



# Louisiana Board of Pharmacy

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



February 3, 2023

Senator P. Page Cortez  
President, Louisiana Senate  
Via Email: [APA.SenatePresident@legis.la.gov](mailto:APA.SenatePresident@legis.la.gov)

## Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2023-03 ~ Pharmacy Benefit Managers

Dear Senator Cortez:

The Board seeks to amend §3005 of its rules relative to pharmacy benefit managers to remove the requirement for a pharmacy benefit manager applicant to include copies of governance documents and the standard generic contract template used by the applicant with the initial permit application. Additionally, the Board gives notice of its intent to repromulgate Chapter 30 in its entirety, as amended, due to Act 536 of the 2022 Regular Session which clarified legislative intent to mandate licensure of pharmacy benefit managers by the Board of Pharmacy.

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

- Notice of Intent Page 2
- Fiscal & Economic Impact Statement Page 6

As indicated in the solicitation, we will convene a public hearing at 9:00 a.m. on Tuesday, March 28, 2023 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](mailto: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](mailto:APA.S-H&W@legis.la.gov)  
Speaker, House of Representatives  
Via Email: [APA.HouseSpeaker@legis.la.gov](mailto:APA.HouseSpeaker@legis.la.gov)  
Chair, House Health & Welfare Committee  
Via Email: [APA.H-HW@legis.la.gov](mailto:APA.H-HW@legis.la.gov)  
Director, Community Competitiveness & Small Business Services, La. Economic Development  
Via Email: [Witty@la.gov](mailto:Witty@la.gov)  
Editor, *Louisiana Register*  
Via Email: [Reg.Submission@la.gov](mailto:Reg.Submission@la.gov)  
Reference File

## NOTICE OF INTENT

### Department of Health Board of Pharmacy

#### Pharmacy Benefit Managers (LAC 46:LIII.Chapter 30)

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 §3005 of its rules relative to pharmacy benefit managers to remove the requirement for a pharmacy benefit manager applicant to include copies of governance documents and the standard generic contract template used by the applicant with the initial permit application. Additionally, the Board gives notice of its intent to repromulgate Chapter 30 in its entirety, as amended, due to Act 536 of the 2022 Regular Session which clarified legislative intent to mandate licensure of pharmacy benefit managers by the Board of Pharmacy.

## Title 46

### PROFESSIONAL AND OCCUPATIONAL STANDARDS

#### Part LIII: Pharmacists

#### Chapter 30. Pharmacy Benefit Managers

##### §3003. Pharmacy Benefit Manager Permit

A. A pharmacy benefit manager, as defined at R.S. 40:2863, shall obtain and maintain a pharmacy benefit manager permit from the board prior to conducting business in Louisiana if it administers, develops, maintains, performs, or provides one or more of the pharmacy services enumerated in R.S. 40:2868 in the state or that affects one or more beneficiaries of a pharmacy benefit management plan, as defined at R.S. 40:2863, administered by the pharmacy benefit manager.

B. A pharmacy benefit manager permit shall authorize the permit holder to administer pharmacy benefit management services.

C. The board shall not issue a pharmacy benefit manager permit to any person or other entity which has not yet registered with the Louisiana Secretary of State to conduct business within the state.

D. A pharmacy benefit manager permit is not transferable from the original owner. The permit shall not be subject to sale, assignment or other transfer, voluntary or involuntary. Moreover, in the event the ownership of the pharmacy benefit manager changes by 50 percent or more after the initial issuance of the permit, the ownership will be deemed sufficiently different as to require a new pharmacy benefit manager permit. The continued operation of a pharmacy benefit manager permit after its ownership has changed by 50 percent or more shall constitute sufficient basis for the board to issue a finding for the operation of a pharmacy benefit manager without a valid permit, in violation of R.S. 40:2865.

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), repromulgated LR

##### §3005. Permitting Procedures

###### A. Application for Initial Issuance of Permit

1. The board shall develop an application form suitable for the pharmacy benefit manager permit. The board may revise that application form on its own initiative in order to collect the information it deems necessary to properly evaluate an applicant.

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

~~a. governance documents, including articles of incorporation, articles of association, partnership agreements, trade name certificates, trust agreements, shareholder agreements, and all amendments to such documents;~~

~~b. the applicant's standard generic contract template which it uses for contracts entered into by the applicant and pharmacies or pharmacy services administrative organizations in this state in the administration of pharmacy benefits for healthcare insurers, providers, or payors;~~

- ~~2. 3.~~ The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.
- ~~3. 4.~~ Once received by the board, an application for the permit shall expire one year thereafter.
- ~~4. 5.~~ In the event any information contained in the application or accompanying documents changes after being submitted to the board and before the issuance of the permit, the applicant shall immediately notify the board in writing and provide corrected information.
- ~~5. 6.~~ The applicant may be required to personally appear before the board or any of its committees prior to any decision on the permit application.
- ~~6. 7.~~ Upon approval of the application, the board shall issue the pharmacy benefit manager permit to the applicant.

B. Application for Renewal of Permit

1. All pharmacy benefit manager permits shall expire two years after the date of its initial issuance and the renewals shall expire every two years thereafter on that anniversary date.
2. The board shall not process applications received by facsimile, or that are incomplete.
3. In the event a pharmacy benefit manager does not submit a properly completed renewal application to the board prior to the expiration of the permit, the permit shall be rendered null and void. The continued operation of a pharmacy benefit manager with an expired permit shall constitute sufficient basis for the board to issue a finding for the operation of a pharmacy benefit manager without a valid permit, in violation of R.S. 40:2865.
4. A pharmacy benefit manager permit not renewed by 30 days after the expiration date shall be automatically terminated by the board.

C. Application for Reinstatement of Terminated, Suspended, or Revoked Permit

1. The applicant shall complete the application form for this specific purpose supplied by the board.
2. Upon the receipt of a properly completed application form, the board staff shall refer the application to the board's reinstatement committee for its consideration and shall notify the applicant of the time and place for the committee meeting.

D. Maintenance of Permit

1. A pharmacy benefit manager permit shall be valid for the entity to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary.
2. Upon receipt of a written request and payment of the fee authorized in R.S. 37:1184, the board shall issue a duplicate or replacement permit to the applicant; however, such duplicate or replacement permit shall not serve or be used as an additional or second permit.

E. Permanent Closure of Permit

1. In the event the pharmacy benefit manager contemplates permanent closure of the pharmacy benefit manager business, the owner of the permit shall notify the board, in writing, 10 days prior to the anticipated date of closure and surrender its permit.
2. The notice required in this Subsection shall include an acknowledgement of the firm's obligation to maintain copies of all records for all patients and pharmacies in Louisiana for a minimum of two years following the date of closure and surrender of its permit, and further, the point of contact for all inquiries and requests for such records during that two-year period of time.

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 48:2105 (August 2022), amended and repromulgated 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 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.

#### **Public Hearing**

A public hearing to solicit comments and testimony on the proposed Rule is scheduled for 9:00 a.m. on Tuesday, March 28, 2023 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.

M. Joseph Fontenot Jr.

Executive Director

### **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 2023 and \$500 in FY 2024. There will be no additional expenditures or cost savings for LBP or other state or local governmental units.

The proposed rule changes amend the rule for pharmacy benefit managers to remove the requirement for a pharmacy benefit manager applicant to include copies of governance documents and the standard generic contract template used by the applicant with the 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 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 will reduce the regulatory burden on pharmacy benefit manager applicants by reducing the documents required with an initial permit application. The LBP estimates this change will impact 19 applications in the near future, as well as any additional future 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:	M. Joseph Fontenot Jr. Executive Director	Dept.: Dept. of Health
Telephone:	225.925.6481	Office: Board of Pharmacy
Return Address:	3388 Brentwood Drive Baton Rouge, LA 70809	Title: Pharmacy Benefit Managers
		Effective Date of Rule: Upon promulgation July 20, 2023 (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 2023 and \$500 in FY 2024. There will be no additional expenditures or cost savings for LBP or other state or local governmental units.

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The proposed rule changes will reduce the regulatory burden on pharmacy benefit manager applicants by reducing the documents required with an initial permit application. The LBP estimates this change will impact 19 applications in the near future, as well as any additional future applications.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

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

M. Joseph Fontenot Jr.  
Digitally signed by M. Joseph Fontenot Jr.  
Date: 2023.02.01 12:46:04 -06'00'  
Signature of Agency Head or Designee

M. Joseph Fontenot Jr., Executive Director  
Typed Name and Title of Agency Head

  
Legislative Fiscal Officer or Designee

2-2-23  
Date of Signature

February 1, 2023  
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 remove the requirement for a pharmacy benefit manager applicant to include copies of governance documents and the standard generic contract template used by the applicant with the 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.

Following its review of LAC 46: LIII. Chapter 30 Pharmacy Benefit Managers (PBM), LBP decided to reduce the documents required in §3005 as part of the application process and to repromulgate Chapter 30 in its entirety due to Act 536 of the 2022 Regular Session which clarified legislative intent to mandate licensure of PBMs by the Board of Pharmacy.

- 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.

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 23	FY 24	FY 25
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 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 2023 and \$500 in FY 2024. There will be no additional expenditures or cost savings for LBP or other state agencies.

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

SOURCE	FY 23	FY 24	FY 25
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.

The proposed rule changes will not impact 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 funding sources 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?

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

<u>REVENUE INCREASE/DECREASE</u>	<u>FY 23</u>	<u>FY 24</u>	<u>FY 25</u>
State General Fund			
Agency Self-Generated			
Dedicated Funds*			
Federal Funds			
Local Funds			
<b>TOTAL</b>	<b>None</b>	<b>None</b>	<b>None</b>

\*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.

N/A

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 changes will reduce the regulatory burden on pharmacy benefit manager applicants by reducing the documents required with an initial permit application. The LBP estimates this change will impact 19 applications in the near future, as well as any additional future applications.

- 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.