local government units resulting from the promulgation of the proposed rule changes. The cost for the Louisiana Board of Pharmacy is approximately $958 in FY 26 for the notice and rule publication in the *Louisiana Register*.

To the extent a government-operated pharmacy participating in centralized prescription dispensing is not currently delivering medication in a manner which ensures the integrity of the medication, there could be additional costs to the pharmacy to ensure appropriate drug delivery. These costs are indeterminate.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed rule changes are not anticipated to impact the revenue collections of state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NON-GOVERNMENTAL GROUPS (Summary)

The proposed rule changes benefit consumers by strengthening safeguards to ensure the integrity of prescription drugs and clarifies labeling requirements for pharmacies. Labels must include information from both the on-site pharmacy and the remote dispenser, a practice already followed by large chain pharmacies under federal requirements. To the extent a pharmacy is not currently ensuring delivery integrity, costs may increase for tamper-evident packaging, temperature controls, or delivery safeguards; however, such costs are expected to be minimal and indeterminable. Because pharmacies are already required to meet state standards for labeling, audit trails, and medication integrity, the rule is not anticipated to increase the overall cost of prescription drugs.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes are not anticipated to impact competition and employment.

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

Person Preparing Statement:	M. Joseph Fontenot Jr. Executive Director	Dept.:	Dept. of Health
Phone:	225.925.6481	Office:	Board of Pharmacy
Return Address:	3388 Brentwood Drive Baton Rouge, LA 70809	Rule Title:	Centralized Prescription Dispensing
		Date Rule Takes Effect:	Upon promulgation February 20, 2026 (est.)

SUMMARY
(Use complete sentences)

In accordance with Section 961 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

Other than the cost of rulemaking, there are no estimated implementation costs or savings for state or local government units resulting from the promulgation of the proposed rule changes. The cost for the Louisiana Board of Pharmacy is approximately $958 in FY 26 for the notice and rule publication in the *Louisiana Register*.

To the extent a government-operated pharmacy participating in centralized prescription dispensing is not currently delivering medication in a manner which ensures the integrity of the medication, there could be additional costs to the pharmacy to ensure appropriate drug delivery. These costs are indeterminate.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

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III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NON-GOVERNMENTAL GROUPS (Summary)

The proposed rule changes benefit consumers by strengthening safeguards to ensure the integrity of prescription drugs and clarifies labeling requirements for pharmacies. Labels must include information from both the on-site pharmacy and the remote dispenser, a practice already followed by large chain pharmacies under federal requirements. To the extent a pharmacy is not currently ensuring delivery integrity, costs may increase for tamper-evident packaging, temperature controls, or delivery safeguards; however, such costs are expected to be minimal and indeterminable. Because pharmacies are already required to meet state standards for labeling, audit trails, and medication integrity, the rule is not anticipated to increase the overall cost of prescription drugs.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes are not anticipated to impact competition and employment.

M. J. Fontenot, Jr.
Signature of Head or Designee

M. Joseph Fontenot, Jr., Executive Director
Typed Name & Title of Agency Head or Designee

October 3, 2025
Date of Signature

Patrice Thomas, Deputy Fiscal Officer
Legislative Fiscal Officer or Designee

10/08/2025
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

The proposed rule changes clarify the existing requirements related to prescription labeling and the maintenance of audit trail information. It further establishes standards for the delivery of prepared prescriptions between a remote dispenser and an on-site pharmacy. Specifically, the proposed amendment requires that delivery be conducted in a manner that ensures the integrity of the medication by adhering to nationally recognized standards, and addresses packaging and temperature control. The proposed Rule amendment addresses possession and control of prescription drugs during delivery, whether by a common carrier, contract carrier, or pharmacy employee, and prohibits dispensing any prescription drug compromised in transit. When prescriptions are not dispensed to patients, the rule requires that they be returned to the remote dispenser pharmacy in situations where the remote dispenser and the on-site pharmacy operate under different ownership. Finally, the proposed Rule amendment specifies that the centralized prescription dispensing of controlled substances must comply with all applicable provisions of federal regulations set forth in 21 CFR Parts 1300 through 1399.

B. Summarize the circumstances, which require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

The proposed rule changes were prompted by questions from pharmacies participating in centralized prescription dispensing. There was confusion regarding the labeling requirements. The Board was also wanting to address delivery standards and used the opportunity to clean up the regulation.

C. Compliance with Act 11 of the 1986 First Extraordinary Session

(1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

The proposed rule changes will not require any additional funding or expenditure of funds.

(2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(a) _____ YES. If yes, attach documentation.

(b) ___XX___ NO. If no, provide justification as to why this rule change should be published at this time

Louisiana Board of Pharmacy operates on self-generated revenue, and they have determined the proposed rule changes are in the public's best interest.

D. Compliance with Act 98 of the 2025 Regular Session

(1) Will the proposed rule change result in either the expenditure of state funds or an economic impact involving costs to regulated entities estimated at $200,000 or more per year or $600,000 or more over three years?

(a) _____ YES.

(b) ___XX___ NO.

(2) If the answer to (1) above is yes, was there a fiscal note for the enacted legislation that required this action (attach documentation) AND did the fiscal note include all costs contemplated in this document?

(a) _____ YES.
(b) ___XX___ NO.

Not applicable.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

COSTS	FY 26	FY 27	FY 28
PERSONAL SERVICES	$0	$0	$0
OPERATING EXPENSES	$958	SEE BELOW	SEE BELOW
PROFESSIONAL SERVICES	$0	$0	$0
OTHER CHARGES	$0	$0	$0
EQUIPMENT	$0	$0	$0
MAJOR REPAIR & CONSTR.	$0	$0	$0
TOTAL	**$958**	**SEE BELOW**	**SEE BELOW**
POSITIONS (#)	**0**	**0**	**0**

2. Provide a narrative explanation of the costs or savings shown in "A. 1.", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

   Other than the cost of rulemaking, there are no estimated implementation costs or savings for state agencies resulting from the promulgation of the proposed rule changes. The cost for the Louisiana Board of Pharmacy is approximately $958 in FY 26 for the notice and rule publication in the *Louisiana Register*

   To the extent a government-operated pharmacy participating in centralized prescription dispensing is not currently delivering medication in a manner which ensures the integrity of the medication, there could be additional costs to the pharmacy to ensure appropriate drug delivery. These costs are indeterminate.

3. Sources of funding for implementing the proposed rule or rule change.

SOURCE	FY 26	FY 27	FY 28
STATE GENERAL FUND	$0	$0	$0
AGENCY SELF-GENERATED	$958	$0	$0
DEDICATED	$0	$0	$0
FEDERAL FUNDS	$0	$0	$0
OTHER (Specify)	$0	$0	$0
TOTAL	**$958**	**$0**	**$0**

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

   Yes, Louisiana Board of Pharmacy has sufficient self-generated funds available to implement the proposed rule changes.

B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

   To the extent a government-operated pharmacy participating in centralized prescription dispensing is not currently delivering medication in a manner which ensures the integrity of the medication, there could be additional costs to the pharmacy to ensure appropriate drug delivery. These costs are indeterminate.

2. Indicate the sources of funding of the local governmental unit, which will be affected by these costs or savings.

   The proposed rule changes will not impact sources of funding of local government units.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

REVENUE INCREASE/DECREASE	FY 26	FY 27	FY 28
STATE GENERAL FUND	$0	$0	$0
AGENCY SELF-GENERATED	$0	$0	$0
DEDICATED	$0	$0	$0
FEDERAL FUNDS	$0	$0	$0
LOCAL FUNDS	$0	$0	$0
TOTAL	**$0**	**$0**	**$0**

*Specify the particular fund being impacted.

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A." Describe all data, assumptions, and methods used in calculating these increases or decreases.

The proposed rule changes will not affect revenue collections of state or local governmental units.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS

A. What persons, small businesses, or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

The proposed rule benefits consumers by strengthening safeguards to ensure the integrity of prescription drugs and clarifies labeling requirements for pharmacies. Labels must include information from both the on-site pharmacy and the remote dispenser, a practice already followed by large chain pharmacies under federal requirements. To the extent a pharmacy is not currently ensuring delivery integrity, costs may increase for tamper-evident packaging, temperature controls, or delivery safeguards; however, such costs are expected to be minimal and indeterminable. Because pharmacies are already required to meet state standards for labeling, audit trails, and medication integrity, the rule is not anticipated to increase the overall cost of prescription drugs.

B. Also provide an estimate and a narrative description of any impact on receipts and/or income resulting from this rule or rule change to these groups.

The proposed rule changes will not have an effect on receipts or income.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

The proposed rule changes are not anticipated to impact competition and employment.