RULE

Department of Health
Bureau of Health Services Financing
and
Office for Citizens with Developmental Disabilities

Targeted Case Management
Reimbursement Methodology
EarlySteps Reimbursement Rate Increase
(LAC 50:XV.10701)

The Department of Health, Bureau of Health Services Financing and the Office for Citizens with Developmental Disabilities has amended LAC 50:XV.10701 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq. This Rule is hereby adopted on the day of promulgation.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part XV. Services for Special Populations
Subpart 7. Targeted Case Management
Chapter 107. Reimbursement
§10701. Reimbursement

A. Reimbursement for case management services for the Infant and Toddler Program (EarlySteps):

1. Effective for dates of service on or after July 1, 2022, case management services provided to participants in the EarlySteps Program shall be reimbursed at a flat rate for each approved unit of service.

a. The standard unit of service is equivalent to one month and covers both service provision and administrative (overhead) costs.

b. Service provision includes the core elements in:

i. Section 10301 of this Subpart;

ii. the case management manual; and

iii. EarlySteps practices.

A.2. - E. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:1040 (May 2004), amended LR 31:2032 (August 2005), LR 35:73 (January 2009), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 35:1903 (September 2009), LR 36:1783 (August 2010), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Public Health, LR 39:97 (January 2013), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:3302 (December 2013), LR 40:1700, 1701 (September 2014), LR 41:1490 (August 2015), amended by the Department of Health, Bureau of Health Services Financing, LR 44:63 (January 2018), LR 47:1128 (August 2021), amended by the Department of Health, Bureau of Health Services Financing and the Office for Citizens with Developmental Disabilities, LR 48:2976 (December 2022).

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Dr. Courtney N. Phillips
Secretary

2212#057

RULE

Department of Health
Office of Public Health

Medical Marijuana Regulation
(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, state health officer, acting through the Department of Health, Office of Public Health (LDH/OPH), has enacted 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 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 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. This Rule is hereby adopted on the day of promulgation.

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: Promulgated by the Department of Health, Office of Public Health, LR 48:2976 (December 2022).

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: Promulgated by the Department of Health, Office of Public Health, LR 48:2977 (December 2022).

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: Promulgated by the Department of Health, Office of Public Health, LR 48:2977 (December 2022).

§503. Permitting

A. Licensees shall contract with only one 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: Promulgated by the Department of Health, Office of Public Health, LR 48:2977 (December 2022).

§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: Promulgated by the Department of Health, Office of Public Health, LR 48:2977 (December 2022).

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: Promulgated by the Department of Health, Office of Public Health, LR 48:2978 (December 2022).

§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 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: Promulgated by the Department of Health, Office of Public Health, LR 48:2978 (December 2022).

§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: Promulgated by the Department of Health, Office of Public Health, LR 48:2978 (December 2022).

§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 48:2979 (December 2022).

§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: Promulgated by the Department of Health, Office of Public Health, LR 48:2979 (December 2022).

§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: Promulgated by the Department of Health, Office of Public Health, LR 48:2979 (December 2022).

§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 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 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, spiroxamine, 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
Bifenzate	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: Promulgated by the Department of Health, Office of Public Health, LR 48:2979 (December 2022).

§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 submerse 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 as 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: Promulgated by the Department of Health, Office of Public Health, LR 48:2980 (December 2022).

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: Promulgated by the Department of Health, Office of Public Health, LR 48:2981 (December 2022).

§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: Promulgated by the Department of Health, Office of Public Health, LR 48:2981 (December 2022).

§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: Promulgated by the Department of Health, Office of Public Health, LR 48:2981(December 2022).

§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: Promulgated by the Department of Health, Office of Public Health, LR 48:2981 (December 2022).

Dr. Joseph Kanter
State Health Officer
and
Dr. Courtney N. Phillips
Secretary

2212#045

RULE

Department of Health
Office of Public Health

Registration of Foods, Drugs, Cosmetics
and Prophylactic Devices—Hemp Products
(LAC 49:I.Chapter 5)

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, the state health officer, acting through the Department of Health, Office of Public Health (LDH-OPH), has reenacted and amended certain sections of Chapter 5 (Registration of Foods, Drugs, Cosmetics and Prophylactic Devices) of Title 49 (*Public Health—Food, Drugs, and Cosmetics*) of the *Louisiana Administrative Code*. The LDH/OPH finds it necessary to make changes to the *Louisiana Administrative Code* as a consequence of changes made to hemp regulations under Act No. 498 of the 2022 Louisiana Legislature. The following changes authorize the LDH/OPH the ability to properly register these items, inspect firms that manufacture such items for human consumption, and conduct oversight of labeling, which could affect the health of Louisiana's citizens and visitors.

This Rule amends §501 and §§517-537 of Chapter 5. §§517, 519 are recodified with new requirement language and the original §§531-533 are relocated to §§535-537. New language is implemented in the current §§531-533 to enact new requirements from the 2022 legislation. Changes to §501 amend existing definitions and add new definitions. This Rule is hereby adopted on the day of promulgation.

ENROLLED

2022 Regular Session

ACT No. 491

HOUSE BILL NO. 697

BY REPRESENTATIVE MAGEE

AN ACT

To amend and reenact R.S. 40:1046(A)(1), (C)(1) and (2)(introductory paragraph), (G), and (H)(1), (2), (6)(a)(introductory paragraph) and (b), and (8)(a)(introductory paragraph) and (iii), to enact R.S. 40:1046(A)(7), (B), and 1046.1 through 1046.3, and to repeal R.S. 40:1046(C)(2)(d), (e), and (h) and (H)(3) through (5), relative to production of marijuana for therapeutic use; to provide for regulation of medical marijuana production by the state; to transfer certain duties with respect to such regulation from the Department of Agriculture and Forestry to the Louisiana Department of Health; to provide for remittance to the Louisiana Department of Revenue of the proceeds of certain fees; to provide relative to permitting and regulation of marijuana pharmacies by the Louisiana Board of Pharmacy; to require the Louisiana Department of Health to license and regulate laboratories that conduct testing of medical marijuana products; to provide for selection of marijuana production contractors by licensed producers of medical marijuana; to provide for oversight and regulation of such contractors; to provide requirements and standards for the business operations of such contractors; to require the continuation of certain laboratory testing services provided by the Department of Agriculture and Forestry; to authorize certain institutions to conduct research on marijuana for therapeutic use; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 40:1046(A)(1), (C)(1) and (2)(introductory paragraph), (G), and (H)(1), (2), (6)(a)(introductory paragraph) and (b), and (8)(a)(introductory paragraph) and

(iii) are hereby amended and reenacted and R.S. 40:1046(A)(7), (B), and 1046.1 through 1046.3 are hereby enacted to read as follows:

§1046. Recommendation and dispensing of marijuana for therapeutic use; rules and regulations of the ~~Louisiana State Board of Medical Examiners and~~ Louisiana Board of Pharmacy; production facility licensing; ~~by the Department of Agriculture and Forestry~~ permitting by the Louisiana Department of Health

A.(1) Notwithstanding any other provision of this Part, any physician licensed by and in good standing with the Louisiana State Board of Medical Examiners to practice medicine in this state may recommend, in any form as permitted by the rules and regulations of the Louisiana Board of Pharmacy, raw or crude marijuana, tetrahydrocannabinols, or a chemical derivative of tetrahydrocannabinols for therapeutic use by any patient clinically diagnosed as suffering from a debilitating medical condition. ~~Nothing in this Paragraph shall be construed to prevent the Louisiana Board of Pharmacy from permitting, by rule, medical marijuana in a form to be administered by metered-dose inhaler. For purposes of this Section, "metered-dose inhaler" means a device that delivers a specific amount of medication to the lungs, in the form of a short burst of medicine that is usually self-administered by the patient via inhalation.~~

* * *

(7) Nothing in this Paragraph shall be construed to prevent the Louisiana Board of Pharmacy from permitting, by rule, medical marijuana in a form to be administered by metered-dose inhaler. For purposes of this Section, "metered-dose inhaler" means a device that delivers a specific amount of medication to the lungs, in the form of a short burst of medicine that is usually self-administered by the patient via inhalation.

B. Nothing in this Part shall be construed or enforced in any manner that prevents a physician authorized by Subsection A of this Section to recommend therapeutic marijuana from recommending therapeutic marijuana through telemedicine, as defined in R.S. 37:1262, in this state.

C.(1) The Louisiana Board of Pharmacy shall adopt rules relating to ~~the dispensing of recommended marijuana for therapeutic use~~ therapeutic marijuana. ~~Any rules published by the Louisiana Board of Pharmacy on or before January 1, 2016, that describe the pharmacist as dispensing medical marijuana based on a physician's prescription should be repromulgated to indicate that the physician is "recommending" use of therapeutic marijuana.~~

(2) The rules promulgated pursuant to this Subsection shall include but not be limited to:

* * *

G.(1) The Louisiana Board of Pharmacy shall develop an annual, nontransferable specialty license for a pharmacy to dispense recommended marijuana for therapeutic use and, except as provided in Paragraph (3) of this Subsection, shall limit the number of ~~such~~ licenses granted in the state to no more than ten licenses. ~~The Louisiana Board of Pharmacy shall develop rules and regulations regarding the geographical locations of dispensing pharmacies in Louisiana.~~ The board shall award one license per region, as delineated in Paragraph (2) of this Subsection and one additional license to the region with the highest population density as of August 1, 2022, and shall award each license through a competitive process. The board shall consider the status of an applicant as a minority-, woman-, or veteran-owned business as a primary factor in awarding a license.

(2) For the purposes of this Subsection, the regions among which the Louisiana Board of Pharmacy shall allocate marijuana pharmacy licenses shall correspond to the sets of parishes comprising, respectively, the administrative regions of the Louisiana Department of Health as those regions existed on August 1, 2022. On and after October 1, 2022, at least one licensed marijuana pharmacy shall be located in each region.

(3)(a) After three thousand five hundred active, qualified patients are identified in the prescription monitoring program in a region, the Louisiana Board of Pharmacy shall allow the marijuana pharmacy licensee in that region to open one

additional marijuana pharmacy location as a satellite location in that region. For the purposes of this Paragraph, "satellite location" shall mean an additional marijuana pharmacy location operated by a marijuana pharmacy licensee within the licensee's geographic region but physically separate from the location of the originally licensed therapeutic marijuana pharmacy.

(b) If the marijuana pharmacy licensee opens a satellite location pursuant to Subparagraph (a) of this Paragraph and the original location and the satellite location are each found to be serving three thousand five hundred active, qualified patients, then the Louisiana Board of Pharmacy shall allow the marijuana pharmacy licensee in that region to open one additional marijuana pharmacy location as a second satellite location in that region.

(c) If a marijuana pharmacy licensee declines to open a second satellite location pursuant to Subparagraph (b) of this Paragraph, then the Louisiana Board of Pharmacy may issue, pursuant to the provisions of Paragraph (1) of this Subsection, an additional marijuana pharmacy license in that region to open one marijuana pharmacy location in lieu of the original licensee's second satellite location in that region.

(d) The board shall consider any unserved parishes within the region when approving a satellite location or additional marijuana pharmacy for licensure pursuant to this Paragraph.

(e) For the purposes of this Paragraph, the active, qualified patient count shall be conducted on or after August 1 of each year using the preceding twelve-month period of August 1 through July 31.

(4)(a) The total number of marijuana pharmacy locations, including satellite locations, approved by the Louisiana Board of Pharmacy pursuant to Paragraph (3) of this Subsection shall not be greater than thirty locations.

(b) The provisions of this Paragraph shall not be construed to authorize a marijuana pharmacy licensee to open more than two satellite locations in a single region.

(5) The provisions of this Subsection shall not be construed to require the closure of any marijuana pharmacy location, including satellite locations, if the active, qualified patient count drops below three thousand five hundred after the location is approved by the board.

(6)(a) No marijuana pharmacy shall locate within a fifteen-mile radius of another marijuana pharmacy.

(b) Notwithstanding the provisions of Subparagraph (a) of this Paragraph, in a region that encompasses any parish with a population of more than three hundred fifty thousand persons according to the most recent federal decennial census, no marijuana pharmacy shall locate within a ten-mile radius of another marijuana pharmacy.

(c) Notwithstanding the provisions of Subparagraph (a) of this Paragraph, in a region that encompasses any municipality with a population of more than three hundred fifty thousand persons according to the most recent federal decennial census, no marijuana pharmacy shall locate within a five-mile radius of another marijuana pharmacy.

(7) Each marijuana pharmacy licensed in accordance with the provisions of this Subsection shall offer home delivery to patients in each zip code within its region at least once per month.

(8) For purposes of this Subsection, "active, qualified patient" means a patient that has acquired a therapeutic marijuana product at least once in the preceding twelve-month period of August 1 through July 31.

H.(1)(a) ~~The Department of Agriculture and Forestry shall develop the rules and regulations regarding the extraction, processing, and production of recommended therapeutic marijuana and the facility producing therapeutic marijuana. The rules and regulations shall require as a minimum standard that the extraction and refining process produce a product that is food-safe and capable of producing pharmaceutical-grade products.~~ The legislature hereby recognizes and declares that both the Louisiana State University Agricultural Center and the Southern University Agricultural Center timely exercised and asserted the intent of

each university to be licensed to produce recommended marijuana for therapeutic use in this state in accordance with the provisions of Act No. 261 of the 2015 Regular Session of the Legislature of Louisiana.

(b) ~~The rules and regulations shall also include but not be limited to the procedures for application, qualifications, eligibility, background checks, and standards for suitability for a license and penalties for violations of the rules and regulations.~~ Each institution identified in Subparagraph (a) of this Paragraph, respectively, shall select and contract with only one contractor authorized to produce therapeutic marijuana in accordance with this Part. The selection process and contracting provided for in the Subparagraph shall be done in accordance with all applicable provisions of the Louisiana Procurement Code, R.S. 39:1551 et seq. Each contractor and the university with which it contracts shall execute an agreement for services.

(2)~~(a) The Department of Agriculture and Forestry shall develop an annual,~~ The Louisiana Department of Health shall issue all of the following annually:

(a) A nontransferable specialty license for the production of recommended marijuana for therapeutic use, which the department shall issue only to the Louisiana State University Agricultural Center and the Southern University Agricultural Center. ~~Other than the licenses granted pursuant to Subparagraph (b) of this Paragraph, the Department of Agriculture and Forestry shall limit the number of such licenses granted in the state to no more than one licensee. The Louisiana State University Agricultural Center and the Southern University Agricultural Center shall have the right of first refusal to be licensed as the production facility, either separately or jointly. If neither of the centers exercise this option, the license shall be awarded pursuant to the requirements provided for in Paragraphs (3) through (5) of this Subsection.~~

(b) ~~Prior to September 1, 2016, the Louisiana State University Agricultural Center and the Southern University Agricultural Center shall each provide written notice to the commissioner of agriculture and forestry of their intent to be licensed as a production facility, either separately or jointly.~~ A permit to cultivate, extract,

process, produce, and transport therapeutic marijuana, which the department shall issue only to the sole contractor selected by each university in accordance with Paragraph (1) of this Subsection.

(c) The Louisiana State University Agricultural Center ~~or,~~ the Southern University Agricultural Center, and the University of Louisiana at Monroe may conduct research on marijuana for therapeutic use ~~if the center is licensed as a production facility pursuant to this Section~~.

(d) ~~Effective January 1, 2020, and annually thereafter~~ On or before February first annually, the Louisiana State University Agricultural Center, ~~and~~ the Southern University Agricultural Center, and the University of Louisiana at Monroe shall each submit ~~a report~~ to the Senate and House committees on health and welfare~~, to include~~ a report which includes data and outcomes of ~~the~~ any research conducted pursuant to Subparagraph (c) of this Paragraph. No such report shall include any proprietary information, intellectual property, or private financial data.

(6)(a) The ~~Department of Agriculture and Forestry~~ Louisiana Department of Health shall collect all of the following information from each licensee:

* * *

(b) The ~~Department of Agriculture and Forestry~~ Louisiana Department of Health shall provide the information collected ~~pursuant to~~ as required by this Paragraph for the previous calendar year in the form of a written report to the ~~Louisiana Legislature~~ legislature no later than February first of each year. The department shall also make a copy of the report required by this Subparagraph available to the public on the ~~Internet~~ internet.

* * *

(8)(a) The ~~department~~ Louisiana Department of Health shall perform the following:

* * *

(iii) Assess a fee of seven percent of the gross sales of therapeutic marijuana. The fee shall be reported and paid by the licensed production facility or permitted contractor that sells therapeutic marijuana to marijuana pharmacies. The fee ~~that~~

shall be collected by the Department of Revenue and shall be subject to the provisions of Chapter 18 of Subtitle II of Title 47 of the Louisiana Revised Statutes of 1950 as amended. Notwithstanding the provisions of Subparagraph (b) of this Paragraph, the Department of Revenue shall transfer monthly to the state treasury for deposit into the Community and Family Support System Fund, as established in R.S. 28:826, the amount of revenues collected in accordance with this Item. An amount shall be allocated to the department, pursuant to legislative appropriation, for regulatory, administrative, investigative, enforcement, legal, and other such expenses as may be necessary to carry out the provisions of this Chapter and for activities associated with the enforcement of law and regulations governing the therapeutic marijuana program.

* * *

§1046.1. Contractors; selection; minimum standards

A. The contractor selected by the licensed university through a competitive bid process to cultivate, extract, process, produce, and transport therapeutic marijuana shall be subject to oversight and inspections by the Louisiana Department of Health as provided in this Section.

B. Initial inspections of contractor facilities shall be conducted in accordance with the following procedures and requirements:

(1) Prior to commencement of operations, the Louisiana Department of Health shall conduct an initial inspection of the contractor's facility, limited strictly to a determination of the following:

(a) That the contractor facility adheres to all of the following:

(i) Is within a building that has a complete roof enclosure supported by connecting walls, constructed of solid materials, that extend from the ground to the roof.

(ii) Has a foundation, slab, or equivalent base to which the floor is securely attached.

(iii) Meets performance standards ensuring that cultivation and processing activities cannot be and are not reasonably perceptible from the structure in terms of

common visual observation, odors, smell, fragrances, or other olfactory stimulus, light pollution, glare, brightness, adequate ventilation to prevent mold, and noise.

(iv) Provides complete visual screening.

(v) Meets the standards of any applicable state and local electrical, fire, plumbing, and building specification codes.

(b) That the contractor possesses and maintains accurate, detailed plans and elevation drawings of all operational areas involved with the cultivation, extraction, processing, and production of therapeutic marijuana.

(c) That the contractor possesses and maintains a written operations plan, which plan shall be limited to standard operating procedures for the cultivation of marijuana in each facility production area, instructions for making each product produced on the premises, equipment operations manuals, procedures for conducting necessary safety checks, sanitization procedures for working surfaces and equipment, quality control procedures, and emergency preparedness procedures.

(d) That the contractor has connection and access to the Louisiana Medical Marijuana Tracking System.

(e) That the contractor has security against unauthorized entry via the presence of operational alarm and video surveillance systems, limited access areas, secure locking systems, and door controls throughout the facility.

(f) The initial inventory and accuracy of inventory reporting.

(g) The existence of current, complete, and accurate personnel records.

(2)(a) Notwithstanding Paragraph (1) of this Subsection, nothing in this Section shall be construed to obstruct or impede the lawful activity of any licensee or permittee.

(b) The provisions of this Subsection are intended to ensure a reliable, adequate, and uninterrupted supply of therapeutic marijuana to Louisiana patients.

C.(1) Inspections of contractor facilities other than initial inspections shall be conducted in accordance with the procedures and requirements provided in Paragraph (2) of this Subsection.

(2) After a contractor commences producing therapeutic marijuana in an approved facility, the Louisiana Department of Health shall inspect each contractor facility at least twice annually to verify the existence or accuracy of the following:

(a) Possession and accuracy of detailed plans and elevation drawings of all operational areas involved with the cultivation, extraction, processing, and production of medical marijuana.

(b) Existence and possession of a current written operations plan.

(c) Connection and accessibility to Louisiana Medical Marijuana Tracking System.

(d) Operational alarm and video surveillance systems.

(e) Secure locks throughout the facility.

(f) Controls to limited access areas.

(g) Current, complete, and accurate personnel records.

(h) Biannual inventory reports.

D. All of the following standards and requirements for security shall apply with respect to contractor facilities:

(1) Any contractor facility alarm or surveillance system shall include the following:

(a) A panic device that sounds an audible alarm and notifies law enforcement.

(b) Surveillance system coverage for all points of ingress and egress to the facility, including but not limited to doorways, windows, and loading bays.

(c) "Duress" or "hold up" features to enable activation of a silent alarm.

(d) Date- and time-stamped recording of all points of ingress and egress, any limited access areas including rooms containing a safe, any room in which any part of the disposal process occurs, and any room or area used to cultivate, extract, process, produce, or store therapeutic marijuana.

(e) Capabilities including continuous recording, archiving, and at least one on-site display monitor connected to the system.

(2) Each contractor facility shall maintain on-site security personnel, at a minimum, during standard United States business hours of eight o'clock a.m. to five o'clock p.m. and shall maintain off-site, electronic security monitoring at all other times.

(3) All surveillance recordings shall be maintained for a minimum of thirty days and access to surveillance controls and monitoring shall be limited to specifically-authorized personnel.

(4) Each contractor shall limit access to and post limited-access signage where marijuana is cultivated, extracted, processed, produced, or stored. Limited access areas shall remain locked and accessible only by authorized personnel.

(5) Each employee, supervisor, or agent of each contractor shall keep a current identification card, in a form approved by the department, on his person when present at a contractor facility.

E. All of the following procedures, restrictions, and authorizations shall apply relative to visitors at contractor facilities:

(1) Persons who do not possess a contractor identification card shall be issued a visitor identification badge after signing a log maintained by the contractor that properly identifies the visitor to the premises. The visitor shall wear the badge for the duration of his time on the premises, and the visitor shall not be left unaccompanied in any area where marijuana or marijuana products are present.

(2) Notwithstanding Paragraph (1) of this Subsection, if it is necessary for a visitor to enter a facility to conduct repairs, maintenance, or other specific duties on the premises, the visitor may be escorted to the work site and left unaccompanied while completing a job if that job is not within a limited access area. If it is necessary for a visitor to enter a facility's limited access area, the visitor shall be escorted to the work area and shall remain accompanied by facility personnel while the work is being completed in the limited access area if marijuana or marijuana products are within the limited access area. The visitor may be left unaccompanied in the limited access area if no marijuana or marijuana products are within the limited access area while the visitor is present. If the visitor is left unaccompanied

in the limited access area, facility personnel shall ensure that the visitor is under video surveillance for the duration of the visitor's time spent on the premises.

F. All of the following requirements shall apply with respect to data management by contractors:

(1) Each contractor shall acquire and maintain all software, hardware, and communications infrastructure necessary to ensure connectivity to and implementation of the Louisiana Medical Marijuana Tracking System, referred to hereafter in this Subsection as the LMMTS, to track therapeutic marijuana from seed to distribution to an approved laboratory, to licensed pharmacies, to another cultivation contractor or to destruction, tagging each plant and product with a unique identification number, and entering the number into LMMTS for tracking. The contractor shall bear the cost of all expenses related to tracking, tagging, and implementation of the LMMTS.

(2) Within twenty-four hours of the respective qualifying event, the contractor shall record the following in the LMMTS:

(a) Any purchase or acquisition of therapeutic marijuana seeds; plants, including immature plants and seedlings; or derivatives thereof.

(b) The sale, transfer, or transport of therapeutic marijuana or its derivatives to another contractor, approved laboratory, or therapeutic marijuana pharmacy.

(c) The disposal of therapeutic marijuana.

(3) Notwithstanding any other provision of this Section, each contractor shall keep all documents and information required by this Part for at least the current year and the three preceding calendar years, including but not limited to business records necessary to fully account for each business transaction conducted by contractor.

G. All of the following standards and requirements shall apply to contractors' inventory:

(1) Each contractor shall maintain a comprehensive inventory of all marijuana, including without limitation usable marijuana available for dispensing, mature marijuana plants, and seedlings at each authorized location. Following an initial inventory, all marijuana shall be inventoried on a weekly basis.

(2) Any therapeutic marijuana waste product shall be properly weighed and recorded in the Louisiana Medical Marijuana Tracking System and stored in a limited-access area of a contractor facility until rendered unusable.

H. Material safety data sheet requirements shall include all of the following:

(1) Any pesticides or chemicals used by a contractor in the production of therapeutic marijuana shall be used and stored according to the contractor's written operations plan.

(2) Each contractor shall maintain a material safety data sheet in each facility area where toxic cleaning compounds, sanitizing agents, solvents used in the production of therapeutic marijuana extracts and concentrates, pesticide chemicals, or other agricultural chemicals are used or stored.

(3) Each contractor shall record the following information when applying a pesticide or other agricultural chemical to therapeutic marijuana at any cultivation stage:

(a) The date and time of the pesticide or chemical application.

(b) The name of each individual who applied the pesticide or chemical.

(c) The identification number of all batches receiving the application.

(d) The amount and name of the pesticide or chemical applied, including the United States Environmental Protection Agency registration number, if any.

I. All of the following requirements shall apply to transportation of therapeutic marijuana by contractors:

(1) Prior to transporting therapeutic marijuana, a contractor shall generate an inventory manifest in the Louisiana Medical Marijuana Tracking System, referred to hereafter in this Subsection as the LMMTS, including all of the following information:

(a) The name of the contractor originating the transport.

(b) The name of the contractor, approved laboratory, or licensed pharmacy receiving the transport.

(c) The quantity by weight or unit of each type of therapeutic marijuana product contained in the transport.

(d) The date and approximate departure and arrival times for the transport.

(e) The identity of the agent or agents accompanying the transport.

(f) The make, model, and license plate number of the transport delivery vehicle.

(2) The contractor originating the transport shall provide the contractor, approved laboratory, or licensed pharmacy receiving the transport with a copy of the LMMTS inventory manifest, which shall not be altered after departing the originating contractor's facility.

(3) The contractor, approved laboratory, or licensed pharmacy receiving the transport shall record the quantities of all therapeutic marijuana products in the LMMTS. However, any contractor, approved laboratory, or licensed pharmacy receiving a therapeutic marijuana transport shall refuse the transport if it is not accompanied by an unaltered LMMTS inventory manifest.

§1046.2. Therapeutic marijuana laboratory; licensure and renewal requirements

A.(1) Prior to analyzing, testing, or handling therapeutic marijuana in Louisiana, an applicant for a therapeutic marijuana laboratory license shall submit an initial license application on a form and in a manner prescribed by the Louisiana Department of Health, referred to hereafter in this Section as the "department".

(2) Approved laboratories may include the Department of Agriculture and Forestry agricultural chemistry laboratory; the colleges, universities, other institutions, and systems governed by the Louisiana Board of Regents; public-private partnerships involving the systems, colleges and universities governed by the Louisiana Board of Regents and private laboratories; and private laboratories. The Department of Agriculture Forestry agricultural chemistry laboratory shall be exempt from the application process and deemed approved but shall comply with Subparagraphs (d) and (e) of this Paragraph. All other applicants shall meet all of the following requirements:

(a) Provide proof of accreditation through either of the following:

(i) Be accredited by the National Institute on Drug Abuse, the National Environmental Laboratory Accreditation Conference, the International Organization

for Standardization, or other accrediting entity approved by the department, which accreditation shall be maintained in active and good standing or other substantially similar status for the duration of licensure.

(ii) Comply with both of the following criteria:

(aa) Provide documentation that the owner has operated a state-approved, active medical marijuana laboratory in another state for at least the past twelve months.

(bb) Be accredited by the International Organization for Standardization or other accrediting entity approved by the department or have an application pending for International Organization for Standardization accreditation. If the accreditation is not achieved within nine months of the department's inspection, the department shall not accept any additional certificates of analysis from the laboratory until the accreditation is received.

(b) Employ or hire a laboratory director or other qualifying individual. The laboratory director or other qualifying individual and any persons involved in the testing of marijuana or marijuana products or whose involvement with the laboratory requires or authorizes access to restricted limited access areas of the laboratory shall obtain a permit in accordance with the requirements of R.S. 40:1047.

(c) Submit to at least one on-site facility inspection conducted by the department prior to licensure.

(d) Implement and utilize the Louisiana Medical Marijuana Tracking System (LMMTS) computerized inventory tracking system to post accurate analyses and results, which shall be subject to review by the department. Payment of any costs associated with access to or implementation or use of LMMTS shall be the responsibility of the laboratory exclusively.

(e) Demonstrate acceptable laboratory performance standards regarding accuracy, precision, proficiency, reportable ranges, specificity, or other quality controls required by the department.

B.(1) Each therapeutic marijuana laboratory license shall be effective for one year and shall be renewed on or before December thirty-first annually.

(2) Each therapeutic marijuana laboratory licensee shall apply for license renewal on or before October thirty-first each year on a form and in a manner prescribed by the department.

(3) Any therapeutic marijuana laboratory license not timely renewed as required by this Subsection shall expire on December thirty-first at midnight. Upon expiration of the license, the laboratory shall cease all operations and destroy all marijuana or marijuana products physically remaining at its location.

(4) Prior to granting a license renewal application, the department shall ensure that the therapeutic marijuana laboratory licensee continues to meet the requirements of this Part, including but not limited to the licensee's compliance with Subsection A of this Section and its good standing with applicable requirements of the secretary of state. The department shall conduct an out-of-cycle inspection of the therapeutic marijuana laboratory licensee if necessary to ensure acceptable lab performance standards, accuracy, precision, proficiency, reportable ranges, specificity, or other quality controls and assurances necessary to protect Louisiana patients.

§1046.3. Testing; sample collection; minimum standards; reporting; remediation

A.(1) Each contractor permitted to cultivate, extract, process, produce, and transport therapeutic marijuana pursuant to this Part shall comply with approved minimum standards by making each batch of therapeutic marijuana subject to random selection, sampling, and analysis conducted by an independent approved laboratory collector in a volume sufficient to ensure compliance.

(2) Each therapeutic marijuana laboratory licensed according to this Part shall maintain test results for no less than three years.

(3) The laboratory shall record test results in the Louisiana Medical Marijuana Tracking System and produce a certificate of analysis to be delivered to the Louisiana Department of Health and contractor permitted to cultivate, extract, process, produce, and transport therapeutic marijuana within twenty-four hours of test completion.

B. Each batch of medical marijuana finished product shall pass all applicable testing standards, including appropriate microbial and fungal limits, acceptable standards for pesticide chemical residues, appropriate residual solvent and heavy metals limits, homogeneity for concentrates and extracts, and complete active ingredient analysis or potency analysis prior to transportation to a medical marijuana pharmacy. The administrative rules of the Louisiana Department of Health shall allow for a variance of no greater than plus fifteen percent or minus fifteen percent from the labeled amount of active ingredients in the ingredient analysis or potency analysis.

C.(1) Neither a contractor nor an approved laboratory authorized pursuant to this Part shall release or approve a therapeutic marijuana product for delivery or sale until a sample from the applicable product batch has complied with all required testing standards.

(2) A contractor may resubmit to an approved laboratory any sample that fails one or more initial tests required by this Part. The sample may be released for delivery and sale only if it passes all tests conducted by an approved laboratory in duplicate. The sample may be remediated according to any reasonably acceptable industry methods if it fails one or more tests conducted by an approved laboratory.

(3) Any remediated sample shall pass remediation testing in duplicate prior to approval for delivery and sale.

(4) A product may be remediated only once, and any product failing remediation testing shall be destroyed within sixty days of the failed test, in addition to the timely destruction of the entire batch from which the sample was collected.

Section 2. R.S. 40:1046(C)(2)(d), (e), and (h) and (H)(3) through (5) are hereby repealed in their entirety.

Section 3. The Department of Agriculture and Forestry, through its agricultural chemistry laboratory, shall continue performing required testing of marijuana produced for therapeutic use according to applicable rules and regulations in effect on the effective date of this Act, subject to any overriding emergency or permanent testing rules and regulations promulgated by the Louisiana Department of Health, until at least two additional laboratories

are approved by the Louisiana Department of Health and have both been operational for a minimum of six months to ensure a reliable, adequate, and uninterrupted supply of therapeutic marijuana to Louisiana patients.

Section 4. To prevent any disruption to the supply chain and to ensure uninterrupted availability of products for patients, if not otherwise provided in this Act, the Louisiana Department of Health shall temporarily follow the applicable rules relative to marijuana for therapeutic use promulgated by the Department of Agriculture and Forestry until such time as it adopts all necessary emergency rules and permanent rules relating to cultivation, extraction, processing, production, and transportation of marijuana for therapeutic use including but not limited to the approval of product labels and packaging.

SPEAKER OF THE HOUSE OF REPRESENTATIVES

PRESIDENT OF THE SENATE

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____

RS 40:1046

PART X-E. THERAPEUTIC USE OF MARIJUANA

§1046. Recommendation and dispensing of marijuana for therapeutic use; rules and regulations of the Louisiana Board of Pharmacy; production facility licensing; permitting by the Louisiana Department of Health

A.(1) Notwithstanding any other provision of this Part, any clinician authorized by the provisions of Subsection B of this Section to recommend medical marijuana, referred to in this Section as an "authorized clinician", may recommend, in any form as permitted by the rules and regulations of the Louisiana Board of Pharmacy, raw or crude marijuana, tetrahydrocannabinols, or a chemical derivative of tetrahydrocannabinols for therapeutic use by any patient clinically diagnosed as suffering from a debilitating medical condition.

(2)(a) For purposes of this Subsection, "debilitating medical condition" means any of the following:

(i) Cancer.

(ii) Glaucoma.

(iii) Any of the following neurodegenerative diseases and conditions:

(aa) Alzheimer's disease.

(bb) Amyotrophic lateral sclerosis.

(cc) Huntington's disease.

(dd) Lewy body dementia.

(ee) Motor neuron disease.

(ff) Parkinson's disease.

(gg) Spinal muscular atrophy.

(iv) Positive status for human immunodeficiency virus.

(v) Acquired immune deficiency syndrome.

(vi) Cachexia or wasting syndrome.

(vii) Seizure disorders.

(viii) Epilepsy.

(ix) Spasticity.

(x) Severe muscle spasms.

(xi) Intractable pain.

(xii) Crohn's disease.

(xiii) Muscular dystrophy.

(xiv) Multiple sclerosis.

(xv) Posttraumatic stress disorder.

(xvi) Any of the following conditions associated with autism spectrum disorder:

(aa) Repetitive or self-stimulatory behavior of such severity that the physical health of the person with autism is jeopardized.

(bb) Avoidance of others or inability to communicate of such severity that the physical health of the person with autism is jeopardized.

(cc) Self-injuring behavior.

(dd) Physically aggressive or destructive behavior.

(xvii) Traumatic brain injury.

(xviii) A concussion diagnosed by an authorized clinician.

(xix) Chronic pain associated with fibromyalgia.

(xx) Chronic pain associated with sickle cell disease.

(xxi) Any condition for which a patient is receiving hospice care or palliative care.

(xxii) Any condition not otherwise specified in this Subparagraph that an authorized clinician, in his clinical opinion, considers debilitating to an individual patient and is qualified through his clinical education and training to treat.

(b) No authorized clinician shall recommend medical marijuana for treatment of any condition associated with autism spectrum disorder for a patient who is under the age of eighteen unless the clinician complies with the provisions of this Section and consults with a pediatric subspecialist. For purposes of this Subparagraph, a pediatric subspecialist is an individual licensed to practice medicine in any state in the United States who provides care to patients with autism spectrum disorder.

(c) Intractable pain means a pain state in which the cause of the pain cannot be removed or otherwise treated with the consent of the patient and which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none has been found after reasonable efforts. It is pain so chronic and severe as to otherwise warrant an opiate prescription.

(d) Repealed by Acts 2019, No. 284, §2.

(e) Repealed by Acts 2019, No. 284, §2.

(3) For purposes of this Part, "recommend" or "recommended" means an opinion of any authorized clinician, provided within a bona fide clinician-patient relationship, that, in the sincere judgment of the clinician, therapeutic cannabis may be helpful to the patient's condition or symptoms and is communicated by any means allowed by the Louisiana Board of Pharmacy.

(4) Any authorized clinician may recommend medical marijuana to any patient suffering from a debilitating medical condition with whom he shares a bona fide clinician-patient relationship.

(5)(a) No pharmacy authorized to dispense marijuana for therapeutic use in accordance with the provisions of this Section shall dispense more than two and one-half ounces, or seventy-one grams, of raw or crude marijuana every fourteen days to any individual patient.

(b) No pharmacy authorized to dispense marijuana for therapeutic use in accordance with the provisions of this Section shall dispense raw or crude marijuana to any person under twenty-one years of age without a recommendation from an authorized clinician specifically recommending marijuana in raw or crude form for that person.

(6) Authorized clinicians shall report adverse events and health outcomes associated with a patient's use of medical marijuana to the data system provided for in R.S. 40:1168.1 et seq.

(7) Nothing in this Subsection shall be construed to prevent the Louisiana Board of Pharmacy from permitting, by rule, medical marijuana in a form to be administered by metered-dose inhaler. For purposes of this Section, "metered-dose inhaler" means a device that delivers a specific amount of medication to the lungs, in the form of a short burst of medicine that is usually self-administered by the patient via inhalation.

B. All of the following licensed health professionals are hereby authorized to recommend medical marijuana to patients and, for purposes of this Part, shall be deemed "authorized clinicians":

(1) Any physician licensed by and in good standing with the Louisiana State Board of Medical Examiners to practice medicine in this state.

(2) Any nurse practitioner licensed by and in good standing with the Louisiana State Board of Nursing to practice advanced practice registered nursing in this state and who has prescriptive authority conferred by the Louisiana State Board of Nursing.

(3) Any medical psychologist licensed by and in good standing with the Louisiana State Board of Medical Examiners to practice medical psychology in this state.

C.(1) The Louisiana Board of Pharmacy shall adopt rules relating to therapeutic marijuana.

(2) The rules promulgated pursuant to this Subsection shall include but not be limited to:

(a) Standards, procedures, and protocols for the effective use of recommended marijuana for therapeutic use as authorized by state law and related rules and regulations.

(b) Standards, procedures, and protocols for the dispensing and tracking of recommended therapeutic marijuana in Louisiana.

(c) Procedures and protocols to provide that no recommended therapeutic marijuana may be dispensed from, produced from, obtained from, sold to, or transferred to a location outside of this state.

(d) Repealed by Acts 2022, No. 491, §2.

(e) Repealed by Acts 2022, No. 491, §2.

(f) The establishment of standards and procedures for the revocation, suspension, and nonrenewal of licenses.

(g) The establishment of other licensing, renewal, and operational standards which are deemed necessary by the Louisiana Board of Pharmacy.

(h) Repealed by Acts 2022, No. 491, §2.

(i) The establishment of health, safety, and security requirements for dispensers of recommended therapeutic marijuana.

(j) Licensure of dispensers of recommended therapeutic marijuana.

(k) The establishment of financial requirements for applicants of therapeutic marijuana dispensing pharmacy license under which each applicant demonstrates the following:

(i) The financial capacity to operate a therapeutic marijuana dispensing pharmacy.

(ii) The ability to maintain an escrow account in a financial institution headquartered in Louisiana in an amount of two million dollars, if required by the Louisiana Board of Pharmacy.

(l) The limitations on dispensing of raw or crude marijuana as provided in Paragraph (A)(5) of this Section.

D. Nothing in this Section shall be construed to prohibit the Louisiana State Board of Medical Examiners or the Louisiana Board of Pharmacy from adopting emergency rules as otherwise provided for in the Administrative Procedure Act.

E. Marijuana, tetrahydrocannabinols, or a chemical derivative of tetrahydrocannabinols recommended pursuant to this Section shall be dispensed in person from a licensed pharmacy in good standing located in Louisiana.

F.(1) A person who recommends and a person who dispenses marijuana, tetrahydrocannabinols, or a chemical derivative of tetrahydrocannabinols pursuant to this Section shall review the patient's information in the database of the prescription monitoring program established in R.S. 40:1001 et seq. prior to the recommending and dispensing thereof.

(2) Any person who dispenses marijuana, tetrahydrocannabinols, or a chemical derivative of tetrahydrocannabinols pursuant to this Section shall comply with the reporting requirements of the prescription monitoring program established in R.S. 40:1001 et seq.

G.(1)(a) The Louisiana Board of Pharmacy shall develop an annual license for a pharmacy to dispense recommended marijuana for therapeutic use and, except as provided in Paragraph (3) of this Subsection, shall limit the number of licenses granted in the state to no more than ten licenses. Except as provided in Subparagraph (b) of this Paragraph, the board shall award one license per region as delineated in Paragraph (2) of this Subsection and one additional license to the region with the highest population density as of August 1, 2022, and shall award each license through a competitive process. The board shall consider the status of an applicant as a minority-, woman-, or veteran-owned business as a primary factor in awarding a license.

(b) The transfer of a membership interest in an entity operating a pharmacy licensed by the

Louisiana Board of Pharmacy to dispense recommended marijuana for therapeutic use shall be subject to approval of the board in the same manner required for the transfer of a membership interest in any other pharmacy licensed by the board.

(2) For the purposes of this Subsection, the regions among which the Louisiana Board of Pharmacy shall allocate marijuana pharmacy licenses shall correspond to the sets of parishes comprising, respectively, the administrative regions of the Louisiana Department of Health as those regions existed on August 1, 2022. On and after October 1, 2022, at least one licensed marijuana pharmacy shall be located in each region.

(3)(a) After three thousand five hundred active, qualified patients are identified in the prescription monitoring program in a region, the Louisiana Board of Pharmacy shall notify and allow the marijuana pharmacy licensee in that region to open one additional marijuana pharmacy location as a satellite location in that region. For the purposes of this Paragraph, "satellite location" shall mean an additional marijuana pharmacy location operated by a marijuana pharmacy licensee within the licensee's geographic region but physically separate from the location of the originally licensed therapeutic marijuana pharmacy.

(b) After seven thousand active, qualified patients are identified in the prescription monitoring program in a region, the Louisiana Board of Pharmacy shall notify and allow the marijuana pharmacy licensee in that region to open one additional marijuana pharmacy location as a second satellite location in that region.

(c) The licensee shall submit an application to open a satellite location provided for in this Paragraph no later than ninety days after receipt of the notification sent by the Louisiana Board of Pharmacy pursuant to Subparagraph (b) of this Paragraph to inform the licensee of his eligibility to open a satellite location. The satellite location shall be operational within three hundred ten days of the approval of the application by the Louisiana Board of Pharmacy. The Louisiana Board of Pharmacy may grant additional time for the satellite location to become operational due to a circumstance beyond the control of the licensee. If a marijuana pharmacy licensee declines to open a satellite location pursuant to Subparagraph (a) or (b) of this Paragraph, then the Louisiana Board of Pharmacy may issue, pursuant to the provisions of Paragraph (1) of this Subsection, an additional marijuana pharmacy license in that region to open one marijuana pharmacy location in lieu of the original licensee's satellite location in that region.

(d) The board shall consider any unserved parishes within the region when approving a satellite location or additional marijuana pharmacy for licensure pursuant to this Paragraph.

(e) For the purposes of this Paragraph, the active, qualified patient count shall be conducted and reviewed on a quarterly basis using the preceding three-month period.

(4)(a) The total number of marijuana pharmacy locations, including satellite locations, approved by the Louisiana Board of Pharmacy pursuant to Paragraph (3) of this Subsection shall not be greater than thirty locations.

(b) The provisions of this Paragraph shall not be construed to authorize a marijuana pharmacy licensee to open more than two satellite locations in a single region.

(5) The provisions of this Subsection shall not be construed to require the closure of any marijuana pharmacy location, including satellite locations, if the active, qualified patient count drops below three thousand five hundred after the location is approved by the board.

(6)(a) No marijuana pharmacy shall locate within a fifteen-mile radius of another license holder's marijuana pharmacy.

(b) Notwithstanding the provisions of Subparagraph (a) of this Paragraph, in a region that encompasses any parish with a population of more than three hundred fifty thousand persons according to the most recent federal decennial census, no marijuana pharmacy shall locate within a ten-mile radius of another license holder's marijuana pharmacy.

(c) Notwithstanding the provisions of Subparagraphs (a) and (b) of this Paragraph, in a region that encompasses any municipality with a population of more than three hundred fifty thousand persons according to the most recent federal decennial census, no marijuana pharmacy shall locate within a five-mile radius of another license holder's marijuana pharmacy.

(7) Each marijuana pharmacy licensed in accordance with the provisions of this Subsection shall offer home delivery to patients in each zip code within its region at least once per month.

(8) For purposes of this Subsection, "active, qualified patient" means a patient who has acquired a therapeutic marijuana product at least once.

H.(1)(a) The legislature hereby recognizes and declares that both the Louisiana State University Agricultural Center and the Southern University Agricultural Center timely exercised and asserted the intent of each university to be licensed to produce recommended marijuana for therapeutic use in this state in accordance with the provisions of Act No. 261 of the 2015 Regular Session of the Legislature of Louisiana.

(b) Each institution identified in Subparagraph (a) of this Paragraph, respectively, shall select and contract with only one contractor authorized to produce therapeutic marijuana in accordance with this Part. The selection process and contracting provided for in this Subparagraph shall be done in accordance with all applicable provisions of the Louisiana Procurement Code, R.S. 39:1551 et seq. Each contractor and the university with which it contracts shall execute an agreement for services.

(2) The Louisiana Department of Health shall issue all of the following annually:

(a) A nontransferable specialty license for the production of recommended marijuana for therapeutic use, which the department shall issue only to the Louisiana State University Agricultural Center and the Southern University Agricultural Center.

(b) A permit to cultivate, extract, process, produce, and transport therapeutic marijuana, which the department shall issue only to the sole contractor selected by each university in accordance with Paragraph (1) of this Subsection.

(c) The Louisiana State University Agricultural Center, the Southern University Agricultural Center, and the University of Louisiana at Monroe may conduct research on marijuana for therapeutic use.

(d) On or before February first annually, the Louisiana State University Agricultural Center, the Southern University Agricultural Center, and the University of Louisiana at Monroe shall each submit to the Senate and House committees on health and welfare a report which includes data and outcomes of any research conducted pursuant to Subparagraph (c) of this Paragraph. No such report shall include any proprietary information, intellectual property, or private financial data.

(3) Repealed by Acts 2022, No. 491, §2.

(4) Repealed by Acts 2022, No. 491, §2.

(5) Repealed by Acts 2022, No. 491, §2.

(6)(a) The Louisiana Department of Health shall collect all of the following information from each licensee:

(i) The amount of gross marijuana produced by the licensee during each calendar year.

(ii) The details of all production costs including but not limited to seed, fertilizer, labor, advisory services, construction, and irrigation.

(iii) The details of any items or services for which the licensee subcontracted and the costs of each subcontractor directly or indirectly working for the contractor.

(iv) The amount of therapeutic chemicals produced resulting from the marijuana grown pursuant to this Section.

(v) The amounts paid each year to the licensee related to the licensee's production of therapeutic marijuana pursuant to this Section.

(vi) The amount of therapeutic marijuana distributed to each pharmacy licensed to dispense therapeutic marijuana in this state during each calendar year.

(b) The Louisiana Department of Health shall provide the information collected as required by this Paragraph for the previous calendar year in the form of a written report to the legislature no later than February first of each year. The department shall also make a copy of the report required by this Subparagraph available to the public on the internet.

(7) No company that has made a contribution to a candidate in a Louisiana election governed by the provisions of the Campaign Finance Disclosure Act within the five years prior to bidding for the license, or is controlled wholly or in part by a person who made such a contribution within the five years prior to the company bidding for the license, may be eligible for the license.

(8)(a) The Louisiana Department of Health shall perform the following:

(i) Establish and collect an annual license fee of one hundred thousand dollars from each contractor permitted to cultivate, extract, process, produce, and transport therapeutic marijuana.

(ii) Collect a nonrefundable application fee of ten thousand dollars.

(iii) Assess a fee of seven percent of the gross sales of therapeutic marijuana. The fee shall be reported and paid by the licensed production facility or permitted contractor that sells therapeutic marijuana to marijuana pharmacies. The fee shall be collected by the Department of Revenue and shall be subject to the provisions of Chapter 18 of Subtitle II of Title 47 of the Louisiana Revised Statutes of 1950 as amended. Notwithstanding the provisions of Subparagraph (b) of this Paragraph, the Department of Revenue shall transfer monthly to the state treasury for deposit into the Disability Services Fund, as established in R.S. 28:826, the amount of revenues collected in accordance with this Item. An amount shall be allocated to the department, pursuant to legislative appropriation, for regulatory, administrative, investigative, enforcement, legal, and other such expenses as may be necessary to carry out the provisions of this Chapter and for activities associated with the enforcement of law and regulations governing the therapeutic marijuana program.

(b) All fees collected by the department shall be used to fund the expenses relating to the regulation and control of therapeutic marijuana.

I. The levels of THC in any marijuana produced pursuant to this Section shall be reduced to the lowest acceptable therapeutic levels available through scientifically accepted methods.

J. Notwithstanding any other provision of law to the contrary, employers and their worker's compensation insurers shall not be obliged or ordered to pay for medical marijuana in claims arising under Title 23 of the Louisiana Revised Statutes of 1950, the Louisiana Workers' Compensation Law.

NOTE: Subsection K eff. until Jan. 1, 2024. See Acts 2023, No. 322.

K. Nothing in this Part shall be construed or enforced in any manner that prevents a physician authorized by Subsection A of this Section to recommend therapeutic marijuana from recommending therapeutic marijuana through telemedicine, as defined in R.S. 37:1262, in this state.

NOTE: Subsection K as amended by Acts 2023, No. 322, eff. Jan. 1, 2024.

K. Nothing in this Part shall be construed or enforced in any manner that prevents a clinician authorized by Subsection A of this Section to recommend therapeutic marijuana from recommending therapeutic marijuana through telehealth as defined in R.S. 40:1223.3 in this state.

L. The provisions of this Section shall terminate on January 1, 2025.

Acts 1991, No. 874, §1; Acts 2006, No. 676, §3, eff. July 1, 2006; Acts 2015, No. 261, §1, eff. June 29, 2015; Acts 2016, No. 96, §§1, 2, eff. May 19, 2016; Acts 2016, No. 567, §1; Acts 2018, No. 206, §4; Acts 2018, No. 496, §§1, 2, eff. May 23, 2018; Acts 2018, No. 708, §§1, 2; Acts 2018, No. 715, §§1, 2; Acts 2019, No. 207, §§1, 3; Acts 2019, No. 284, §§1, 2; Acts 2019, No. 331, §§2, 3, eff. July 1, 2019; Acts 2020, No. 286, §§1, 2; Acts 2021, No. 424, §1, eff. Jan. 1, 2022; Acts 2022, No. 271, §4; Acts 2022, No.

444, §1; Acts 2022, No. 491, §§1, 2; Acts 2022, No. 492, §1, eff. June 16, 2022; Acts 2023, No. 311, §1, eff. June 13, 2023; Acts 2023, No. 322, §4, eff. Jan. 1, 2024.