

NOTICE OF INTENT
Louisiana Department of Health
Office of Public Health
Regulation of Medical Marijuana
LAC 51:XXIX:101-907

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 enact a new Part of Title 51 of the Louisiana Administrative Code (also known as the “Louisiana State Sanitary Code”) as a consequence of changes made to medical marijuana regulations under Act No. 491 and Act No. 492 of the 2022 Louisiana Legislature. The following changes will authorize the LDH/OPH the ability to transition to conducting oversight of the manufacture and distribution of medical marijuana products, which could affect the health of Louisiana’s citizens and visitors. Further, this Emergency Rule will provide the state health officer the ability to make critical decisions that protect human health.

This rule adds a new Part, Part XXIX, to Title 51 of the Louisiana Administrative Code, consisting of nine Chapters enumerating 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 to be regulated herein are subject to federal law. Chapter 5 describes the permitting process for contractors and the licensure process for the two statutorily-prescribed licensees. Chapter 7 lists the inspection requirements for medical marijuana facilities and the operational requirements for the firms. Chapter 9 indicates the requirements for medical marijuana testing laboratories.

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

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 eight inches produced from a cutting, clipping or seedling.

Licensee—as defined in La. R.S. 40:1046(H)(2)(a), the Louisiana State University Agricultural Center or the Southern University Agricultural Center.

Louisiana Medical Marijuana Tracking System (LMMTS)—the required seed-to-sale tracking system that tracks medical marijuana from either the seed or immature plant stage until the plant material is sold as a finished product to a licensed medical marijuana pharmacy or destroyed.

Medical Marijuana—any parts of the plant genus *Cannabis* and all derivatives of all strains of this genus, whether growing or not; the seeds thereof; the resin extracted therefrom; any compound, mixture, or preparation of such plant, its seeds, or resin, including tetrahydrocannabinol (THC), cannabidiol (CBD), and all other naturally-occurring phytocannabinoids, whether produced directly or indirectly by extraction. This term does not include the mature stalks of such plant; fiber produced from such stalks; oil or cake made from the seeds of such plant; any other compound, salt, derivative, mixture, or preparation of such mature stalks (except for the resin extracted therefrom); fiber, oil, or cake; or sterilized seed incapable of germination.

Medical Marijuana Waste—medical marijuana that is unusable or that cannot be processed into a useable form.

Permittee—contractor employed by the licensee to grow, cultivate, process, transport, and distribute medical marijuana.

Therapeutic Marijuana—see *Medical Marijuana*.

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

HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 48:

Chapter 3. Authority; Preemption

§301. Authority

A. The rules specified in this Part are promulgated under the authority of R.S. Title 40, Chapter 4, Part X-E (R.S. 40:1046 et seq.).

B. In accordance with the provisions of 21 U.S.C. 812, medical marijuana remains classified as a Schedule I Controlled Dangerous Substance by the government of the United States. No Louisiana law or regulation may preempt or supersede federal law, and the products regulated in the rules described in this Part remain subject to such laws as are applicable to Schedule I substances.

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

HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 48:

Chapter 5. Licensure and Permitting

§501. Licensure of Authorized Entities

A. The department shall issue a nontransferable license to the Louisiana State University Agricultural Center and to the Southern University Agricultural Center to produce medical marijuana. Such license shall be renewable annually on July 1. Requirements for renewal include the maintenance of a contractual relationship with a single permittee.

B. No other entity is authorized to receive a license 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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.
HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 48:

§503. Permitting

A. Licensees shall contract with only one (1) permittee, and this permittee shall apply to the department for an annual permit to engage in growing, cultivating, processing, transporting, and distributing medical marijuana.

B. Permits are nontransferable and subject to an application review process and a license fee of \$100,000.00. Permits expire on and shall be renewed annually on July 1.

C. Permittees 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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.
HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 48:

§505. Application Process

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

B. Applicants shall supply the following information as a condition of receiving a new permit:

1. detailed plans of the facility, including a site plan and plumbing, electrical, mechanical, HVAC, and drainage schedules as well as schedules of finishes for floors, walls, and ceilings in all areas;

2. plans including layouts and lists of equipment used for surveillance of the facility, including cameras, motion-sensing devices, locking mechanisms, points of secured entry and egress, and monitoring stations;

3. proposed hours of operation and approximate estimated staffing levels;

4. product safety plans, including the protocol for processing each kind of medical marijuana manufactured at the site, including procedures for identifying, monitoring, and controlling any relevant biological, physical, or chemical hazards reasonably likely to occur during the growth, cultivation and harvesting, and production and packaging phases of the operation;

5. lists of required per-batch production records used for the manufacture of medical marijuana, including relevant laboratory testing of raw materials, components, excipients, and other constituents;

6. a recall plan;

7. a document provided by the licensee affirming that all criminal background checks on contractor personnel required by R.S. 40:1047 have been completed to the licensee's satisfaction; and

8. any other information or plans required to be provided under R.S. Title 40, Chapter 4, Part X-E (R.S. 40:1046 et seq.).

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

1. the gross quantity of medical marijuana grown during the preceding calendar year;
2. a detailed report of associated production costs, including seed, fertilizer, labor, advisory services, construction and maintenance, and irrigation;
3. a detailed list of items for which subcontractors were employed and the associated costs for each service rendered by subcontractors;
4. the total quantity of medical marijuana generated as a finished product within that year and the quantity distributed to each licensed marijuana pharmacy;
5. costs paid to the licensee related to medical marijuana production; and
6. any other information or plans required to be provided under R.S. Title 40, Chapter 4, Part X-E (R.S. 40:1046 et seq.).

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

HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 48:

Chapter 7. Inspections and Operational Requirements

§701. Inspections

A. Permittee 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. the facility is of solid construction and designed in such a way to secure the knowledge of the nature of its operations from a casual observer by means of odor control and secure enclosed spaces;
2. the facility, staff, and documents meet the necessary minimum standards to ensure the production of safe medical marijuana;
3. operational documents as described in §505.B are maintained on-premises;
4. the firm has current access to the Louisiana Medical Marijuana Tracking System (LMMTS);
5. the facility has adequate site and product security measures in place, including visitor logs and employee activity records;
6. the facility has an inventory tracking system as described in §703-705 of this Chapter in place;
7. the facility has complete personnel records in place;
8. compliance with the requirements of §715 of this Part; and
9. the facility complies with all applicable requirements of R.S. Title 40, Chapter 4, Part X-E (R.S. 40:1046 et seq.).

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. Routine inspections of permitted 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: Adopted by the Louisiana Department of Health, Office of Public Health, LR 48:

§703. Product and Site Security

A. Permittee 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 video and audio surveillance cameras with recording capabilities that meets the following additional requirements:
 - a. video surveillance shall cover all points of entry and exit and restricted-access areas;
 - b. video surveillance shall have accurate date and time stamps;
 - c. video surveillance recordings shall be maintained for at least 30 (thirty) days.
3. a “panic” device with the ability to contact law enforcement;
4. a “duress” device capable of contacting law enforcement by means of a “silent alarm” and;
5. restricted access to sensitive areas (where medical marijuana products are cultivated, extracted, processed or stored).

B. Surveillance systems shall be monitored onsite between the hours of 8:00 and 17:00, but off-site monitoring may be provided during other hours.

C. Restricted-access areas shall be noted in the firm’s security plan and posted with suitable signage. These areas shall remain locked during all hours and access shall be controlled by means of employee badge scanners or similar devices.

D. Visitors shall be required to sign a log indicating their firm, purpose of visit, and date and time in and out of the facility. Visitors shall be allowed on the premises for official purposes only and shall be issued visitor badges for the duration of their visits. Visitors shall not remain in restricted-access areas unaccompanied by an authorized staff member unless no medical marijuana is present in the area at the time of the visit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.
HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 48:

§705. Louisiana Medical Marijuana Tracking System

A. Permittee facilities shall possess and maintain required hardware and software to connect to the Louisiana Medical Marijuana Tracking System.

B. Each plant and medical marijuana product originating at the facility shall be assigned a unique tag and identification number for tracking purposes.

C. Within 24 hours of the occurrence of one of the following events, it shall be documented in the LMMTS:

1. purchase or other acquisition of marijuana plants or seeds, including immature plants and seedlings;

2. sale, transfer or transport of medical marijuana to another contractor, approved laboratory, or medical marijuana pharmacy;

3. disposal of medical marijuana waste.

D. All records relating to transactions referenced in Subsection C., above, must be maintained for at least the current calendar year as well as the three preceding calendar years (if applicable).

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

HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 48:

§707. Inventory Control

A. Permittee 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. Medical marijuana waste shall be tracked in the LMMTS and stored in a restricted-access area until it is incinerated or removed to a composting facility or landfill.

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

HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 48:

§709. Toxic Chemical Use and Storage

A. Permittee 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. Restricted-use pesticides shall only be handled by individuals with the required certifications.

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

D. When applying pesticides to a crop, the facility shall maintain the following records:

1. date and time of application;

2. name of the individual applying the pesticide;

3. batch numbers of all chemicals used; and

4. the amount and name of the chemicals used, including the EPA registration number, if applicable.

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

HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 48:

§711. Transportation of Medical Marijuana

A. Permittee 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:

1. name of the originating firm;

2. name of the receiving facility;
3. quantity expressed in terms of weight measure or unit of each type of medical marijuana comprising the shipment;
4. the date and approximate departure and arrival times of the shipment;
5. the identity of the agents involved in the transportation; and
6. the make, model, and license plate number of the transport vehicle.

B. Prior to initiating transport, the originating facility shall supply a copy of the inventory manifest referenced in Subsection A to the receiving facility.

C. Upon receipt, the receiving facility shall update the relevant records in the LMMTS, except that the shipment shall be refused if unaccompanied by a valid, unaltered LMMTS inventory-manifest document.

D. Shipments that are refused under the provisions of Subsection C shall be returned to the originating facility at its expense and the appropriate documentation shall be generated and provided to the transporter and the receiving facility prior to returning the materials to the receiver. Updates to the material records in the LMMTS shall be made as needed.

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

HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 48:

§713. Sampling Requirements

A. Permittees shall sample every batch of product to ensure compliance with the standards of quality outlined below. Permittees 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 permittee. A batch shall only be remediated once, and if subsequent sampling fails to correct the exceedance, the affected batch shall be destroyed.

D. Sample medical marijuana waste held at an approved laboratory shall be destroyed within 60 days of completion of testing.

E. Minimally-processed plant material shall be subject to all testing requirements below except testing for solvent residues.

F. Medical marijuana samples shall be required to meet the following standards of quality:

1. microbiological contaminants:
 - a. mold/yeast <10,000 CFU/g;
 - b. pathogenic *Escherichia coli* and *Salmonella* spp. < 1CFU/g;
 - c. aflatoxins < 20 ppb;
 - d. ochratoxins < 20 ppb.
2. solvent residues:
 - a. butanes < 800 ppm;
 - b. heptanes < 500 ppm;
 - c. benzene <1 ppm;

- d. toluene <1 ppm;
 - e. hexanes < 10 ppm;
 - f. xylenes < 1ppm;
 - g. ethanol < 5,000 ppm.
3. heavy-metal contaminants:
- a. arsenic < 10 ppm;
 - b. cadmium < 4.1 ppm;
 - c. lead < 10 ppm;
 - d. mercury < 2 ppm.
4. pesticide residues: see Table 1 for maximum contaminant levels for finished products; any pesticide not listed shall not have detectable residues in finished products.
5. homogeneity: each aliquot shall have a variance of no more than plus or minus fifteen (15) percent of the total average result for THC content.
6. potency: the product shall have a variance of no more than plus or minus fifteen (15) percent of the THC content specified on the product label.

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

Name	Ingested	Inhaled
Category I (includes aldicarb, carbofuran, chlorpyrifos, coumaphos, daminozide, dichlorvos, dimethoate, ethoprop(hos), etofenprox, fenoxycarb, imazalil, methocarb, methyl parathion, mevinphos, paclobutrazol, propoxur, spiromamine, and thiacloprid)	0	0
Category II		
Abamectin	0.3	0.1
Acephate	5	0.1
Acetamiprid	5	0.1
Acequinocyl	4	0.1
Azoxystrobin	40	0.1
Bifentate	5	0.1
Bifenthrin	0.5	3
Boscalid	10	0.1
Captan	5	0.7
Carbaryl	0.5	0.5
Chlorantraniliprole	40	10
Clofentezine	0.5	0.1
Cyfluthrin	1	2
Cypermethrin	1	1

Diazinon	0.2	0.1
Dimethomorph	20	2
Etoxazole	1.5	0.1
Fenhexamid	10	0.1
Fenpyroximate	2	0.1
Flonicamid	2	0.1
Fludioxionil	30	0.1
Hexythiazox	2	0.1
Imidacloprid	3	5
Kresoxim-methyl	1	0.1
Malathion	5	0.5
Metalaxyl	15	2
Methomyl	0.1	1
Myclobutanil	9	0.1
Naled	0.5	0.1
Oxamyl	0.2	0.5
Pentachloronitrobenzene	0.2	0.1
Permethrin	20	0.5
Phosmet	0.2	0.1
Piperonylbutoxide	8	3
Prallethrin	0.4	0.1
Propiconazole	20	0.1
Pyrethrins	1	0.5
Pyradiben	3	0.1
Spinetoram	3	0.1
Spinosad	3	0.1
Spiromesifen	12	0.1
Spirotetramat	13	0.1
Tebuconazole	2	0.1
Thiamethoxam	4.5	5
Trifloxystrobin	30	0.1

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.
HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 48:

§715. Basic Facility Requirements

- A. Permittee facilities shall provide finishes to floors, walls, and ceilings that are durable, light in color, and easily cleanable.
- B. Facilities 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. receipt, storage, and withholding from use components pending sampling (if required), identification and release by quality assurance personnel;

3. holding of rejected components or finished products pending disposal or rework;
 4. storage of containers, packaging and labeling;
 5. manufacturing and processing operations;
 6. packaging and labeling operations; and
 7. storage of finished products.
- C. Facilities shall provide lighting, ventilation, and screening as needed to do the following:
1. prevent contamination of products with extraneous adulterants;
 2. minimize dissemination of microorganisms from one area to another.
- D. Facilities shall provide locker rooms for storage of employee personal equipment and belongings.
- E. Facilities shall provide a plumbing system designed and installed in accordance with 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. where all equipment is not clean-in-place, at least one three-compartment sink with compartments adequate in size to submerge the largest utensil used in manufacturing operations;
 3. an adequate number of hand lavatories supplied with hot-and-cold running water through a mixer-type faucet and hand soap and paper towels located convenient to manufacturing operation areas;
 4. at least one utility sink for the disposal of mop wastes;
 5. adequate means of sanitary disposal of wastewater.
- F. Facilities 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 components, finished products, facility surfaces, grounds or water supplies.
- G. Facilities shall provide toilet rooms in accordance with the Louisiana State Uniform Construction Code. Additionally toilet rooms shall be maintained in proper working order and in a sanitary condition. Toilet rooms shall have self-closing doors and shall not open directly into manufacturing areas. Toilet rooms shall include signs directing employees to wash hands with soap and water after using the toilet.
- H. Facilities shall be located on premises that are maintained free of 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.
- I. Equipment used in manufacturing operations shall not be additive, reactive, or absorptive to any product or its components and shall be installed in such a manner as to facilitate cleaning and not to contribute to potential cross-contamination of finished products.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq..
HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 48:

Chapter 9. Approved Laboratories for Testing Medical Marijuana

§901. General Requirements

- A. Permittee facilities shall only utilize approved laboratories, as defined in this Section, for testing of medical marijuana.
- B. Prior to testing medical marijuana to verify compliance, a laboratory shall apply for and receive a medical marijuana laboratory license from the Louisiana Department of Health.
- C. A laboratory holding or seeking a medical marijuana laboratory license shall comply with all applicable requirements of R.S. Title 40, Chapter 4, Part X-E (R.S. 40:1046 et seq.).

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.
HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 48:

§903. Application Process

- A. Applications for initial licensure and renewal of licensure shall be made using documents supplied by the department for this purpose.
- B. Applicants shall be required to supply the following documentation as part of the application process:
 - 1. proof of accreditation through the National Institute on Drug Abuse (NIDA), the National Environmental Laboratory Accreditation Conference (NELAC), or the International Organization for Standardization (ISO); or proof of operation of a licensed or permitted medical marijuana testing laboratory in another state for the previous 12 months, and accreditation or pending accreditation through ISO;
 - 2. an affidavit that representatives of the State Health Officer shall be granted access to all areas of the facility utilized for medical marijuana testing upon request; and
 - 3. documentation indicating that the firm is currently able to access and utilize the Louisiana Medical Marijuana Tracking System (LMMTS).
- C. Approved medical marijuana testing laboratory licenses shall be renewable annually every December 31. Applications for renewal shall be submitted to the Louisiana Department of Health no later than October 31; applicants shall provide copies of current accreditation-verification and permit documents in order for a new license to be issued to the facility.
- D. Failure to renew in a timely fashion shall trigger a requirement to destroy all medical marijuana located at the facility after midnight on December 31. Any product remaining on the premises at that time shall be subject to seizure under the provisions of La. R.S. 40:632 *et seq.*

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.
HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 48:

§905. Exemptions

- A. The Agricultural Chemistry Laboratory of the Louisiana Department of Agriculture and Forestry is exempt from the requirements of §901 and §903.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.
HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 48:

§907. Records

A. Laboratories shall maintain all records related to testing of medical marijuana for no less than three years. Such records shall be made available for review to representatives of the State Health Officer upon request.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046 et seq.
HISTORICAL NOTE: Adopted by the Louisiana Department of Health, Office of Public Health, LR 48:

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 Tuesday, October 25, 2022 at COB, 4:30 p.m., and should be addressed to Michael Vidrine, 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, October 10, 2022. If the criteria set forth in R.S. 49:961(B)(1) are satisfied, LDH will conduct a public hearing at 9:00 a.m. on Tuesday, October 25, 2022, 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 October 10, 2022. 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. Joseph Kanter
State Health Officer
and
Dr. Courtney N. Phillips
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

Person

Preparing

Statement: Brian R. Warren

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Return

Address: 628 N. 4th Street
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Dept.: Louisiana Department of Health

Office: Office of Public Health

Rule Title: Regulation of Medical Marijuana

Date Rule Takes Effect: December 20, 2022

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)

Other than publication costs, the proposed rule will have no impact on overall state or local costs or savings. Implementation of the rule will shift the cost of regulating medical marijuana from the Department of Agriculture and Forestry (LDAF) to the Department of Health. Most of this cost shift include software licensing fees (approximately \$60,000) for the Louisiana Medical Marijuana Tracking System and the cost of travel associated with inspecting the facilities (approximately \$6,000).

In accordance with Acts 491 and 492 of the 2022 RLS, the proposed rule creates a regulatory framework for medical marijuana products within LDH. Specifically, this rule adds a new Part XXIX to Title 51 of the LAC and 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 to be regulated herein are subject to federal law. Chapter 5 describes the permitting process for contractors and the licensure process for the two statutorily-prescribed licensees. Chapter 7 lists the inspection requirements for medical marijuana facilities and the operational requirements for the facilities. Chapter 9 indicates the requirements for medical marijuana testing laboratories.

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

The proposed rule will have no impact on overall state collections. This rule is anticipated to increase revenue collections for LDH by \$200,000 and decrease revenue collections by the Department of Agriculture and Forestry by the same amount. The source of revenue is licensing fees paid by LSU and Southern University Ag Centers to cultivate, extract, process, produce, and transport therapeutic marijuana.

Note: The annual licensing fee for each contractor permitted to cultivate, extract, process, produce, and transport therapeutic marijuana is \$100,000. Currently, there are two contractors, LSU and Southern University Ag Centers.

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

The proposed rule is not anticipated to result in costs to or have economic impacts on directly affected persons, small businesses, or non-governmental groups. This rule sets up the regulatory framework within LDH for medical marijuana, which LDAF previously regulated. Under LDAF, producers paid for lab testing and background checks. This is anticipated to remain the same under LDH.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule will not impact competition or employment.

Signature of Agency Head or Designee

Doris Brown
Assistant Secretary, Office of Public Health
Typed Name & Title of Agency Head or Designee

Date of Signature

Legislative Fiscal Officer or Designee

Date of Signature

