Small Business Analysis

The proposed Rule should have no adverse impact on small businesses as defined in the Regulatory Flexibility Act.

Provider Impact Statement

The proposed Rule should not have any known or foreseeable impact on providers as defined by HCR 170 of the 2014 Regular Legislative Session. In particular, there should be no known or foreseeable effect on:

1. the effect on the staffing level requirements or qualifications required to provide the same level of service;
2. the total direct and indirect effect on the cost to the providers to provide the same level of service; or
3. the overall effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments on the proposed Rule. Such comments must be received no later than Monday, November 11, 2024 at COB, 4:30 p.m., and should be addressed to Tiffany Meche, Director, Sanitarian Services, P.O. Box 4489, Baton Rouge, LA 70821.

Public Hearing

Interested persons may submit a written request to conduct a public hearing either by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on Monday, November 11, 2024. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 10 am on Monday, December 2, 2024, in Room 118 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Allen Enger at (225) 342-1342 after Monday, November 11, 2024. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing attendees when the parking ticket is presented to LDH staff at the hearing.

Dr. Ralph Abraham
Surgeon General
and
Michael Harrington, MBA, MA
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Registration of Foods, Drugs, Cosmetics and Prophylactic Devices

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

Besides the cost of publishing, the proposed rule change is anticipated to result in implementation costs or savings. The cost of rulemaking is anticipated to increase expenditures for the Office of Public Health (OPH) by approximately $905 in FY 24-25 for the publication of the proposed rule. It is not anticipated that any other state or local governmental units will incur costs or savings as a result of this rule change.

The proposed rule amends the requirements for regulating consumable hemp product manufacturing and distribution as required by Act 752 of the 2024 Louisiana Legislature.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There will be no effect on revenue collections of state or local governmental units as a result of this proposed rule.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS (Summary)

It is anticipated that this proposed rule will significantly constrict the market in terms of what products may be available to consumers and this will have a detrimental impact on industry stakeholders.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The adoption of this proposed rule will have an effect on competition because it limits the number of retailers which would affect competition.

Tonya Joiner
Assistant Secretary
2410#050

Alan M. Boxberger
Legislative Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Department of Health
Office of Public Health

Regulation of Medical Marijuana
(LAC 51:XXIX.Chapters 1, 3, 5, 7, 9, 21, 23, and 25)

Under the authority of R.S. 40:4 and 40:5, and in accordance with R.S. 49:950 et seq., the Administrative Procedure Act, notice is hereby given that state health officer, acting through the Louisiana Department of Health, Office of Public Health (LDH/OPH), intends to reenact and amend certain sections of Part XXIX of Title 51 of the *Louisiana Administrative Code* (also known as the *Louisiana State Sanitary Code*) and enact a new Subpart as a consequence of changes made to medical marijuana regulations under Act No. 150 and Act No. 693 of the 2024 Louisiana Legislature. The following changes will update the language in Part XXIX to address terminology changes and alter the pesticide-testing schedule to streamline product testing and approval. The new Subpart 2. Marijuana Dispensaries authorizes the LDH/OPH to transition to conducting oversight of the retail distribution of medical marijuana products through the network of approved dispensaries. Chapter 21 provides for general requirements and definitions. Chapter 23 provides for the transfer of new LDH-issued permits for dispensaries that currently hold marijuana-pharmacy permits through the Louisiana Board of Pharmacy as of November 2024 and application requirements for new applicants should a current permit-holder neglect to renew its existing permit. Chapter 25 provides for general operational requirements for marijuana dispensaries, including dispensing requirements, recommendations, home-delivery services, disposal procedures for waste products, inventory control, point-of-sale tracking systems, and general design, construction, and sanitary requirements.

Title 51
PUBLIC HEALTH—SANITARY CODE
Part XXIX. Medical Marijuana
Subpart 1. Marijuana Manufacturers

Chapter 1. General Requirements

§101. Definitions

A. Except as may be otherwise defined in any provision of this Part, and unless the context or use thereof clearly indicates otherwise, the following words and terms used in this Part of the Sanitary Code are defined for the purposes thereof, and for purposes of any other Parts which are adopted or may hereafter be adopted, as follows.

Immature Plant—nonflowering medical marijuana (as defined below) plant that is no taller than 8 inches produced from a cutting, clipping or seedling.

Licensee—as defined in R.S. 40:1046(H)(1)(a), an entity authorized by the Louisiana Department of Health to cultivate, extract, process, produce and transport therapeutic marijuana.

* * *

Permittee—Repealed.

* * *

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2976 (December 2022), amended, LR 51:

Chapter 5. Licensure

§501. Licensure of Authorized Entities

A. The department shall issue a nontransferable license to the licensees successfully completing the application process referenced in §505 of this Chapter to produce medical marijuana. Such license shall be renewable annually on July 1.

B. Only a total of two licenses may be issued for the production of medical marijuana.

C. Licensees shall comply with all applicable requirements of R.S. Title 40, Chapter 4, Part X-E (R.S. 40:1046 et seq.), including payment of all fees, allowance of all inspections, and provision of all information required thereunder. Each license is subject to an annual administration fee of $100,000.

D. New licenses may be issued only under the following circumstances:

1. a current licensee surrenders its active license voluntarily; or

2. a current licensee fails to renew its active license in a timely fashion. A license may only be revoked in this circumstance if the licensee fails to respond to a written notification by the department with the necessary documentation and fees within a 30-day timeframe.

E. New licenses shall be awarded by means of a competitive bid process in accordance with the applicable provisions of the Louisiana Procurement Code (R.S. 39:1551 et seq.).

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2976 (December 2022), amended, LR 51:

§503. Permitting

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2976 (December 2022), repealed LR 51:

§505. Application Process

A. Applications for licensure shall be made using documents supplied by the department for this purpose.

B. - B.5. …

6. a recall plan; and

7. Repealed.

8. …

C. As a condition of renewal of a license, the licensee shall supply the following additional information in writing to the department by January 10 of the renewal year:

1. - 3. …

4. the total quantity of medical marijuana generated as a finished product within that year and the quantity distributed to each licensed marijuana dispensary;

5. - 6. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2976 (December 2022), amended LR 51:

Chapter 7. Inspections and Operational Requirements

§701. Inspections

A. Licensee facilities require a preoperational or initial inspection and this shall follow review and acceptance of the plans required in §505. Inspections are designed to ensure the following:

1. - 9. …

B. As a condition of its license, the licensee shall allow the state health officer or his/her designee(s) to review all records relevant to the operations and management of the licensed facility.

C. Routine inspections of licensed facilities to assess continued compliance shall occur no less frequently than twice per fiscal year. Complaint-based inspections may be conducted at any time during business hours and without prior notice.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2976 (December 2022), amended, LR 51:

§703. Product and Site Security

A. Licensee facilities shall maintain an onsite security system that includes, at a minimum, the following components:

A.1. - D.…

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Louisiana Department of Health, Office of Public Health, LR 48:2976 (December 2022), amended, LR 51:

§705. Louisiana Medical Marijuana Tracking System

A. Licensee facilities shall possess and maintain required hardware and software to connect to the Louisiana Medical Marijuana Tracking System (LMMTS).

B. - D. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2976 (December 2022), amended, LR 51:

§707. Inventory Control

A. Licensee facilities shall maintain an inventory of medical marijuana, including medical marijuana waste, on their premises and update these records no less frequently than once per week.

B. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2976 (December 2022), amended, LR 51:

§709. Toxic Chemical Use and Storage

A. Licensee facilities shall handle and store any chemicals for direct or indirect contact with medical marijuana in accordance with its written operations plan and the manufacturer's directions.

B. …

C. Licensees shall maintain records of material safety data sheets (MSDS) for all chemicals currently in use at the facility.

D. - D.4.…

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2976 (December 2022), amended, LR 51:

§711. Transportation of Medical Marijuana

A. Licensee facilities shall generate an inventory manifest prior to transporting any medical marijuana to a licensed marijuana pharmacy, laboratory, contractor or disposal site. The manifest shall include the following items:

A.1. - D.…

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2976 (December 2022), amended, LR 51:

§713. Sampling Requirements

A. Licensees shall sample every batch of product to ensure compliance with the standards of quality outlined below. Licensees shall not release any batch of product for sale until the representative sample has been verified as compliant. Batches may be tested prior to portioning or packaging.

B. Sample verification shall be by means of the issuance of a certificate of analysis from the approved laboratory conducting the sample analysis issued to the Louisiana Department of Health and the originating facility no later than 24 hours after testing is complete.

C. Any batch with a sample failing one or more of the tests (by exceeding allowable limits for contaminants or residues) shall be remediated or destroyed, at the option of the licensee. A batch shall only be remediated once, and if subsequent sampling fails to correct the exceedance, the affected batch shall be destroyed.

D. - F.6. …

G. Table 1. Pesticide Residue Maximum Contaminant Levels (MCL) in parts per million (ppm) by dosage form.

Name	Ingested	Inhaled
Abamectin	0.5	0.5
Acephate	0.4	0.4
Acetamiprid	0.2	0.2
Acequinocyl	2	2
Azoxystrobin	0.2	0.2
Bifenzate	0.2	0.2
Bifenthrin	0.2	0.2
Boscalid	0.4	0.4
Carbaryl	0.2	0.2
Carbofuran	0.2	0.2
Chlorantraniliprole	0.2	0.2
Chlorfenapyr	1	1
Chlorpyrifos	0.2	0.2
Clofentezine	0.2	0.2
Cyfluthrin	1	1
Cypermethrin	1	1
Daminozide	1	1
DDVP (Dichlorvos)	0.1	0.1
Diazinon	0.2	0.2
Dimethoate	0.2	0.2
Ethoprophos	0.2	0.2
Etofenprox	0.4	0.4
Etoxazole	0.2	0.2
Fenoxycarb	0.2	0.2
Fenpyroximate	0.4	0.4
Fipronil	0.4	0.4
Flonicamid	1	1
Fludioxionil	0.4	0.4
Hexythiazox	1	1
Imazalil	0.2	0.2
Imidacloprid	0.4	0.4
Kresoxim-methyl	0.4	0.4
Malathion	0.2	0.2
Metalaxyl	0.2	0.2
Methiocarb	0.2	0.2
Methomyl	0.4	0.4
Methyl parathion	0.2	0.2
MGK-264	0.2	0.2
Myclobutanil	0.2	0.2
Naled	0.5	0.5
Oxamyl	1	1
Paclobutrazol	0.4	0.4
Permethrins*	0.2	0.2
Phosmet	0.2	0.2
Piperonylbutoxide	2	2
Prallethrin	0.2	0.2
Propiconazole	0.4	0.4
Propoxur	0.2	0.2
Pyrethrins**	1	1
Pyradiben	0.2	0.2
Spinosad	0.2	0.2
Spiromesifen	0.2	0.2
Spirotetramat	0.2	0.2
Spiroxamine	0.4	0.4
Tebuconazole	0.4	0.4
Thiacloprid	0.2	0.2
Thiamethoxam	0.2	0.2
Trifloxystrobin	0.2	0.2

*Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers.

**Pyrethrins should be measured as the cumulative residue of pyrethrin 1, cinerin 1, and jasmolin 1.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Louisiana Department of Health, Office of Public Health, LR 48:2976 (December 2022), amended, LR 51:

§715. Basic Facility Requirements

A. Licensee facilities shall provide finishes to floors, walls, and ceilings that are durable, light in color, and easily cleanable.

B. - I. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2976 (December 2022), amended, LR 51:

Chapter 9. Approved Laboratories for Testing Medical Marijuana

§901. General Requirements

A. Licensee facilities shall only utilize approved laboratories, as defined in this Section, for testing of medical marijuana.

B. - C. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2976 (December 2022), amended, LR 51:

Subpart 2. Marijuana Dispensaries

Chapter 21. General Requirements

§2101. Definitions

A. Except as may be otherwise defined in any provision of this Part, and unless the context or use thereof clearly indicates otherwise, the following words and terms used in this Part of the Sanitary Code are defined for the purposes thereof, and for purposes of any other Parts which are adopted or may hereafter be adopted, as follows.

Authorized Clinician—licensed health professional authorized to recommend therapeutic marijuana as defined in R.S. 40: 1046.

CFR—Code of Federal Regulations

Department—herein, unless otherwise indicated, the Louisiana Department of Health.

Dispensary—retail facility meeting the requirements of this Subpart that dispenses therapeutic marijuana to patients or caregivers.

Marijuana Product—any product containing marijuana, including raw plant material, that requires no further processing

Pharmacist—a natural person holding an active license to practice as a pharmacist issued by the Louisiana Board of Pharmacy.

Recommendation—a written or electronic communication from an authorized clinician to a dispensary indicating that in the clinician's professional judgment a patient would benefit from therapeutic marijuana.

Usable Marijuana—the dried leaves and flowers of the marijuana plant, and any mixtures or preparations of such leaves and flowers that are appropriate for the therapeutic use of marijuana, but does not include the seeds, stalks, and roots of the marijuana plant.

Use—to assimilate therapeutic marijuana into the body by ingestion, inhalation, topical application or any other route of administration by the patient, whether aided or unaided.

Visiting Qualifying Patient—non-resident of the state of Louisiana or person who has been a resident for fewer than 30 days who provides a Louisiana dispensary with a copy of a medical-marijuana registry card or similar credential indicating that the patient currently receives medical marijuana in another state under that jurisdiction's medical-marijuana laws and rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40: 1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§2103. Marijuana Product Requirements

A. Dispensaries may only stock marijuana products obtained from in-state licensed medical marijuana manufacturing facilities. No other sources may be utilized for the supply of marijuana products to patients.

B. Dispensaries may distribute only the following acceptable dosage forms of formulated therapeutic marijuana to patients:

1. oils, extracts, tincture or sprays;
2. solid oral dosage forms (e.g., pills, capsules, tablets);
3. liquid oral dosage forms (e.g., solutions or suspensions);
4. gelatin- or pectin-based chewables;
5. topical creams, unguents, or lotions;
6. transdermal patches;
7. suppositories; or
8. metered-dose inhalers.

C. Dispensaries may also distribute edible products (intended for ingestion) and combustible forms (intended for inhalation) made from marijuana flower.

D. No therapeutic marijuana product of any kind may include or be incorporated into the following:

1. an alcoholic beverage;
2. a dietary supplement; or
3. a drug other than marijuana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40: 1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

Chapter 23. Permits

§2301. Transfer of Existing Board of Pharmacy-Issued Permits

A. Any firm holding a permit to operate a marijuana pharmacy issued by the Louisiana Board of Pharmacy as of November 1, 2024 shall be issued an equivalent dispensary permit by the Louisiana Department of Health.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40: 1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§2303. Application Requirements

A. In accordance with the statutory limits provided for in R.S. 40: 1046(G), the department may issue no more than 30 permits for therapeutic marijuana dispensaries and their approved satellite locations.

B. Permits are not transferable to other locations or owners.

C. In the circumstance that one of the existing permit-holders for a primary dispensary location or its satellite chooses to surrender that permit or the facility undergoes a change-of-ownership, an applicant may submit a packet for review to include the following:

1. a completed application form provided by the department;

2. detailed plans of the facility, including a site plan and plumbing, electrical, mechanical, HVAC, and drainage schedules as well as a schedule of finishes for floors, walls, and ceilings in all areas; plans should include measures to secure the area where marijuana product is being dispensed to prevent the entry of unauthorized personnel;

3. proposed hours of operation, anticipated staffing levels, and a list of other goods and services to be provided on the premises;

4. the name and contact telephone number and email address of the registered pharmacist designated to be available to the dispensary; and

5. a notarized, sworn affidavit that the proposed location meets the separation distance requirements stipulated in R.S. 40:1040(G)(6) and that any applicable zoning requirements have been met.

D. Any plans packet that is incomplete or lacks the required supporting documentation will be returned without processing.

E. To comply with statutory population-survey requirements and as a condition of permitting, each permitted facility must supply the department with registered patient counts based on the previous 24-month period on a quarterly basis.

F. Per the provisions of R.S. 40:1046(F), each permitted facility must designate at least one registered pharmacist to be available to the primary site and its satellite locations by virtue of the pharmacist's physical presence or availability by telephone or videoconference during its hours of operation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40: 1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§2305. Renewal, Suspension, and Revocation

A. A marijuana pharmacy/dispensary permit issued by the Louisiana Board of Pharmacy or the Louisiana Department of Health shall be subject to renewal on a calendar-year basis utilizing a form supplied by the Louisiana Department of Health.

B. Renewal packets (to include ancillary documentation required by the renewal form) must be submitted to LDH no later than December 1 to renew for the following year.

C. Permits that are not renewed by December 31 are subject to suspension until such time as the proper packet has been submitted, reviewed, and accepted by LDH.

D. Permits that have not been renewed by March 1 of the subsequent calendar year or whose holders have been documented to be in violation of any provisions of this Subpart may be subject to revocation in accordance with the applicable provisions of LAC 51:I.113.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40: 1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§2307. Renovations

A. Any permitted marijuana dispensary that is undergoing substantial renovations (per LAC 51.I:101) must submit plans for review and approval to the Louisiana Department of Health. The department must approve the plans prior to the onset of construction/substantial renovations to the existing facility.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40: 1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

Chapter 25. Inspections and Operational Requirements

§2501. Inspections

A. Permitted facilities are required to be inspected at least once annually. Inspections are intended to verify compliance with the provisions of this Subpart, including §2511.

B. As a condition of its permit, the permittee shall allow the state health officer or his/her designee(s) to review all records relevant to the operations and management of the permitted facility.

C. Complaint-based inspections may be conducted at any time during business hours and without prior notice to the firm.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40: 1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§2503. Product and Site Security

A. Permitted facilities shall maintain an onsite security system that includes, at a minimum, the following components:

1. secured locks on doors throughout the facility;

2. audible alarms and a system of audio and video surveillance cameras that cover points of entry and egress as well as restricted-access areas;

3. restricted-access areas denoted by suitable signage and secured by means of card-access locks where marijuana products are held and dispensed. Only those directly involved in dispensing marijuana products are to be granted access to these areas.

B. The security system shall be documented in detail in the firm's security plan and subject to review during inspection by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40: 1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§2505. Inventory Control and Required POS (Point-of-Sale) System

A. Permitted facilities shall be required to maintain a point-of-sale software system that will interface with the Louisiana Medical Marijuana Tracking System to allow for seed-to-sale tracking of all medical marijuana transactions (including home deliveries and waste disposal) conducted at the facility.

B. The system shall be capable of documenting the amount of marijuana, dosage form, and amount dispensed under the active recommendation for each patient registered at the dispensary.

C. Additionally, the system shall allow the dispensing agent or pharmacist to cross-reference the patient's dispensing history in the LMMTS. A dispensary shall perform such cross-reference prior to sale, and shall refuse a sale if necessary to ensure that no patient receives more than 71 g of raw marijuana in a 14-day period or any amount of another dosage form in excess of the authorized clinician's recommendation.

D. Dispensary staff must maintain a perpetual inventory of marijuana products received, held, dispensed, and disposed of by the facility. Inventory reconciliations shall be conducted on at least a semi-annual (every six months) basis and documents related to reconciliations shall be maintained on the premises for at least two calendar years.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40: 1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§2507. Deliveries, Dispensing and Labeling/Packaging Requirements

A. Dispensaries may refuse delivery from a manufacturing facility of marijuana products if it is determined at receiving that the product is misbranded, adulterated, expired, or otherwise in a non-saleable condition. Such refusals shall be recorded in the POS system and the Louisiana Medical Marijuana Tracking System.

B. Marijuana products may be dispensed by appropriate dispensary staff to a patient or the patient's caregiver on the premises or by delivery to the patient's or caregiver's home address.

1. Patients or caregivers must have an authorized clinician send a paper or electronic recommendation bearing the clinician's signature directly to the dispensary prior to dispensing.

2. Recommendations must include the following information, at a minimum:

a. the name, address, and telephone number of the authorized clinician;

b. name, address and date-of-birth of the patient;

c. the name of the debilitating medical condition listed in R.S. 40:1046 for which the therapeutic marijuana will act as a treatment;

d. type of marijuana product requested;

e. date of recommendation and expiration of the recommendation; and

f. self-certification that the authorized clinician is registered as a therapeutic-marijuana provider with the Louisiana State Board of Medical Examiners.

3. The designated pharmacist may transfer an unexpired recommendation to a satellite or to a different dispensary at the patient's request, but no patient may have an active recommendation affiliated with multiple dispensaries simultaneously.

4. The dispensary shall provide laboratory test results for any marijuana product available for dispensing to the patient upon request.

C. Deliveries must be made available upon request at least once per month per ZIP code serviced by the dispensary; however, no delivery may be made outside the state of Louisiana.

D. Any marijuana product that is part of a delivery that is not completed must be returned to the dispensary of origin, and if the packaging integrity cannot be verified by dispensary staff, it must be disposed of by a department-approved method and that disposal documented in the firm's POS system.

E. Marijuana products, whether dispensed on- or off-premises, must be packaged in tightly-sealed and light-impermeable packaging.

F. Dispensary-affiliated pharmacists may compound marijuana products for specific patients in accordance with that patient's recommendation.

G. Dispensaries may utilize a recommendation issued by an authorized clinician to supply a patient on multiple occasions with marijuana products, provided that the dispensing is consistent with the requirements of §2505.C and that the dispensing does not exceed the amount indicated on the recommendation or consist of a dosage form not specified under §2103.B of this Subpart.

H. Provided that no marijuana product is dispensed to an out-of-state address, dispensary staff may provide marijuana products to a visiting qualifying patient in compliance with the provisions of this Section and R.S. 40:1046.1. A dispensary shall retain all documents required by R.S. 40:1046.1(C)(2) for at least three years.

I. No marijuana product may be dispensed by the dispensary unless it bears a label including the following information:

1. the name, address, and telephone number of the dispensing firm;

2. the name of the authorized clinician recommending the product;

3. the name of the patient;

4. date of dispensing;

5. transaction identification number, which shall be a unique identifier;

6. the identity of the product being dispensed;

7. quantity of product in the package;

8. directions for use; and

9. expiration date, as provided by the manufacturing facility.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40: 1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§2509. Disposal of Marijuana Product Waste

A. If marijuana waste is generated from compounding activities or marijuana product in inventory is no longer suitable for dispensing due to deterioration, expiration or other conditions rendering the product unsaleable, it shall be stored in a temporary morgue area pending disposal. Waste products may not be held on the premises longer than 30 days.

B. Waste products must be rendered into a non-usable state by grinding and mixing with non-marijuana waste products such that the end product is at least 50 percent non-marijuana waste by volume, and this end product may then be transported from the premises and disposed of by means of the following processes:

1. composting;

2. incineration; or

3. compaction and subsurface burial.

C. Acceptable materials for mixing include yard waste; paper or cardboard waste; plastic waste; or soil.

D. Dispensary personnel must document every disposal activity in the facility's POS system, including the identifying characteristics of the waste, the quantity of waste, and the method of its disposal.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40: 1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§2511. Basic Facility Requirements

A. Dispensaries shall provide and maintain finishes to floors, walls, and ceilings in all public areas that are smooth, light-in-color, durable, and easy-to-clean.

B. Dispensaries shall be sufficient in size to allow space for the following:

1. orderly placement of equipment and materials to minimize the possibility of contamination;

2. holding of waste products in secure storage while pending disposal;

3. storage of packages, containers, and labeling;

4. packaging and labeling operations;

5. dispensing operations; and

6. secure storage of marijuana products and compounded products pending dispensing.

C. Dispensaries shall provide lighting, ventilation, and screening (if applicable) as needed to do the following:

1. prevent contamination of products in storage with extraneous adulterants; and

2. minimize dissemination of microorganisms from one area to another.

D. Dispensaries shall provide locker rooms adequate for the storage of employee personal belongings.

E. Dispensaries shall provide a plumbing system designed and installed to meet the requirements of the Louisiana State Uniform Construction Code. Additionally the system shall include the following:

1. no cross-connections between any potable and non-potable water supply;

2. at least one hand lavatory in the dispensing and compounding areas equipped with hot-and-cold running water by means of a mixer-type faucet as well as adequate supplies of hand soap and paper towels and a suitable waste-receptacle located nearby.

3. at least one utility sink for the disposal of mop wastes; and

4. adequate means of sanitary disposal of wastewater.

F. Dispensaries shall provide adequate means of conveyance, storage, and disposal of refuse and non-medical marijuana waste products so as to minimize the development of odors, prevent waste products from becoming an attractant to and harborage for vermin, and prevent contamination of marijuana products, other products, facility surfaces, grounds, or water supplies.

G. Dispensaries shall provide toilet rooms as required by the Louisiana State Uniform Construction Code. Additionally toilet rooms shall be maintained in proper working order and in a sanitary condition. Adequate security measures shall be put into place to prevent the use of marijuana products in toilet rooms and signage shall be provided advising that such use is prohibited by law. Toilet rooms shall be equipped with self-closing doors and shall provide signage advising employees to wash hands with soap and water after using the toilet.

H. Dispensaries shall be located on premises that are maintained free from the following:

1. disused equipment, waste, debris or other materials that may serve as harborages for or attractants to vermin;

2. overgrowth of vegetation;

3. poorly-drained areas; and

4. excessively-dusty areas.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40: 1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

Family Impact Statement

The proposed Rule should not have any known or foreseeable impact on family formation, stability, and autonomy. In particular, the proposed Rule has no known or foreseeable impact on:

1. the stability of the family;

2. the authority and rights of persons regarding the education and supervision of their children;

3. the functioning of the family;

4. family earnings and family budget;

5. the behavior and personal responsibility of children;

6. the ability of the family or a local government to perform the function as contained in the proposed Rule.

Poverty Impact Statement

The proposed Rule should not have any known or foreseeable impact on any child, individual or family as defined by R.S. 49:973(B). In particular, there should be no known or foreseeable effect on:

1. the effect on household income, assets, and financial security;

2. the effect on early childhood development and preschool through postsecondary education development;

3. the effect on employment and workforce development;

4. the effect on taxes and tax credits;

5. the effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

Small Business Analysis

The proposed Rule should have no adverse impact on small businesses as defined in the Regulatory Flexibility Act.

Provider Impact Statement

The proposed Rule should not have any known or foreseeable impact on providers as defined by HCR 170 of the 2014 Regular Legislative Session. In particular, there should be no known or foreseeable effect on:

1. the effect on the staffing level requirements or qualifications required to provide the same level of service;

2. the total direct and indirect effect on the cost to the providers to provide the same level of service; or

3. the overall effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments on the proposed Rule. Such comments must be received no later than Monday, November 11, 2024 at COB, 4:30 pm, and should be addressed to Tiffany Meche, Director, Sanitarian Services, P.O. Box 4489, Baton Rouge, LA 70821.

Public Hearing

Interested persons may submit a written request to conduct a public hearing either by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on Monday, November 11, 2024. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 10 am on Monday, December 2, 2024, in Room

118 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Allen Enger at (225) 342-1342 after Monday, November 11, 2024. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing attendees when the parking ticket is presented to LDH staff at the hearing.

Dr. Ralph Abraham
Surgeon General
and
Michael Harrington, MBA, MA
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Regulation of Medical Marijuana

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

The proposed rule change is anticipated to increase expenditures for the Office of Public Health (OPH) by approximately $12,428 in FY 24-25 for the publication of the proposed rule as well as increased costs for travel ($7,200 for a car rental, $1,500 for overnight lodging, $300 for fuel costs, $3,428 in publication costs). It is not anticipated that any other state or local governmental units will incur costs or savings as a result of this rule change. Ongoing costs for subsequent fiscal years will be approximately $9,180 for travel-related expenses involved in conducting routine inspections of the 30 facilities added to the Cannabis Program's inventory.

In accordance with Acts 150 and 693 of the 2024 RLS, the proposed rule creates a regulatory framework for medical marijuana products within LDH. Specifically, this rule adds a new Subpart to Part XXIX of Title 51 of the LAC, which consists of five chapters detailing the various provisions of the regulation of medical marijuana. Chapter 1 explains definitions that are unique to this regulation. Chapter 3 specifies the enabling legislation and notes that the products regulated herein are subject to federal law. Chapter 5 describes the permitting process and operational requirements for dispensaries.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There will be no effect on revenue collections of state or local governmental units as a result of this proposed rule. These laws do not allow the department to collect any fees to fund this program. The program could end on December 31, 2029, if not renewed, but LDH has no authority to collect revenue.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS (Summary)

It is anticipated that this proposed rule will have no effect on costs or benefits of this program to stakeholders.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The adoption of this proposed rule should not engender or have any effect on competition among marijuana dispensaries.

Tonya Joiner
Assistant Secretary
2410#075

Alan M. Boxberger
Legislative Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Department of Insurance
Office of the Commissioner

Regulation 112—Adoption of NAIC Handbooks, Guidelines, Forms, and Instructions
(LAC 37:XIII.Chapter 161)

The Department of Insurance, pursuant to the authority of the Louisiana Insurance Code, R.S. 22:1 et seq., and in accordance with the Administrative Procedure Act, R.S. 49:950 et seq., hereby gives notice of its intent to amend Regulation 112.

The purpose of the amendment to Regulation 112 is to identify and to incorporate by reference the current edition of handbooks, guidelines, forms, and instructions adopted by the National Association of Insurance Commissioners (NAIC) and referenced in the Louisiana Insurance Code.

Title 37
INSURANCE
Part XIII.Regulations

Chapter 161. Regulation Number 112—Adoption of NAIC Handbooks, Guidelines, Forms and Instructions

§16101. NAIC Handbooks, Guidelines, Forms and Instructions Incorporated by Reference

A. ...

B. The following NAIC handbooks, guidelines, forms, and instructions are hereby adopted and incorporated by reference:

1. The Financial Condition Examiner's Handbook, 2023 edition.

2. The Annual and Quarterly Statement Instructions, Property and Casualty, 2023 edition.

3. The Annual and Quarterly Statement Instructions, Life, Accident, and Health, 2023 edition.

4. The Annual and Quarterly Statement Instructions, Health, 2023 edition.

5. The Annual and Quarterly Statement Instructions, Title, 2023 edition.

6. The Annual and Quarterly Statement Instructions, Fraternal, 2023 edition.

7. The Annual and Quarterly Statement Blanks, Property and Casualty, 2023 edition.

8. The Annual and Quarterly Statement Blanks, Life, Accident, and Health, 2023 edition.

9. The Annual and Quarterly Statement Blanks, Health, 2023 edition.

10. The Annual and Quarterly Statement Blanks, Title, 2023 edition.

11. The Annual and Quarterly Statement Blanks, Fraternal, 2023 edition.

12. The Accounting Practices and Procedures Manual, 2023 edition.

13. The Financial Analysis Handbook, 2023 edition.

14. The Own Risk and Solvency Assessment Guidance Manual, 2023 edition.

15. The Purposes and Procedures Manual of the NAIC Investment Analysis Office, 2023 edition.

16. The Risk-Based Capital Forecasting and Instructions, 2023 edition.

17. The Market Regulation Handbook, 2023 edition.