



Louisiana Board of Pharmacy

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



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 2019-13 ~ Controlled Substance License for Third Party Logistics Providers

Dear Senator Alario:

The Board has initiated the rulemaking process to amend a portion of its rules for controlled substances to implement the provisions of Act 186 of the 2018 Legislature which requires third party logistics providers distributing controlled substances to obtain a controlled substance license from the Board. In connection with this regulatory project, the following documents are attached.

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|--|---------|
| • Waiver from Occupational Licensing Review Commission | Page 2 |
| • Notice of Intent | Page 4 |
| • Proposed Rule Changes | Page 5 |
| • Family Impact Statement | Page 9 |
| • Poverty Impact Statement | Page 10 |
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| • Regulatory Flexibility Analysis | Page 12 |
| • Solicitation of Comments | Page 13 |
| • Fiscal & Economic Impact Statement | Page 14 |
| • Act 186 of 2018 Legislature | Page 19 |

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

From: [Occupational Licensing Review Commission](#)
To: [Malcolm J. Broussard](#); [Occupational Licensing Review Commission](#)
Cc: [Catherine Brindley](#); [Reg Submission](#)
Subject: RE: Pharmacy Board / **Regulatory Project 2019-13 ~ CDS License for Third Party Logistics Providers**
Date: Monday, April 22, 2019 10:13:33 AM
Attachments: [image001.png](#)

Malcolm,

The Pharmacy Board may proceed with the normal APA procedures without going through the OLRC for this rule.

Thanks,

Ellen

Ellen Palmintier

Assistant Executive Counsel

Director of Boards & Commissions



225.342.0919

225.208.1531 (fax)

ellen.palmintier@la.gov

gov.louisiana.gov

From: Malcolm J. Broussard [mailto:mbroussard@pharmacy.la.gov]
Sent: Wednesday, April 17, 2019 2:31 PM
To: Occupational Licensing Review Commission
Cc: Catherine Brindley; Reg Submission
Subject: Pharmacy Board / Regulatory Project 2019-13 ~ CDS License for Third Party Logistics Providers

The Board of Pharmacy has directed the initiation of the rulemaking process to amend its rules for controlled substances, to license and regulate third party logistics providers which distribute controlled substances within the state. In connection with [Regulatory Project 2019-13 ~ CDS License for Third Party Logistics Providers](#), you should find the following documents attached to this message:

- Memorandum to Occupational Licensing Review Commission;
- Notice of Intent; and
- Fiscal & Economic Impact Statement.

We look forward to your review of this regulatory project to determine the necessity for its consideration by the Commission. If your determination is that no approval by the Commission is required, we would appreciate your communication to that effect. In the alternative, we thank you for confirming the scheduling of the Commission's consideration.

Please let me know if you have any questions or need additional information.

Thanks,
Malcolm



Malcolm J. Broussard
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Telephone 225.925.6481
mbroussard@pharmacy.la.gov

In compliance with Act 2018-655, the Board gives notice to its licensees and applicants of their opportunity to file a complaint about board actions or board procedures. You may submit such complaints to one or more of the following organizations:

- (1) Louisiana Board of Pharmacy; 3388 Brentwood Dr.; Baton Rouge, LA 70804; 225.925.6496; info@pharmacy.la.gov.
- (2) Committee on House & Governmental Affairs; La. House of Representatives; PO Box 94062; Baton Rouge, LA 70804; 225.342.2403; obriens@legis.la.gov.
- (3) Committee on Senate & Governmental Affairs; La. Senate; PO Box 94183; Baton Rouge, LA 70804; 225.342.9845; s&g@legis.la.gov.

Notice of Intent

Department of Health Board of Pharmacy

Controlled Substance License for Third Party Logistics Providers (LAC 46:LIII.Chapter 27)

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 within Chapter 27 of its rules relative to controlled substances. Act 186 of the 2018 Legislature amended the state controlled substance law to require the licensure of third party logistics providers which elect to distribute controlled substances to authorized entities within the state. The proposed changes in Section 2701 insert definitions of third party logistics providers and reverse distributors and make other technical changes. The proposed changes in Section 2705 add third party logistics providers to the list of entities required to obtain a state controlled substance license to engage in certain activities with controlled substances. The proposed change in Section 2707 is a technical change in licensing procedures. The proposed changes in Sections 2731, 2733, 2735, 2741, and 2751 add third party logistics providers to the list of entities required to keep certain types of records for their activities with controlled substances.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 27. Controlled Dangerous Substances

Subchapter A. General Provisions

§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:

* * *

Department – the Louisiana Department of Health and Hospitals.

* * *

Distributor or Wholesaler – a facility authorized by law and licensed by the Louisiana State Board of Wholesale Drug and Device Distributors to engage in the distribution of drugs or devices, including controlled substances.

* * *

Reverse distribute – means to acquire controlled substances from another registrant or law enforcement for the purpose of: (1) Return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer’s behalf; or (2) Destruction.

Reverse distributor – is a person registered by the DEA as a reverse distributor.

* * *

Supplier – means any person registered by the DEA who is entitled to fill order forms for controlled substances.

Third-party logistics provider – means a person who provides or coordinates warehousing, facilitation of delivery, or other logistic services for a legend drug or legend device in interstate or intrastate commerce on behalf of a manufacturer, distributor, or dispenser of a legend drug or legend device but does not take ownership of the legend drug or legend device nor have responsibility to direct the sale or disposition of the legend drug or legend device.

* * *

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

* * *

§2705. Licenses and Exemptions

- A. Every person who conducts research with, manufactures, distributes, procures, possesses, prescribes, or dispenses any controlled dangerous substance within this state, including third-party logistics providers, or who proposes to engage in the research, manufacture, distribution, procurement, possession, prescribing, or dispensing of any controlled dangerous substance within this state shall obtain a Controlled Dangerous Substance (CDS) License from the board prior to engaging in such activities. Only persons actually engaged in such activities are required to obtain a CDS license; related or affiliated persons, e.g., stockholder in manufacturing corporation, who are not engaged in such activities, are not required to be licensed. The performance of such activities in the absence of a valid CDS license shall be a violation of R.S. 40:973 and these rules this Part.

B. – C.3. ...

- 4. A physician in possession of a valid, verifiable and unrestricted license to practice medicine the appropriate credential issued by the Louisiana State Board of Medical Examiners may apply for and be issued a CDS license to authorize the prescribing prescription or recommendation of the following controlled substances classified in Schedule I: marijuana, tetrahydrocannabinols, and synthetic

derivatives of tetrahydrocannabinols; provided however that such ~~prescribing prescriptions or recommendations shall only be authorized for therapeutic use by patients clinically diagnosed with glaucoma, spastic quadriplegia, or symptoms resulting from the administration of cancer chemotherapy treatment in compliance with R.S. 40:1046.~~

D. – E. ...

F. Manufacturers, and Distributors and Third-Party Logistics Providers

1. The issuance of a CDS license to a manufacturer, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential from the Food and Drug Control Unit of the Office of Public Health in the Louisiana Department of Health ~~and Hospitals~~, or its successor. Further, the applicant shall submit to an initial and periodic inspection by the board or its designee.
2. The issuance of a CDS license to a distributor, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential from the Food and Drug Control Unit of the Office of Public Health in the Louisiana Department of Health ~~and Hospitals~~, as well as the Louisiana ~~State~~ Board of ~~Wholesale Drug and Device~~ Distributors, or their successors. Further, the applicant shall submit to an initial and periodic inspection by the board or its designee.
3. The issuance of a CDS license to a third-party logistics provider, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential from the Louisiana Board of Drug and Device Distributors.
- 3 4. The sale or transportation of controlled substances within the State of Louisiana by manufacturers, ~~and~~ distributors and third-party logistics providers located outside the State of Louisiana shall require the possession of a valid CDS license issued by the board prior to the engagement of such activities.

G. – J. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2129 (October 2008), amended LR 39:312 (February 2013), amended by the Department of Health, Board of Pharmacy, LR

§2707. Licensing Procedures

A. Application for Initial Issuance of CDS License

1. – 3. ...

4. Applicants not in possession of a valid and verifiable license or other credential from a standing professional board of the State of Louisiana, or from the Department of Health ~~and Hospitals~~, Bureau of Health Services Financing, Health Standards, or their successors, shall submit to a criminal history record check upon request by the board. The applicant shall pay for the cost of the criminal history record check. The board shall evaluate the findings of the report of the criminal history record check prior to the issuance of the CDS license.

A.5 – D.5.e. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2131 (October 2008), amended by the Department of Health, Board of Pharmacy, LR 43:957 (May 2017), amended by the Department of Health, Board of Pharmacy, LR

* * *

Subchapter E. Recordkeeping Requirements

§2731. General Information

A. – B.4. ...

5. Each manufacturer, distributor, third-party logistics provider, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:

B.5.a. – C.2. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2139 (October 2008), amended by the Department of Health, Board of Pharmacy, LR

§2733. Inventory Requirements

- A. – C.1.b.iv. ...
- D. Inventories of Manufacturers, Distributors, Third-Party Logistics Providers, Dispensers, Researchers, Importers, Exporters, and Chemical Analysts. Each person registered or authorized to manufacture, distribute, dispense, import, export, provide logistics services, conduct research or chemical analysis with controlled substances and required to keep records shall include in the inventory the information listed below.
 - D.1. – D.1.d.iii. ...
 - 2. Inventories of Distributors and Third-Party Logistics Providers.
Except for reverse distributors covered in this Section, each person authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to this Section.
- D.3. – D.5. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2141 (October 2008), amended by the Department of Health, Board of Pharmacy, LR

§2735. Continuing Records

- A. – A.4. ...
- B. Records for Manufacturers, Distributors, Third-Party Logistics Providers, Dispensers, Researchers, Importers, and Exporters
 - B.1. – B.1.b.ix. ...
 - 2. Records for Distributors and Third-Party Logistics Providers. Each person authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to this Section.
- B.3. – F.5. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2142 (October 2008), amended by the Department of Health, Board of Pharmacy, LR

* * *

§2741. Distribution

- A. A distributor ~~licensee~~ or third-party logistics provider handling controlled substances in Schedules I or II shall maintain complete and accurate records of the original copies of all order forms received and filled for orders of controlled substances within these schedules. This file shall be kept separate from the licensee's other business and professional records and shall be kept in this file a minimum of two years from the date the order was filled.
- B. A distributor ~~licensee~~ or third-party logistics provider handling controlled substances in Schedules III, IV, and V shall maintain complete and accurate records of all distributions for a minimum of two years from the date of each distribution. These records shall contain the full name, address, and registration number, if any, of the recipient, the common or established name of the controlled substance, its dosage, form, and strength, amount, and date of distribution.
- C. A distributor or third-party logistics provider shall not sell or distribute drugs or drug devices except to a person or facility authorized by law or regulation to procure or possess drugs or drug devices.
- D. A distributor or third-party logistics provider shall maintain and follow a written procedure to assure the proper handling and disposal of returned goods.
- E. A distributor or third-party logistics provider shall maintain a written policy for handling recalls and withdrawals of products due to:
 - E.1 – E.3. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2147 (October 2008), amended by the Department of Health, Board of Pharmacy, LR

* * *

§2751. Distributions and Transfers of Controlled Substances

A. – A.3. ...

B. Distribution to Supplier, Third-Party Logistics Provider, or Manufacturer

B.1. – B.2. ...

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.

The reporting requirements in the proposed rule changes mirror current federal rules.

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

The scheduled and deadlines in the proposed rule changes mirror current federal rules.

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

The reporting requirements in the proposed rule changes mirror current federal rules.

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

The design and operational standards in the proposed rule changes mirror current federal rules.

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 (LBP) 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 implement new controlled dangerous substance (CDS) licensure procedures for third party logistics providers.

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. Third party logistics providers currently transporting controlled dangerous substances in Louisiana are presently required to have CDS licenses and to remit the associated \$50 license fee. LBP presently classifies third party logistics providers in their own category for existing CDS licenses and does not establish a new license. Therefore, it is not anticipated that the proposed rule changes will affect revenue collections in the aggregate.

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

Act 186 of the 2018 Legislature amended the state controlled substance law to add third party logistics providers to the list of entities required to obtain a controlled substance license before engaging in certain activities with controlled substances. The proposed rule changes will implement the legislation by establishing a license type for third party logistics providers that elect to distribute controlled substances. Third party logistics providers are currently licensed in the licensure database as distributors, but the proposed rule changes will identify third party logistics providers separately. The costs and recordkeeping requirements will be the same as those currently required of distributors.

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
Phone:	(225) 925-6481	Office:	Board of Pharmacy
Return Address:	3388 Brentwood Drive Baton Rouge, LA 70809	Title:	Controlled Substance License for Third Party Logistics Providers
		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 (LBP) 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 implement new controlled dangerous substance (CDS) licensure procedures for third party logistics providers.

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. Third party logistics providers currently transporting controlled dangerous substances in Louisiana are presently required to have CDS licenses and to remit the associated \$50 license fee. LBP presently classifies third party logistics providers in their own category for existing CDS licenses and does not establish a new license. Therefore, it is not anticipated that the proposed rule changes will affect revenue collections in the aggregate.

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

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IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

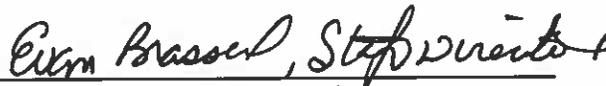
The proposed rule changes will not affect competition or employment.



Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director

Typed Name and Title of Agency Head or Designee



Legislative Fiscal Officer or Designee

Date of Signature 11/8/19

November 7, 2019

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 amend the Board's current rules for the licensure and regulation of entities engaging in certain activities with controlled substances, to add third party logistics providers to the list of entities required to obtain a controlled substance license, and to add third party logistics providers to the list of entities required to keep certain types of records of their activities with controlled substances. Currently licensed as distributors, the proposed rule changes will require third party logistics providers to keep the same types of records as distributors.

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

Act 186 of the 2018 Legislature amended the state controlled substance law to add third party logistics providers to the list of entities required to obtain a state controlled substance license, and fixed their fee at the same fee they have been paying as a distributor.

- 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 rules for the licensure and regulation of entities engaging in certain activities with controlled substances, consistent with new state law.

- 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 third party logistics provider would qualify as a small business, information from their primary licensing agency, the La. Board of Drug & Device Distributors, indicates there are approximately 25 entities licensed by that agency as third party logistics providers which have indicated they distribute controlled substances.

- (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.

The reporting, recordkeeping and other administrative costs required by the proposed rule changes are the same currently required of them, which mirror current federal rules.

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

The proposed rule changes will have no effect on small businesses since it is simply a re-characterization of their license type, as third party logistics providers instead of distributors.

- (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 (LBP) 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 implement new controlled dangerous substance (CDS) licensure procedures for third party logistics providers.

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 amendments.

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.

The proposed rule change will have no cost savings for 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?

<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 change 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.

Act 186 of the 2018 Legislature amended the state controlled substance law to add third party logistics providers to the list of entities required to obtain a controlled substance license before engaging in certain activities with controlled substances. The proposed rule changes will implement the legislation by establishing a license type for third party logistics providers which elect to distribute controlled substances. Third party logistics providers are currently included in the licensure database as distributors, but the proposed rule changes will identify third party logistics providers separately. The costs and recordkeeping requirements will be the same as those currently required of distributors.

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

ACT No. 186

2018 Regular Session

HOUSE BILL NO. 45

BY REPRESENTATIVE CONNICK

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AN ACT

To amend and reenact R.S. 40:972(B)(7) through (14) and 973(A)(1) and to enact R.S. 40:961(41) and 972(B)(15), relative to entities required to obtain a controlled dangerous substance license issued by the Louisiana Board of Pharmacy; to establish within the Uniform Controlled Dangerous Substances Law a definition of "third-party logistics provider"; to require such providers to obtain controlled dangerous substance licenses; to provide relative to fees collected by the Louisiana Board of Pharmacy for registration and licensing; to establish the fee for a controlled dangerous substance license for third-party logistics providers; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 40:972(B)(7) through (14) and 973(A)(1) are hereby amended and reenacted and R.S. 40:961(41) and 972(B)(15) are hereby enacted to read as follows:

§961. Definitions

As used in this Part, the following terms shall have the meaning ascribed to them in this Section unless the context clearly indicates otherwise:

* * *

(41) "Third-party logistics provider" means a person who provides or coordinates warehousing, facilitation of delivery, or other logistic services for a legend drug or legend device in interstate and intrastate commerce on behalf of a manufacturer, distributor, or dispenser of a legend drug or legend device but does not

