



Louisiana Board of Pharmacy

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November 8, 2019

Senator John A. Alario, Jr, President
Louisiana Senate
Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2019-15 ~ Drug Disposal by Pharmacies

Dear Senator Alario:

The Board has initiated the rulemaking process to amend several sections of its rules to enable pharmacies to accept previously dispensed drugs for return and disposal. In connection with this regulatory project, the following documents are attached.

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|--|---------|
| • Approval from Occupational Licensing Review Commission | Page 2 |
| • Notice of Intent | Page 5 |
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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 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 Outreach Services, La. Economic Development
Via Email: Pat.Witty@la.gov
Editor, *Louisiana Register*
Via Email: 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

Drug Disposal by Pharmacies (LAC 46:LIII.1503, 1519, 2503, 2517, 2701, and 2749)

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 several sections of its rules to authorize pharmacies to accept returns of previously dispensed drugs for disposal, and to establish standards for the destruction of certain types of drugs. The proposed amendment of §1503 is a technical amendment. The proposed amendment of §1519 permits a hospital pharmacy to accept drug returns for disposal, and further, requires compliance with certain federal standards for the disposal of controlled substances and for hazardous drugs. The proposed amendment of §2503 applies the same requirements to all other types of pharmacies. The proposed amendment of §2517 inserts the same set of requirement in this section for the dispensing of prescription drugs. The proposed amendment of §2701 is a technical amendment. The proposed amendment of §2749 specifies the disposal standards for controlled substances.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

* * *

§1503. Definitions

- A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section: CFR – Code of Federal Regulations

* * *

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 29:2093 (October 2003), effective January 1, 2004, amended LR 33:1132 (June 2007), amended LR 39:1282 (May 2013), amended LR 40:2256 (November 2014), effective January 1, 2015, amended LR 41:2147 (October 2015), amended by the Department of Health, Board of Pharmacy, LR

* * *

§1519. Drug Returns; Drug Disposal

- A. In a hospital with a permitted hospital pharmacy on site, unused drugs may be returned to the pharmacy for re-dispensing in accordance with good professional practice standards.
- B. When a patient or his designee wishes to return previously dispensed prescription drugs to a pharmacy for disposal, the pharmacy shall inform the patient or his designee of the disposal mechanisms available to him. In the event the pharmacy elects to accept such previously dispensed products for disposal, the pharmacy shall comply with the following requirements:
 - 1. From the time of receipt of such products until the time of disposal, the pharmacy shall quarantine such products to keep them separate from its active dispensing stock and shall take appropriate security measures to prevent the theft or diversion of such products.
 - 2. The pharmacy shall comply with the provisions of 21 CFR §1317 or its successor for the pharmacy’s disposal of controlled substances and other non-hazardous waste pharmaceuticals.
 - 3. The pharmacy shall comply with the provisions of 40 CFR §261 or its successor for the pharmacy’s disposal of hazardous waste pharmaceuticals.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2094 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR.

* * *

§2503. Drug Returns; Drug Disposal

- A. Unless otherwise allowed by law, drugs dispensed on prescription to a patient shall not be accepted for return, exchange, or re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises where they were dispensed.
- B. When a patient or his designee wishes to return previously dispensed prescription drugs to a pharmacy for disposal, the pharmacy shall inform the patient or his designee of the disposal mechanisms available to him. In the event the pharmacy elects to accept such previously dispensed products for disposal, the pharmacy shall comply with the following requirements:
 - 1. From the time of receipt of such products until the time of disposal, the pharmacy shall quarantine such products to keep them separate from its active dispensing stock and shall take appropriate security measures to prevent the theft or diversion of such products.
 - 2. The pharmacy shall comply with the provisions of 21 CFR §1317 or its successor for the pharmacy’s disposal of controlled substances and other non-hazardous waste pharmaceuticals.
 - 3. The pharmacy shall comply with the provisions of 40 CFR §261 or its successor for the pharmacy’s disposal of hazardous waste pharmaceuticals.

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 29:2102 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR

* * *

§2517. Prescription Dispensing; Equivalent Drug Product Interchange; Drug Returns; Drug Disposal

A. – C. ...

- D. When a patient or his designee wishes to return previously dispensed prescription drugs to a pharmacy for disposal, the pharmacy shall inform the patient or his designee of the disposal mechanisms available to him. In the event the pharmacy elects to accept such previously dispensed products for disposal, the pharmacy shall comply with the following requirements:
1. From the time of receipt of such products until the time of disposal, the pharmacy shall quarantine such products to keep them separate from its active dispensing stock and shall take appropriate security measures to prevent the theft or diversion of such products.
 2. The pharmacy shall comply with the provisions of 21 CFR §1317 or its successor for the pharmacy's disposal of controlled substances and other non-hazardous waste pharmaceuticals.
 3. The pharmacy shall comply with the provisions of 40 CFR §261 or its successor for the pharmacy's disposal of hazardous waste pharmaceuticals.

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 29:2104 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 43:2162 (November 2017), amended LR

* * *

§2701. Definitions

- A. Words not defined in this Chapter shall have their common usage and meaning as stated in the Merriam-Webster's Collegiate Dictionary – Tenth Edition, as revised, and other similarly accepted reference texts. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section unless the context clearly indicates otherwise.

* * *

CFR – Code of Federal Regulations

* * *

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2127 (October 2008), amended by the Department of Health, Board of Pharmacy, LR

* * *

§2749. Disposal of Controlled Substances

A. – C. ...

- D. When a patient or his designee wishes to return previously dispensed controlled dangerous substances to a pharmacy for destruction, the pharmacy shall accept such products previously dispensed by that pharmacy and may accept such products previously dispensed by another pharmacy, but only for destruction.
1. From the time of receipt of such products until the time of destruction, the pharmacy shall quarantine such products to keep them separate from its active dispensing stock and shall take appropriate security measures to prevent the theft or diversion of such products.
 2. The pharmacy shall comply with the provisions of 21 CFR §1317 or its successor for the pharmacy's disposal of controlled substances.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2157 (October 2008), 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 disposal of controlled substances and hazardous drugs are federal in origin and apply to all pharmacies and other types of healthcare providers.

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 will require all pharmacies to advise consumers of their drug disposal options and will allow pharmacies to accept drug returns for disposal purposes.

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 will require all pharmacies to advise consumers of their drug disposal options and will allow pharmacies to accept drug returns for disposal purposes. For pharmacies electing to accept drug returns for disposal, the proposed rule changes require compliance with federal standards relative to the disposal of controlled substances and hazardous drugs. To the extent pharmacies electing to accept drugs for disposal are unable to comply with the aforementioned requirements, such as quarantining products returned for disposal, they may incur unknown though likely marginal costs to be able to properly accept returned products.

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: Drug Disposal by Pharmacies
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)

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 will require all pharmacies to advise consumers of their drug disposal options and will allow pharmacies to accept drug returns for disposal purposes.

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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 require pharmacies to advise consumers of their drug disposal options and will allow pharmacies to accept drug returns for disposal purposes.

- 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 has determined the public health would be well served by requiring pharmacies to advise consumers of their drug disposal options and permitting pharmacies to accept drug returns for disposal purposes.

- 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 improve public health by facilitating the proper disposal of unnecessary controlled substances and other prescription medications.

- 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 licensed by the Board.

- (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.

To the extent a pharmacy elects to accept drug returns for disposal, the pharmacy will incur material and labor costs to install and secure a disposal receptacle. The pharmacy may also elect to contract with a reverse distributor to remove the disposed drugs from the pharmacy's premises.

- (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 |
| TOTAL | \$ 2,000 | \$ 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 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 will require all pharmacies to advise consumers of their drug disposal options and will allow pharmacies to accept drug returns for disposal purposes.

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 |
| TOTAL | \$ 2,000 | \$ 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?

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

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

- 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.
- 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 elects to accept drug returns for disposal purposes, the pharmacy will incur materials and labor charges to install and secure an appropriate disposal receptacle, and further, may contract with a reverse distributor to remove the disposed drugs from the pharmacy's premises.

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 |
| TOTAL | \$ 0 | \$ 0 | \$ 0 |

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 have no effect on revenue collections of 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 will require all pharmacies to advise consumers of their drug disposal options and will allow pharmacies to accept drug returns for disposal purposes. For pharmacies electing to accept drug returns for disposal, the proposed rule changes require compliance with federal standards relative to the disposal of controlled substances and hazardous drugs. To the extent pharmacies electing to accept drugs for disposal are unable to comply with the aforementioned requirements, such as quarantining products returned for disposal, they may incur unknown though likely marginal costs to be able to properly accept returned products.

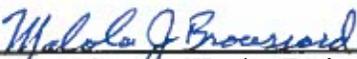
Also provide an estimate and a narrative description of any impact on receipts and/or income (revenue) resulting from this rule or rule change to these groups.

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