

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.

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

57 issued a CDS license to authorize the ~~prescribing~~ prescription or recommendation of the following
 58 controlled substances classified in Schedule I: marijuana, tetrahydrocannabinols, and synthetic
 59 derivatives of tetrahydrocannabinols; provided however that such ~~prescribing prescriptions or~~
 60 recommendations shall only be authorized for therapeutic use ~~by patients clinically diagnosed with~~
 61 glaucoma, spastic quadriplegia, or symptoms resulting from the administration of cancer chemotherapy
 62 treatment in compliance with R.S. 40:1046.

63 D. – E. ...

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

- 65 1. The issuance of a CDS license to a manufacturer, and the renewal thereof, shall require the possession
 66 of a valid and verifiable license or other credential from the Food and Drug Control Unit of the Office
 67 of Public Health in the Louisiana Department of Health ~~and Hospitals~~, or its successor. Further, the
 68 applicant shall submit to an initial and periodic inspection by the board or its designee.
- 69 2. The issuance of a CDS license to a distributor, and the renewal thereof, shall require the possession of a
 70 valid and verifiable license or other credential from the Food and Drug Control Unit of the Office of
 71 Public Health in the Louisiana Department of Health ~~and Hospitals~~, as well as the Louisiana ~~State~~
 72 Board of ~~Wholesale Drug and Device~~ Distributors, or their successors. Further, the applicant shall
 73 submit to an initial and periodic inspection by the board or its designee.
- 74 3. The issuance of a CDS license to a third-party logistics provider, and the renewal thereof, shall require
 75 the possession of a valid and verifiable license or other credential from the Louisiana Board of Drug
 76 and Device Distributors.
- 77 ~~3~~ 4. The sale or transportation of controlled substances within the State of Louisiana by manufacturers, ~~and~~
 78 distributors and third-party logistics providers located outside the State of Louisiana shall require the
 79 possession of a valid CDS license issued by the board prior to the engagement of such activities.

80 G. – J. ...

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

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

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 87 **§2707. Licensing Procedures**

88 A. Application for Initial Issuance of CDS License

89 1. – 3. ...

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

96 A.5 – D.5.e. ...

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

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

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 105 **Subchapter E. Recordkeeping Requirements**

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 107 **§2731. General Information**

108 A. – B.4. ...

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

112 B.5.a. – C.2. ...

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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 34:2139 (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

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§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.

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

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175 **§2751. Distributions and Transfers of Controlled Substances**

176 A. – A.3. ...

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

178 B.1. – B.2. ...
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180 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

181 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2157
182 (October 2008), amended by the Department of Health, Board of Pharmacy, LR
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