



Louisiana Board of Pharmacy

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



April 8, 2022

Senator P. Page Cortez
President, Louisiana Senate
Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2022-4 ~ Pharmacy Benefit Managers

Dear Senator Cortez:

The Board seeks to amend its rules for pharmacy benefit managers to repeal the requirement for the inclusion of an audited financial statement in the application for a new pharmacy benefit manager permit.

The Occupational Licensing Review Commission approved the initiation of this project during their March 10, 2022 meeting. In connection with this regulatory project, the following items are appended:

- Notice of Intent Page 2
- Fiscal & Economic Impact Statement Page 5

As indicated in the solicitation, we will convene a public hearing on May 27, 2022 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 mbroussard@pharmacy.la.gov or 225.925.6481.

For the Board:

Malcolm J. Broussard
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
Director, Community Competitiveness & Small Business Services, La. Economic Development
Via Email: Witty@la.gov
Editor, *Louisiana Register*
Via Email: Reg.Submission@la.gov
Reference File

NOTICE OF INTENT

Department of Health Board of Pharmacy

Pharmacy Benefit Managers (LAC 46:LIII.3001 and 3005)

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 Louisiana Board of Pharmacy hereby gives notice of its intent to amend §§3001 and 3005 of its rules relative to pharmacy benefit managers to reduce the regulatory burden on pharmacy benefit manager permit applicants by eliminating the requirement to provide an audited financial statement. The proposed change in §3001 repeals the definition of audited financial statement and the proposed change in §3005 removes the application requirement to provide a copy of an audited financial statement by the applicant.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII: Pharmacists

Chapter 30. Pharmacy Benefit Managers

§3001. Definitions

A. The following terms shall have the meaning ascribed to them in this Section:

~~Audited Financial Statement—the financial statement and related disclosures prepared by an independent certified public accountant in accordance with United States Generally Accepted Accounting Principles (GAAP) of the specific entity or licensee intending to operate or operating in Louisiana. Repealed.~~

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1253.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 47:591 (May 2021), amended LR

* * *

§3005. Permitting Procedures

A. Application for Initial Issuance of Permit

1. ...

2. The application shall include copies of the following documents:

a. – b. ...

~~c.—an audited financial statement for the applicant’s previous fiscal year.~~

A.3. – E.2. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1253.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 47:591 (May 2021), 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 rule 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 or 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 compliance or 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 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 standards.

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 the qualifications for that staff 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 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 changes 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 mail carrier, or in the alternative by personal delivery to Joe Fontenot, Executive Director - Designate, 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.

Public Hearing

A public hearing to solicit comments and testimony on the proposed Rule is scheduled for 9:00 a.m. on Friday, May 27, 2022 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. noon that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

Joe Fontenot

Executive Director – Designate

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

RULE TITLE: Pharmacy Benefit Managers

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

The proposed rule changes will require the Louisiana Board of Pharmacy (LBP) to publish the proposed and final rules in the state register, resulting in printing expenses of \$500 in FY 2022 and \$500 in FY 2023. There will be no additional expenditures or cost savings for LBP or other state or local governmental units.

The proposed changes reduce the regulatory burden on pharmacy benefit manager applicants by eliminating the requirement to provide a copy of an audited financial statement with an initial permit application.

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

The proposed rule changes will not affect revenue collections for 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 will reduce the regulatory burden on pharmacy benefit manager applicants by eliminating the requirement to provide a copy of an audited financial statement with an initial permit application. This will impact an anticipated 40 applications.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

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

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

Person Preparing Statement: Joe Fontenot
Executive Director-Designate
Dept.: Dept. of Health
Office: Board of Pharmacy
Telephone: 225.925.6481
Title: Pharmacy Benefit Managers
Return Address: 3388 Brentwood Drive
Baton Rouge, LA 70809
Effective Date of Rule: Upon promulgation
Aug. 20, 2022 (est.)

SUMMARY
(Use complete sentences)

In accordance with Section 953 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 proposed rule changes will require the Louisiana Board of Pharmacy (LBP) to publish the proposed and final rules in the state register, resulting in printing expenses of \$500 in FY 2022 and \$500 in FY 2023. There will be no additional expenditures or cost savings for LBP or other state or local governmental units.

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IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

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Joe Fontenot

Digitally signed by Joe Fontenot
DN: cn=Joe Fontenot, o=Louisiana Board of Pharmacy,
ou=Executive Director, email=jfontenot@pharmacy.la.gov, c=US
Date: 2022.04.07 16:06:13 -0500

Signature of Agency Head or Designee

Joe Fontenot, Executive Director-Designate

Typed Name and Title of Agency Head

April 07, 2022

Date of Signature

Evan Brasse, Interim Deputy
Legislative Fiscal Officer or Designee
Fiscal Officer

4/8/22
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

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 amend the rule for pharmacy benefit managers to (1) repeal the definition of audited financial statement and (2) removes the requirement to provide a copy of an audited financial statement with an initial permit application. A copy of the notice of intent is appended.

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

The original rule became effective on May 20, 2021 and the Board's Application Review Committee began the process of reviewing and approving applications shortly thereafter. The original rule required a copy of an audited financial statement for the applicant's previous fiscal year as part of the application. After a period of reviewing applications the committee determined a copy of the audited financial statement was not necessary and recommended a removal of the requirement.

- 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.

LBP has allocated \$1,000 for printing the Notice of Intent and the Rule. LBP operates on self-generated 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) No NO. If no, provide justification as to why this rule change should be published at this time

LBP operates on self-generated funds, and they have determined the proposed rule changes reflect an appropriate reduction of the permitting requirements.

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 22	FY 23	FY 24
Personal Services			
Operating Expenses	\$500	\$500	
Professional Services			
Other Charges			
Equipment			
Major Repairs & Constr.			
TOTAL	\$500	\$500	None
POSITIONS (#)	None	None	None

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 proposed changes will require LBP to print the Notice of Intent and Rule in the state register at a cost of \$500 in FY 2022 and \$500 in FY 2023.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

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

SOURCE	FY 22	FY 23	FY 24
State General Fund			
Agency Self-Generated	\$ 500	\$500	
Dedicated			
Federal Funds			
Other (Specify)			
TOTAL	\$500	\$500	None

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

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

SOURCE	FY 22	FY 23	FY 24
State General Fund			
Agency Self-Generated			
Dedicated			
Federal Funds			
Other (Specify)			
TOTAL	None	None	None

The proposed rule changes do not impact local governmental units.

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

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

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

<u>REVENUE INCREASE/DECREASE</u>	<u>FY 22</u>	<u>FY 23</u>	<u>FY 24</u>
State General Fund			
Agency Self-Generated			
Dedicated Funds*			
Federal Funds			
Local Funds			
TOTAL	None	None	None

*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.

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 changes will reduce the regulatory burden on pharmacy benefit manager applicants by eliminating the requirement to provide a copy of an audited financial statement with an initial permit application.

**FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET**

- 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.

NOTICE OF INTENT

Department of Health Board of Pharmacy

Pharmacy Benefit Managers (LAC 46:LIII.3001 and 3005)

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Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII: Pharmacists

Chapter 30. Pharmacy Benefit Managers

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§3005. Permitting Procedures

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2. The application shall include copies of the following documents:

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Public Comments

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Public Hearing

A public hearing to solicit comments and testimony on the proposed Rule is scheduled for ~~(time, date, location)~~. 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. noon that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

Joe Fontenot
Executive Director – Designate

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

RULE TITLE: Pharmacy Benefit Managers

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