



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



February 10, 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 2025-04 ~ Emergency Drug Kit (EDK) Permit

Dear Senator Henry:

The Board of Pharmacy seeks to amend Section 1711 of its rules relative to Emergency Drug Kit Permits. The proposed Rule change removes the requirement for the administrator of the applicant facility to sign the application for the EDK permit, and require the online permit verification to be readily retrievable at its location, since the board no longer issues paper permits.

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 Monday, March 31, 2025 to receive public comments and testimony on these 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.
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

Emergency Drug Kit Permit (LAC 46:LIII.1711)

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 §1711 of its rules relative to Emergency Drug Kit Permits. The proposed Rule change removes the requirement for the administrator of the applicant facility to sign the application for the EDK permit, and require the online permit verification to be readily retrievable, since the board no longer issues paper permits.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII. Pharmacists

Chapter 17. Institutional Pharmacy

Subchapter B. Emergency Drug Kits

§1711. Emergency Drug Kit Permit

A. ...

B. Permit Application and Requirements. Application for an EDK permit shall be made on a form provided by the board.

1. The provider pharmacy shall apply to the board for an EDK permit. ~~The administrator of the applicant facility shall also sign the application for said permit.~~ Upon compliance with the required provisions, the provider pharmacy shall be issued a permit by the board for the provider pharmacy to establish and maintain an EDK in the facility.

2. – 5. ...

6. ~~The original~~ A copy of the EDK permit online verification from the board's website shall be readily retrievable ~~at the provider pharmacy. A copy of the EDK permit shall be maintained~~ in the room where the EDK is located.

C. – 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 29:2095 (October 2003), effective January 1, 2004, amended by the Department of Health Board of Pharmacy, LR 46:584 (April 2020), 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 amendment 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 amendment 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 amendment will have no effect on the functioning of the family.
4. The Effect on Family Earnings and Family Budget. The proposed rule amendment will have no effect on family earnings and family budget.
5. The Effect on the Behavior and Personal Responsibility of Children. The proposed rule amendment 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 rule amendment 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 amendment 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 amendment 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 amendment will have no effect on employment and workforce development.

4. The Effect on Taxes and Tax Credits. The proposed rule amendment 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 amendment 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 amendment 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 amendment 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 amendment 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 amendment 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 amendment.

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 amendment 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 amendment will have no effect on the cost to the provider to provide the same level of service.

3. The Overall Effect on the Ability of the Provider to Provide the Same Level of service. The proposed rule amendment will have no effect 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 carrier, 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 amendment. The deadline for the receipt of all written comments is 12 p.m. on Monday, March 31, 2025.

Public Hearing

A public hearing to solicit comments and testimony on the proposed Rule change is scheduled for 9 a.m. on Monday, March 31, 2025. 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: Emergency Drug Kit Permit

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

The cost for the Louisiana Board of Pharmacy is approximately \$1,000 in FY 25 for the notice and rule publication in the Louisiana Register. 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 change.

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)

There are no anticipated economic losses resulting from these proposed rule changes. The proposed rule changes will benefit pharmacies by eliminating the requirement to obtain the signature of the facility administrator on Emergency Drug Kit permit applications. This streamlines the application process, reducing administrative burdens without additional costs.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes will have no effect on competition or 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:	Emergency Drug Kit (EDK) Permit
		Date Rule Takes Effect:	Upon promulgation June 20, 2025 (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)

The cost for the Louisiana Board of Pharmacy is approximately \$1,000 in FY 25 for the notice and rule publication in the *Louisiana Register*. 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 change.

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

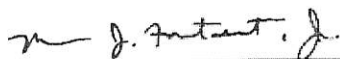
The proposed rule changes are not anticipated to impact the revenue collections of state or local governmental units.

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

There are no anticipated economic losses resulting from these proposed rule changes. The proposed rule changes will benefit pharmacies by eliminating the requirement to obtain the signature of the facility administrator on Emergency Drug Kit permit applications. This streamlines the application process, reducing administrative burdens without additional costs.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes will have no effect on competition or employment.



Signature of Head or Designee

Melvin J. Fontenot, Jr.

Typed Name & Title of Agency Head or Designee

02-10-2025

Date of Signature


Legislative Fiscal Officer or Designee

2/10/2025

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 in section 1711 eliminate the requirement for the administrator of the applicant facility to sign the application for the EDK permit. Additionally, the changes require that the online permit verification be readily accessible in the room where the EDK is located, as the Board no longer issues paper permits.

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

The Board of Pharmacy has proposed eliminating the requirement for obtaining the signature of a facility administrator on applications for pharmacies to acquire or renew an EDK permit, as the pharmacy permit and the Pharmacist-in-Charge (PIC) are accountable for the permit. Additionally, since the Board no longer issues paper permits, the requirement to maintain the original EDK permit at the provider pharmacy was deemed outdated. After reviewing these issues, the Board determined it appropriate to amend its rules related to EDK permits.

- 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. Rulemaking costs are included in the Board's operating budget.

- (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) X _____ 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.

**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 25	FY 26	FY 27
PERSONAL SERVICES	\$0	\$0	\$0
OPERATING EXPENSES	\$1,000	\$0	\$0
PROFESSIONAL SERVICES	\$0	\$0	\$0
OTHER CHARGES	\$0	\$0	\$0
EQUIPMENT	\$0	\$0	\$0
MAJOR REPAIR & CONSTR.	\$0	\$0	\$0
TOTAL	\$1,000	\$0	\$0
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.

The cost for the Louisiana Board of Pharmacy is approximately \$1,000 in FY 25 for the notice and rule publication in the *Louisiana Register*. 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 change.

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

SOURCE	FY 25	FY 26	FY 27
STATE GENERAL FUND	\$0	\$0	\$0
AGENCY SELF-GENERATED	\$1,000	\$0	\$0
DEDICATED	\$0	\$0	\$0
FEDERAL FUNDS	\$0	\$0	\$0
OTHER (Specify)	\$0	\$0	\$0
TOTAL	\$1,000	\$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?

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.

The proposed rule changes will not result in costs or savings to local governmental units.

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 governmental 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 25	FY 26	FY 27
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.

There are no anticipated economic losses resulting from these proposed rule changes. The proposed rule changes will benefit pharmacies by eliminating the requirement to obtain the signature of the facility administrator on EDK permit applications. This streamlines the application process, reducing administrative burdens without additional costs.

- 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 impact a licensee's receipts or revenue.

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 will have no effect on competition or employment.