



# 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)



November 11, 2019

Senator John A. Alario, Jr, 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 2019-16 ~ Pharmacy Compounding

Dear Senator Alario:

The Board has initiated the rulemaking process to amend its rules for pharmacies compounding copies of commercially available drug products, consistent with recent guidance from the federal food and drug administration. In connection with this regulatory project, the following documents are attached.

- Approval from Occupational Licensing Review Commission Page 2
- Notice of Intent Page 5
- Proposed Rule Changes Page 6
- Family Impact Statement Page 8
- Poverty Impact Statement Page 9
- Provider Impact Statement Page 10
- Regulatory Flexibility Analysis Page 11
- Solicitation of Comments Page 12
- Fiscal & Economic Impact Statement Page 13

As indicated in the solicitation, we will convene a public hearing on December 27, 2019 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](mailto: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](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 Outreach Services, La. Economic Development  
Via Email: [Pat.Witty@la.gov](mailto:Pat.Witty@la.gov)  
Editor, *Louisiana Register*  
Via Email: [Reg.Submission@la.gov](mailto:Reg.Submission@la.gov)  
Reference File



**WHEREAS**, it is necessary for the Occupational Licensing Review Commission (OLRC) to issue a resolution regarding the approval or denial of specific occupational regulations submitted for its review:

**NOW, THEREFORE, BE IT RESOLVED BY THE OCCUPATIONAL LICENSING REVIEW COMMISSION**, that the following occupational regulations, as defined by Louisiana Revised Statutes 37:43(7), shall be known to have been approved by the OLRC at a duly called meeting of its members on August 29, 2019. The OLRC finds that these occupational regulations comply with the state policy set forth in Louisiana Revised Statutes 37:44 and authorizes the respective occupational licensing boards to initiate promulgation of the regulations in accordance with the Administrative Procedure Act.

**A. Louisiana Behavior Analyst Board**

- i. LAC 46: VIII.501-517 Supervision

**B. Louisiana Board of Examiners for Speech Language Pathology and Audiology**

- i. LAC 46: LXXV.103. Definitions
- ii. LAC 46: LXXV.107. Qualifications for Licensure
- iii. LAC 46: LXXV.109. Licensure Application Procedure
- iv. LAC 46: LXXV.121. Duties
- v. LAC 46: LXXV.125. Renewals
- vi. LAC 46: LXXV.127. Continuing Education Requirements
- vii. LAC 46: LXXV.501. Investigation of Complaints

**C. State Board of Certified Public Accountants of Louisiana**

- i. LAC 46: XIX.505.F.1.b

**D. Louisiana State Board of Embalmers and Funeral Directors**

- i. LAC 46: XXXVII.701. Renewal and Reinstatement
- ii. LAC 46: XXXVII.905. Application; Fee
- iii. LAC 46: XXXVII.1701. Reports on Prepaid Funeral Services or Merchandise
- iv. LAC 46: XXXVII.1901. Survivors Clause
- v. LAC 46: XXXVII.1902. Heirship Clause
- vi. LAC 46: XXXVII.2001. Procedure to Follow

**E. Louisiana State Board of Dentistry**

- i. LAC 46: XXXIII.1503
- ii. LAC 46: XXXIII.1607
- iii. LAC 46: XXXIII.1615.

**F. State Board of Architectural Examiners**

- i. LAC 46: I.1101. Registration Information
- ii. LAC 46: I.1105. Licenses
- iii. LAC 46: I.1301. Renewal Practices

**G. Louisiana State Board of Social Work Examiners**

- i. LAC 46: XXV.503. LMSWs Seeking the LCSW Credential

**H. Louisiana Licensed Professional Counselors Board of Examiners**

- i. LAC 46: LX.3105. Definitions for Licensed Marriage and Family Therapists and Provisional Licensed Marriage and Family Therapists
- ii. LAC 46: LX.3309. Academic Requirements for MFT Licensure or Provisional Licensure
- iii. LAC 46: LX.3315. Application, Practice, and Renewal Requirements for Provisional Licensed Marriage and Family Therapists
- iv. LAC 46: LX. 3317. Qualifications of the LMFT-Approved Supervisor, LMFT-Registered Supervisor Candidate, Board-Approved Supervisor, and Registered Supervisor Candidate.
- v. LAC 46: LX.3319. Responsibilities of the Provisional Licensed Marriage and Family Therapist

**I. Louisiana Liquefied Petroleum Gas Commission**

- i. LAC 55: IX.105. Applications
- ii. LAC 55: IX.107. Requirements
- iii. LAC 55: IX.109. Compliance with Rules
- iv. LAC 55: IX.113. Classes of Permits and Registrations
- v. LAC 55: IX.133. Shall Purchase Containers Manufactured by Manufacturers Acceptable to the Authority Having Jurisdiction
- vi. LAC 55: IX.177. Appliance Installation and Connections
- vii. LAC 55: IX.181. National Fire Protection Association Pamphlet Numbers 54 and 58
- viii. LAC 55: IX.205. Installation of Liquefied Petroleum Gas Systems Used as Engine Fuel System for School Bus/Mass Transit Vehicles
- ix. LAC 55: IX.1513. Classes of Permits

**J. Louisiana State Board of Optometry Examiners**

- i. LAC 46: LI.301. Continuing Education
- ii. LAC 46: LI.303. Continuing Education Requirement for Controlled Dangerous Substances
- iii. LAC 46: LI.501. Professional Conduct
- iv. LAC 46: LI.503. License to Practice Optometry
- v. LAC 46: LI.505. Prescriptions for Eyeglasses or Contact Lenses
- vi. LAC 46: LI.611. Mandatory Access and Review of Prescription Monitoring Program Data; Exceptions

**K. Louisiana Professional Engineering and Land Surveying Board**

- i. LAC 46: LXI.105. Definitions
- ii. LAC 46: LXI.2305. Supervising Professional

**L. Louisiana Board of Professional Geoscientists**

- i. LAC 46: XXXI.1501. Use of Seals

**M. Louisiana Manufactured Housing Commission**

- i. LAC 55: V.553. Definitions
- ii. LAC 55: V.555. Repair Requirements

**N. Louisiana Board of Pharmacy**

- i. LAC 46: LIII.1103, 1105, 1109, 1113, 1115, 1119, 1121, 1123, 1124, 1145, 1147, 1501, 1503, 1505, 1507, 1509, 1525, 1527, 1701, 1703, 1705, 1711, 1713, 1717, 1719, 1721, 1725, 2507, 2511, 2513, 2519, 2521. Pharmacy Records
- ii. LAC 46: LIII.2447. Licensure of Marijuana Pharmacies
- iii. LAC 46: LIII.2425. Telepharmacy Dispensing Sites
- iv. LAC 46: LIII.503, 903. Delays of Licensure Examinations
- v. LAC 46: LIII.903, 905. License Transfer for Pharmacy Technicians
- vi. LAC 46: LIII.507. Continuing Education Records
- vii. LAC 46: LIII.1503, 1519, 2503, 2517, 2701, 2749. Drug Disposal by Pharmacies
- viii. LAC 46: LIII.2535. **Pharmacy Compounding**

**O. Louisiana State Board of Nursing**

- i. LAC 46: XLVII.3303
- ii. LAC 46: XLVII.3307

This Resolution was ADOPTED by unanimous vote of the Commission on August 29, 2019.

  
Erin Monroe Wesley, Chair

## **Notice of Intent**

### **Department of Health Board of Pharmacy**

Pharmacy Compounding (LAC 46:LIII.2535)

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy hereby gives notice of its intent to amend the section of its rules containing standards for pharmacy compounding. The proposed amendment of Paragraph A.2 updates the references to federal law and rule. The proposed amendment of Subsection F updates the standards for compounding copies of commercially available products consistent with recent guidance information from the federal Food and Drug Administration.

# Louisiana Administrative Code

## Title 46 – Professional and Occupational Standards

### Part LIII: Pharmacists

#### Chapter 25. Prescriptions, Drugs, and Devices

\* \* \*

##### §2535. General Standards

- A. Compounding Practices. Compounded medications may be prepared using prescription medications, over-the-counter medications, chemicals, compounds, or other components.
1. ...
  2. All compounding shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment, ~~as well as~~ and in compliance with the Federal Food, Drug and Cosmetic Act of 1938 as subsequently amended, most recently in November 2013, the 2016 current edition of Title 21 of the Code of Federal Regulations (CFR), and all relevant chapters of the 2014 edition of the United States Pharmacopeia-National Formulary (USP 37 – NF 32).
- A.2.a. – E.4. ...
- F. ~~Compounding Copies of Commercial Drug Products not Available. A pharmacy may prepare a copy of a commercial product when that product is not available as evidenced by either of the following:~~
- ~~1. Products appearing on a website maintained by the federal Food and Drug Administration (FDA) and/or the American Society of Health System Pharmacists (ASHP).~~
  - ~~2. Products temporarily unavailable from manufacturers, as demonstrated by invoice or other communication from the distributor or manufacturer.~~
  1. Copies of commercial drug products contain the same active pharmaceutical ingredient(s) in the same, similar, or easily substitutable dosage strength which can be used by the same route of administration. Changes in strength of less than 10 percent from the commercial drug product shall not be considered significant enough to warrant the preparation of a copy of a commercial drug product. In the event a prescriber determines a change in the formulation of a commercial drug product is necessary to produce a significant clinical difference for the patient and that determination is documented on the prescription, the pharmacy may prepare a variation of the commercial drug product, provided:
    - a. The prescriber's determination shall identify both the relevant change requested and the clinically significant difference the change will produce for the patient; and
    - b. The pharmacy does not prepare copies of commercial drug products regularly or in inordinate amounts.
  2. A pharmacy may prepare a copy of a commercial drug product when that product has been discontinued and is no longer marketed, or the product appears on the drug shortage list maintained by the federal Food and Drug Administration, or the product is temporarily unavailable as demonstrated by invoice or other communication from the distributor or manufacturer.
- G. – G.2.i. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1316 (October 1997), amended LR 29:2105 (October 2003), effective January 1, 2004, amended LR 41:97 (January 2015), amended LR 42:891 (June 2016), amended by the Department of Health, Board of Pharmacy, LR

FAMILY IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

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.

I. The effect on the stability of the family.

The proposed rule changes will have no effect on the stability of the family.

II. 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.

III. The effect on the functioning of the family.

The proposed rule changes will have no effect on the functioning of the family.

IV. The effect on family earnings and family budget.

The proposed rule changes will have no effect on family earnings or family budget.

V. 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.

VI. 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  
FOR ADMINISTRATIVE RULES

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.

I. The effect on household income, assets, and financial security.

The proposed rule changes will have no effect on household income, assets, or financial security.

II. 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.

III. The effect on employment and workforce development.

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

IV. The effect on taxes and tax credits.

The proposed rule changes will have no effect on taxes or tax credits.

V. 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.

PROVIDER IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

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:

I. 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.

II. 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.

III. 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.

REGULATORY FLEXIBILITY ANALYSIS  
FOR ADMINISTRATIVE RULES

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:

I. The establishment of less stringent compliance or reporting requirements for small businesses.

There are no reporting requirements in the proposed rule changes.

II. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

There are no specific reporting requirements in the proposed rule changes.

III. The consolidation or simplification of compliance or reporting requirements for small businesses.

There are no specific reporting requirements in the proposed rule changes.

IV. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed rule.

The standards for the compounding of drugs are federal in origin and apply to all pharmacies.

V. 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.

## SOLICITATION OF COMMENTS

Interested persons may submit written comments, via United States Postal Service or other mail carrier, or in the alternative by personal delivery to Malcolm J Broussard, Executive Director, at the office of the Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700. He is responsible for responding to inquiries regarding the proposed rule amendment. A public hearing to solicit comments and testimony on the proposed rule amendment is scheduled for 9:00 a.m. on Tuesday, November 26, 2019. During the hearing, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12:00 noon that same day. To request reasonable accommodations for persons with disabilities, please call the Board office at 225.925.6496.

Malcolm J Broussard  
Executive Director  
Louisiana Board of Pharmacy

FISCAL AND ECONOMIC IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

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:

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

The proposed rule changes will require the Louisiana Board of Pharmacy to publish the proposed and final rules in the state register, at a cost of \$2,000 for FY 20. There are no other costs or savings for other local or state governmental units. The proposed rule changes update standards for compounding copies of commercially available product to align with current guidance from the Food and Drug Administration (FDA).

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 OR NON-GOVERNMENTAL GROUPS (Summary)

The proposed rule changes benefits pharmacists, as they update references to current federal law and rule. The standards for the compounding of commercially available products clarify the current limitation of compounding by stating that the strength of the active ingredient must change by more than 10% for the compounded preparation to be recognized as an authorized copy of a commercially available product. The proposed rule changes also remove a private website as a source of information for drugs in shortage, in favor of the website maintained for that purpose by the federal Food and Drug Administration. To the extent a pharmacy compounds copies of commercially available products with changes in strength of the active ingredient of less than 10%, the proposed rule changes will require the pharmacy to terminate such activity.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes will not affect competition or employment.

FISCAL AND ECONOMIC IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

Person Preparing Statement: Malcolm J. Broussard  
Executive Director  
Dept.: Health  
Office: Board of Pharmacy  
Phone: (225) 925-6481  
Title: Pharmacy Compounding  
Return Address: 3388 Brentwood Drive  
Baton Rouge, LA 70809  
Effective Date of Rule: Upon promulgation  
April 1, 2020 (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)

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The proposed rule changes benefits pharmacists, as they update references to current federal law and rule. The standards for the compounding of commercially available products clarify the current limitation of compounding by stating that the strength of the active ingredient must change by more than 10% for the compounded preparation to be recognized as an authorized copy of a commercially available product. The proposed rule changes also remove a private website as a source of information for drugs in shortage, in favor of the website maintained for that purpose by the federal Food and Drug Administration. To the extent a pharmacy compounds copies of commercially available products with changes in strength of the active ingredient of less than 10%, the proposed rule changes will require the pharmacy to terminate such activity.

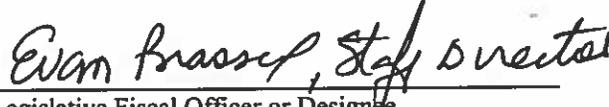
IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes will not affect competition or employment.

  
\_\_\_\_\_  
Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director  
\_\_\_\_\_  
Typed Name and Title of Agency Head or Designee

November 7, 2019  
\_\_\_\_\_  
Date of Signature

  
\_\_\_\_\_  
Legislative Fiscal Officer or Designee

11/8/19  
\_\_\_\_\_  
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 will update the references to current federal law and rule, will clarify the current limitation by stating the minimum change in strength of the active ingredient required to escape classification of the compounded preparation as an unauthorized copy of a commercially available product, and will remove a private website as an approved source of information for drugs in shortage in favor of the website maintained for that purpose by the federal Food and Drug Administration.

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

The Board is proposing to update its standards for the compounding of drugs by pharmacies by providing clarity on a current limitation on the compounding of copies of commercially available products consistent with recently-issued federal guidance.

- 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 Board has allocated \$1,000 each for printing the Notice of Intent and the Final Rule. The Board 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. If no, provide justification as to why this rule change should be published at this time.

The Board seeks to update its standards for pharmacy compounding to protect public health from substandard pharmacy compounded preparations.

- D. Compliance with Act 820 of the 2008 Regular Session

(1) An identification and estimate of the number of small businesses subject to the proposed rule.

Given the criteria in the statutory definition of "small businesses", the Board is unable to specifically identify small businesses because the Board does not collect information from pharmacies concerning the number of employees or any information on sales, net worth, or other financial data. To the extent any pharmacy licensed by the Board would qualify as a small business, there are 2,003 pharmacies currently licensed.

(2) The projected reporting, record keeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record.

There are no specific reporting, recordkeeping or other administrative costs required by the proposed rule changes.

(3) A statement of the probable effect on impacted small businesses.

There should be little to no effect on small businesses. To the extent a pharmacy has been compounding copies of commercially available products with very little or no differences in the strength of the active ingredient in the compounded preparation, the proposed rule change will clarify that compounded preparations with less than 10% change will be classified as unauthorized copies of commercially available products.

(4) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule.

There are no alternative methods for achieving the purpose of the proposed rule changes.

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?

<u>COSTS</u>	<u>FY 19-20</u>	<u>FY 20-21</u>	<u>FY 21-22</u>
PERSONAL SERVICES	\$ 0	\$ 0	\$ 0
OPERATING EXPENSES	\$ 2,000	\$ 0	\$ 0
PROFESSIONAL SERVICES	\$ 0	\$ 0	\$ 0
OTHER CHARGES	\$ 0	\$ 0	\$ 0
EQUIPMENT	\$ 0	\$ 0	\$ 0
MAJOR REPAIR & CONSTR.	\$ 0	\$ 0	\$ 0
<b>TOTAL</b>	<b>\$ 2,000</b>	<b>\$ 0</b>	<b>\$ 0</b>
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 proposed rule changes will require the Louisiana Board of Pharmacy to publish the proposed and final rules in the state register, at a cost of \$2,000 for FY 20. There are no other costs or savings for other local or state governmental units. The proposed rule changes update standards for compounding copies of commercially available product to align with current guidance from the Food and Drug Administration (FDA).

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

<u>SOURCE</u>	<u>FY 19-20</u>	<u>FY 20-21</u>	<u>FY 21-22</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 2,000	\$ 0	\$ 0
DEDICATED	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
OTHER (Specify)	\$ 0	\$ 0	\$ 0
<b>TOTAL</b>	<b>\$ 2,000</b>	<b>\$ 0</b>	<b>\$ 0</b>

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

The Board has sufficient funds available to implement the proposed rule changes.

**B. COST 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 source of funding of the local governmental unit that will be affected by these costs or savings.

To the extent a local governmental unit operates a pharmacy that compounds copies of commercially available products with changes in strength of the active ingredient of less than 10%, the proposed rule will require the pharmacy to terminate such activity.

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

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

<u>SOURCE</u>	<u>FY 19-20</u>	<u>FY 20-21</u>	<u>FY 21-22</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 0	\$ 0	\$ 0
DEDICATED FUNDS	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
LOCAL FUNDS	\$ 0	\$ 0	\$ 0
<b>TOTAL</b>	<b>\$ 0</b>	<b>\$ 0</b>	<b>\$ 0</b>

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 for state or local governmental units.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS

- A. What persons 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 benefits pharmacists, as they update references to current federal law and rule. The standards for the compounding of commercially available products clarify the current limitation of compounding by stating that the strength of the active ingredient must change by more than 10% for the compounded preparation to be recognized as an authorized copy of a commercially available product. The proposed rule changes also remove a private website as a source of information for drugs in shortage, in favor of the website maintained for that purpose by the federal Food and Drug Administration. To the extent a pharmacy compounds copies of commercially available products with changes in strength of the active ingredient of less than 10%, the proposed rule changes will require the pharmacy to terminate such activity.

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

The proposed rule changes will have no effect on 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 not affect competition or employment.

  
\_\_\_\_\_  
Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director  
Typed Name and Title of Agency Head or Designee

November 7, 2019  
\_\_\_\_\_  
Date of Signature