

RULE

**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 (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Louisiana Board of Pharmacy has amended 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 changes in §2701 insert definitions of third party logistics providers and reverse distributors and make other technical changes. The changes in §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 change in §2707 is a technical change in licensing procedures. The changes in §§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. This Rule is hereby adopted on the day of promulgation.

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.

* * *

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

* * *

Reverse Distribute—to acquire controlled substances from another registrant or law enforcement for the purpose of:

- a. return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; or
- b. destruction.

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

* * *

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

Third-Party Logistics Provider—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.

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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 46:569 (April 2020).

Subchapter B. Licenses

§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 this Part.

B. - C.3. ...

4. A physician in possession of the appropriate credential issued by the Louisiana State Board of Medical Examiners may apply for and be issued a CDS license to authorize the prescription or recommendation of the following controlled substances classified in Schedule I: marijuana, tetrahydrocannabinols, and synthetic derivatives of tetrahydrocannabinols; provided however that such prescriptions or recommendations shall only be authorized for therapeutic use in compliance with R.S. 40:1046.

D. - E. ...

F. Manufacturers, 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, 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, as well as the Louisiana Board of 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.

4. The sale or transportation of controlled substances within the State of Louisiana by manufacturers, 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 46:570 (April 2020).

§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, 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. ...

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Subchapter E. Recordkeeping Requirements

§2731. General Information

A. - B.4. ...

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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 46:570 (April 2020).

§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.

1. - 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.

3. - 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 46:570 (April 2020).

§2735. Continuing Records

A. - A.4. ...

B. Records for Manufacturers, Distributors, Third-Party Logistics Providers, Dispensers, Researchers, Importers, and Exporters

1. - 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 46:571 (April 2020).

§2741. Distribution

A. A distributor 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 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:

1 - 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 46:571 (April 2020).

§2751. Distributions and Transfers of Controlled Substances

A. - A.3. ...

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

1. - 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 46:571 (April 2020).

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