HLS 22RS-883 ORIGINAL

2022 Regular Session

HOUSE BILL NO. 697

1

BY REPRESENTATIVE MAGEE

MEDICAL MARIJUANA: Reforms the state systems for regulating the production of marijuana for therapeutic use and for the dispensing of such product

AN ACT

2 To amend and reenact R.S. 40:1046(A)(1), (C)(1) and (2)(introductory paragraph), (g), and 3 (h), (G), and (H)(1), (2), and (6)(a)(introductory paragraph) and (b), to enact R.S. 4 40:1046(A)(7), (B), and 1046.1 through 1046.3, and to repeal R.S. 40:1046(H)(3) 5 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 6 7 with respect to such regulation from the Department of Agriculture and Forestry to 8 the Louisiana Department of Health; to provide relative to permitting and regulation 9 of marijuana pharmacies by the Louisiana Board of Pharmacy; to require the board 10 to license and regulate laboratories that conduct testing of medical marijuana 11 products; to provide for selection of marijuana production contractors by licensed 12 producers of medical marijuana; to provide for oversight and regulation of such 13 contractors; to provide requirements and standards for the business operations of 14 such contractors; to require the continuation of certain laboratory testing services 15 provided by the Department of Agriculture and Forestry; to provide for 16 effectiveness; and to provide for related matters.

17 Be it enacted by the Legislature of Louisiana:

18 Section 1. R.S. 40:1046(A)(1), (C)(1) and (2)(introductory paragraph), (g), and (h),

19 (G), and (H)(1), (2), and (6)(a)(introductory paragraph) and (b) are hereby amended and

CODING: Words in struck through type are deletions from existing law; words <u>underscored</u> are additions.

1	reenacted and R.S. 40:1046(A)(7), (B), and 1046.1 through 1046.3 are hereby enacted to
2	read as follows:
3	§1046. Recommendation and dispensing of marijuana for therapeutic use; rules and
4	regulations of the Louisiana State Board of Medical Examiners and
5	Louisiana Board of Pharmacy; production facility licensing; by the
6	Department of Agriculture and Forestry permitting by the Louisiana
7	Department of Health
8	A.(1) Notwithstanding any other provision of this Part, any physician
9	licensed by and in good standing with the Louisiana State Board of Medical
10	Examiners to practice medicine in this state may recommend, in any form as
11	permitted by the rules and regulations of the Louisiana Board of Pharmacy, raw or
12	crude marijuana, tetrahydrocannabinols, or a chemical derivative of
13	tetrahydrocannabinols for therapeutic use by any patient clinically diagnosed as
14	suffering from a debilitating medical condition. Nothing in this Paragraph shall be
15	construed to prevent the Louisiana Board of Pharmacy from permitting, by rule,
16	medical marijuana in a form to be administered by metered-dose inhaler. For
17	purposes of this Section, "metered-dose inhaler" means a device that delivers a
18	specific amount of medication to the lungs, in the form of a short burst of medicine
19	that is usually self-administered by the patient via inhalation.
20	* * *
21	(7) Nothing in this Paragraph shall be construed to prevent the Louisiana
22	Board of Pharmacy from permitting, by rule, medical marijuana in a form to be
23	administered by metered-dose inhaler. For purposes of this Section, "metered-dose
24	inhaler" means a device that delivers a specific amount of medication to the lungs,
25	in the form of a short burst of medicine that is usually self-administered by the
26	patient via inhalation.
27	B. Nothing in this Part shall be construed or enforced in any manner that
28	prevents a physician authorized by Subsection A of this Section to recommend

2	telemedicine, as defined in R.S. 37:1262, in this state.
3	C.(1) The Louisiana Board of Pharmacy shall adopt rules relating to the
4	dispensing of recommended marijuana for therapeutic use therapeutic marijuana.
5	Any rules published by the Louisiana Board of Pharmacy board on or before January
6	1, 2016, that describe the pharmacist as dispensing medical marijuana based on a
7	physician's prescription should be repromulgated to indicate that the physician is
8	"recommending" use of therapeutic marijuana.
9	(2) The rules <u>promulgated pursuant to this Subsection</u> shall include but not
10	be limited to:
11	* * *
12	(g) The establishment of other licensing, renewal, and operational standards
13	which are deemed necessary by the Louisiana Board of Pharmacy. Licensing,
14	renewal, and operational standards including but not limited to therapeutic marijuana
15	product labeling and packaging approval.
16	(h) The establishment of standards and procedures for testing recommended
17	therapeutic marijuana samples for levels of tetrahydrocannabinol (THC) or other
18	testing parameters deemed appropriate by the Louisiana Board of Pharmacy. Testing
19	standards deemed appropriate by the board, including but not limited to testing of
20	therapeutic marijuana samples for appropriate microbial and fungal limits,
21	acceptable standards for pesticide chemical residues, appropriate residual solvent and
22	heavy metals limits, homogeneity for concentrates and extracts, and complete active
23	ingredient analysis or potency analysis to establish the presence of all active
24	ingredients and their concentrations for accurate calculations of amounts needed for
25	the production of products and to ensure accurate dosing. The rules shall allow for
26	a variance of no greater than plus fifteen percent or minus fifteen percent from the
27	labeled amount of active ingredients in the ingredient analysis or potency analysis.
28	* * *

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G.	(1) The Louisiana Board of Pharmacy shall develop an annual,
nontransfe	erable specialty license permit for a pharmacy to dispense recommended
marijuana	for therapeutic use and shall limit the number of such licenses granted in
the state t	to no more than ten licensees. The Louisiana Board of Pharmacy shall
develop ru	ules and regulations regarding the geographical locations of dispensing
pharmacie	es in Louisiana. For purposes of allocating marijuana pharmacy permits
pursuant to	o this Subsection, the board shall recognize as regions of the state all of the
following:	<u>:</u>
<u>(a)</u>	The Metropolitan Region, which shall be comprised of the parishes of
Jefferson,	Orleans, Plaquemines, and Saint Bernard.
<u>(b)</u>	The Capital Region, which shall be comprised of the parishes of
Ascension	n, East Baton Rouge, East Feliciana, Iberville, Pointe Coupee, West Baton
Rouge, an	d West Feliciana.
<u>(c)</u>	The Teche Region, which shall be comprised of the parishes of
Assumption	on, Lafourche, Saint Charles, Saint James, Saint John the Baptist, Saint
Mary, and	Terrebonne.
<u>(d)</u>	The Acadiana Region, which shall be comprised of the parishes of
Acadia, E	vangeline, Iberia, Lafayette, Saint Landry, Saint Martin, and Vermilion.
<u>(e)</u>	The Southwest Region, which shall be comprised of the parishes of
Allen, Bea	auregard, Calcasieu, Cameron, and Jefferson Davis.
<u>(f)</u>	The Central Region, which shall be comprised of the parishes of
Avoyelles	, Catahoula, Concordia, Grant, LaSalle, Rapides, Vernon, and Winn.
<u>(g)</u>	The Northwest Region, which shall be comprised of the parishes of
Bienville,	Bossier, Caddo, Claiborne, DeSoto, Natchitoches, Red River, Sabine, and
Webster.	
<u>(h)</u>	The Northeast Region, which shall be comprised of the parishes of
Caldwell,	East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita,
Richland	Tensas, Union, and West Carroll.

2	Livingston, Saint Helena, Saint Tammany, Tangipahoa, and Washington.
3	(2) The board shall reserve one marijuana pharmacy permit for each of the
4	nine regions identified in Paragraph (1) of this Subsection. Within three months
5	after the registration of five thousand qualified patients, as recorded in the
6	prescription monitoring program, within any region identified in Paragraph (1) of
7	this Subsection, the board shall issue to an existing marijuana pharmacy licensed and
8	operating in that region one additional marijuana pharmacy permit for a location in
9	the region. Thereafter, the board shall issue an additional marijuana pharmacy
10	permit after the registration of each additional increment of five thousand qualified
11	patients, as recorded in the prescription monitoring program, within any region
12	identified in Paragraph (1) of this Subsection.
13	(3) No marijuana pharmacy shall locate within a five-mile radius of another
14	marijuana pharmacy.
15	(4) Each marijuana pharmacy shall offer home delivery to each zip code with
16	active qualified patients within its respective region at least once per month.
17	H.(1)(a) The Department of Agriculture and Forestry shall develop the rules
18	and regulations regarding the extraction, processing, and production of
19	recommended therapeutic marijuana and the facility producing therapeutic
20	marijuana. The rules and regulations shall require as a minimum standard that the
21	extraction and refining process produce a product that is food-safe and capable of
22	producing pharmaceutical-grade products. The legislature hereby recognizes and
23	declares that both the Louisiana State University Agricultural Center and the
24	Southern University Agricultural Center timely exercised and asserted the intent of
25	each university to be licensed to produce recommended marijuana for therapeutic use
26	in this state in accordance with the provisions of Act No. 261 of the 2015 Regular
27	Session of the Legislature of Louisiana.
28	(b) The rules and regulations shall also include but not be limited to the
29	procedures for application, qualifications, eligibility, background checks, and

(i) The Southeast Region, which shall be comprised of the parishes of

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.

1	(c) The Louisiana State University Agricultural Center or the Southern
2	University Agricultural Center may conduct research on marijuana for therapeutic
3	use if the center is licensed as a production facility pursuant to this Section.
4	(d) Effective January 1, 2020, and annually thereafter On or before February
5	1 annually, the Louisiana State University Agricultural Center and the Southern
6	University Agricultural Center shall each submit a report to the Senate and House
7	committees on health and welfare, to include a report which includes data and
8	outcomes of the any research conducted pursuant to Subparagraph (c) of this
9	Paragraph. No such report shall include any proprietary information, intellectual
10	property, or private financial data.
11	(6)(a) The Department of Agriculture and Forestry Louisiana Department of
12	<u>Health</u> shall collect <u>all of</u> the following information from each licensee:
13	* * *
14	(b) The Department of Agriculture and Forestry <u>Louisiana Department of</u>
15	Health shall provide the information collected pursuant to as required by this
16	Paragraph for the previous calendar year in the form of a written report to the
17	Louisiana Legislature legislature no later than February first of each year. The
18	department shall also make a copy of the report required by this Subparagraph
19	available to the public on the internet.
20	* * *
21	§1046.1. Contractors; selection; minimum standards
22	A. The contractor selected by the licensed university through a competitive
23	bid process to cultivate, extract, process, produce, and transport therapeutic
24	marijuana shall be subject to oversight by its licensed university and inspections by
25	the Louisiana Department of Health as provided in this Section.
26	B. Initial inspections of contractor facilities shall be conducted in accordance
27	with the following procedures and requirements:

1	(1) Prior to commencement of operations, the Louisiana Department of
2	Health and the licensed university shall conduct an initial inspection of the
3	contractor's facility, limited strictly to a determination of the following:
4	(a) That the contractor facility adheres to all of the following:
5	(i) Is within a building that has a complete roof enclosure supported by
6	connecting walls, constructed of solid materials, and extending from the ground to
7	the roof.
8	(ii) Has a foundation, slab, or equivalent base to which the floor is securely
9	attached.
10	(iii) Meets performance standards ensuring that cultivation and processing
11	activities cannot be and are not reasonably perceptible from the structure in terms of
12	common visual observation, odors, smell, fragrances, or other olfactory stimulus,
13	light pollution, glare, brightness, adequate ventilation to prevent mold, and noise.
14	(iv) Provides complete visual screening.
15	(v) Meets the standards of any applicable state and local electrical, fire,
16	plumbing, and building specification codes.
17	(b) That the contractor possesses and maintains accurate, detailed plans and
18	elevation drawings of all operational areas involved with the cultivation, extraction,
19	processing, and production of therapeutic marijuana.
20	(c) That the contractor possesses and maintains a written operations plan,
21	which plan shall be limited to standard operating procedures for the cultivation of
22	marijuana in each facility production area, instructions for making each product
23	produced on the premises, equipment operations manuals, procedures for conducting
24	necessary safety checks, sanitization procedures for working surfaces and equipment,
25	quality control procedures, and emergency preparedness procedures.
26	(d) That the contractor has connection and access to the Louisiana Medical
27	Marijuana Tracking System.

1	(e) That the contractor has security against unauthorized entry via the
2	presence of operational alarm and video surveillance systems, limited access areas,
3	secure locking systems, and door controls throughout the facility.
4	(f) The initial inventory and accuracy of inventory reporting.
5	(g) The existence of current, complete, and accurate personnel records.
6	(2)(a) Notwithstanding Paragraph (1) of this Subsection, nothing in this
7	Section shall be construed to obstruct or impede the lawful activity of any licensee
8	or permittee.
9	(b) The provisions of this Subsection are intended to ensure a reliable,
10	adequate, and uninterrupted supply of therapeutic marijuana to Louisiana patients.
11	C.(1) Inspections of contractor facilities other than initial inspections shall
12	be conducted in accordance with the procedures and requirements provided in
13	Paragraph (2) of this Subsection:
14	(2) After a contractor commences producing therapeutic marijuana in an
15	approved facility, the Louisiana Department of Health and the licensed university
16	shall inspect each contractor facility at least twice annually to verify the existence
17	or accuracy of the following:
18	(a) Possession and accuracy of detailed plans and elevation drawings of all
19	operational areas involved with the cultivation, extraction, processing, and
20	production of medical marijuana.
21	(b) Existence and possession of a current written operations plan.
22	(c) Connection and accessibility to Louisiana Medical Marijuana Tracking
23	System.
24	(d) Operational alarm and video surveillance systems.
25	(e) Secure locks throughout the facility.
26	(f) Controls to limited access areas.
27	(g) Current, complete, and accurate personnel records.
28	(h) Biannual inventory reports.

1	D. All of the following standards and requirements for security shall apply
2	with respect to contractor facilities:
3	(1) Any contractor facility alarm or surveillance system shall include the
4	following:
5	(a) A panic device that sounds an audible alarm and notifies law
6	enforcement.
7	(b) Surveillance system coverage for all points of ingress and egress to the
8	facility, including but not limited to doorways, windows, and loading bays.
9	(c) "Duress" or "hold up" features to enable activation of a silent alarm.
10	(d) Date- and time-stamped recording of all points of ingress and egress, any
1	limited access areas including rooms containing a safe, any room in which any part
12	of the disposal process occurs, and any room or area used to cultivate, extract,
13	process, produce, or store therapeutic marijuana.
14	(e) Capabilities including continuous recording, archiving, and at least one
15	on-site display monitor connected to the system.
16	(2) Each contractor facility shall maintain on-site security personnel, at a
17	minimum, during standard United States business hours of eight o'clock a.m. to five
18	o'clock p.m. and shall maintain off-site, electronic security monitoring at all other
19	times.
20	(3) All surveillance recordings shall be maintained for a minimum of thirty
21	days and access to surveillance controls and monitoring shall be limited to
22	specifically-authorized personnel.
23	(4) Each contractor shall limit access to and post limited-access signage
24	where marijuana is cultivated, extracted, processed, produced, or stored. Limited
25	access areas shall remain locked and accessible only by authorized personnel.
26	(5) Each employee, supervisor, or agent of each contractor shall keep a
27	current identification card, in a form approved by the department, on his person
28	when present at a contractor facility.

2	apply relative to visitors at contractor facilities:
3	(1) Persons who do not possess a contractor identification card shall be
4	issued a visitor identification badge after signing a log maintained by the contractor
5	that properly identifies the visitor to the premises. The visitor shall wear the badge
6	for the duration of his time on the premises, and the visitor shall not be left
7	unaccompanied in any area where marijuana or marijuana products are present.
8	(2) Notwithstanding Paragraph (1) of this Subsection, if it is necessary for
9	a visitor to enter a facility to conduct repairs, maintenance, or other specific duties
10	on the premises, the visitor may be escorted to the work site and left unaccompanied
11	while completing a job if that job is not within a limited access area. If it is
12	necessary for a visitor to enter a facility's limited access area, the visitor shall be
13	escorted to the work area and must remain accompanied by facility personnel while
14	the work is being completed in the limited access area if marijuana or marijuana
15	products are within the limited access area. The visitor may be left unaccompanied
16	in the limited access area if no marijuana or marijuana products are within the
17	limited access area while the visitor is present. If the visitor is left unaccompanied
18	in the limited access area, facility personnel shall ensure that the visitor is under
19	video surveillance for the duration of the visitor's time spent on the premises.
20	F. All of the following requirements shall apply with respect to data
21	management by contractors:
22	(1) Each contractor shall acquire and maintain all software, hardware, and
23	communications infrastructure necessary to ensure connectivity to and
24	implementation of the Louisiana Medical Marijuana Tracking System, referred to
25	hereafter in this Subsection as the LMMTS, to track therapeutic marijuana from seed
26	to distribution to an approved laboratory, to licensed pharmacies, to another
27	cultivation contractor or to destruction, tagging each plant and product with a unique
28	identification number, and entering the number into LMMTS for tracking. The

E. All of the following procedures, restrictions, and authorizations shall

1	contractor shall bear the cost of all expenses related to tracking, tagging, and
2	implementation of the LMMTS.
3	(2) Within twenty-four hours of the respective qualifying event, the
4	contractor shall record the following in the LMMTS:
5	(a) Any purchase or acquisition of therapeutic marijuana seeds; plants,
6	including immature plants and seedlings; or derivatives thereof.
7	(b) The sale, transfer, or transport of therapeutic marijuana or its derivatives
8	to another contractor, approved laboratory, or therapeutic marijuana pharmacy.
9	(c) The disposal of therapeutic marijuana.
10	(3) Notwithstanding any other provision of this Section, each contractor shall
11	keep all documents and information required by this Part for at least the current year
12	and the three preceding calendar years, including but not limited to business records
13	necessary to fully account for each business transaction conducted by contractor.
14	G. All of the following standards and requirements shall apply to contractors'
15	<u>inventory:</u>
16	(1) Each contractor shall maintain a comprehensive inventory of all
17	marijuana, including, without limitation, usable marijuana available for dispensing,
18	mature marijuana plants, and seedlings at each authorized location. Following an
19	initial inventory, all marijuana shall be inventoried on a weekly basis.
20	(2) Any therapeutic marijuana waste product shall be properly weighed and
21	recorded in the Louisiana Medical Marijuana Tracking System and stored in a
22	limited-access area of a contractor facility until rendered unusable.
23	H. Material safety data sheet requirements shall include all of the following:
24	(1) Any pesticides or chemicals used by a contractor in the production of
25	therapeutic marijuana shall be used and stored according to the contractor's written
26	operations plan.
27	(2) Each contractor shall maintain a material safety data sheet in each facility
28	area where toxic cleaning compounds, sanitizing agents, solvents used in the

1	production of therapeutic marijuana extracts and concentrates, pesticide chemicals,
2	or other agricultural chemicals are used or stored.
3	(3) Each contractor shall record the following information when applying a
4	pesticide or other agricultural chemical to therapeutic marijuana at any cultivation
5	stage:
6	(a) The date and time of the pesticide or chemical application.
7	(b) The name of each individual who applied the pesticide or chemical.
8	(c) The identification number of all batches receiving the application.
9	(d) The amount and name of the pesticide or chemical applied, including the
10	United States Environmental Protection Agency registration number, if any.
11	I. All of the following requirements shall apply to transportation of
12	therapeutic marijuana by contractors:
13	(1) Prior to transporting therapeutic marijuana, a contractor shall generate
14	an inventory manifest in the Louisiana Medical Marijuana Tracking System, referred
15	to hereafter in this Subsection as the LMMTS,, including all of the following
16	information:
17	(a) The name of the contractor originating the transport.
18	(b) The name of the contractor, approved laboratory, or licensed pharmacy
19	receiving the transport.
20	(c) The quantity by weight or unit of each type of therapeutic marijuana
21	product contained in the transport.
22	(d) The date and approximate departure and arrival times for the transport.
23	(e) The identity of all agents accompanying the transport.
24	(f) The make, model, and license plate number of the transport delivery
25	vehicle.
26	(2) The contractor originating the transport shall provide the contractor,
27	approved laboratory, or licensed pharmacy receiving the transport with a copy of the
28	LMMTS inventory manifest, which shall not be altered after departing the
29	originating contractor's facility.

1	(3) The contractor, approved laboratory, or licensed pharmacy receiving the
2	transport shall record the quantities of all therapeutic marijuana products in the
3	LMMTS. However, any contractor, approved laboratory, or licensed pharmacy
4	receiving a therapeutic marijuana transport shall refuse the transport if it is not
5	accompanied by an unaltered LMMTS inventory manifest.
6	§1046.2. Therapeutic marijuana laboratory; licensure and renewal requirements
7	A.(1) Prior to analyzing, testing, or handling therapeutic marijuana in
8	Louisiana, an applicant for a therapeutic marijuana laboratory license shall submit
9	an initial license application on a form and in a manner prescribed by the Louisiana
10	Board of Pharmacy, referred to hereafter in this Section as the "board".
11	(2) Approved laboratories may include the Department of Agriculture and
12	Forestry agricultural chemistry laboratory; the colleges, universities, other
13	institutions, and systems governed by the Louisiana Board of Regents; public-private
14	partnerships involving the systems, colleges and universities governed by the
15	Louisiana Board of Regents and private laboratories; and private laboratories. The
16	Department of Agriculture Forestry agricultural chemistry laboratory shall be exempt
17	from the application process and deemed approved but shall comply with
18	Subparagraphs (d) and (e) of this Paragraph. All other applicants shall meet all of
19	the following requirements:
20	(a) Be accredited by the National Institute on Drug Abuse, the National
21	Environmental Laboratory Accreditation Conference, the International Organization
22	for Standardization, or other accrediting entity approved by the board, which
23	accreditation shall be maintained in active and good standing or other substantially
24	similar status for the duration of licensure.
25	(b) Employ or hire a laboratory director or other qualifying individual. The
26	laboratory director or other qualifying individual and any persons involved in the
27	testing of marijuana or marijuana products or whose involvement with the laboratory
28	requires or authorizes access to restricted limited access areas of the laboratory shall
29	obtain a permit in accordance with the requirements of R.S. 40:1047.

1	(c) Submit to at least one on-site facility inspection conducted by the board
2	or its designee prior to licensure.
3	(d) Implement and utilize the Louisiana Medical Marijuana Tracking System
4	(LMMTS) computerized inventory tracking system to post accurate analyses and
5	results, which shall be subject to board review. Payment of any costs associated with
6	access to or implementation or use of LMMTS shall be the responsibility of the
7	laboratory exclusively.
8	(e) Demonstrate acceptable laboratory performance standards regarding
9	accuracy, precision, proficiency, reportable ranges, specificity, or other quality
10	controls required by the board or its designee.
11	B.(1) Each therapeutic marijuana laboratory license shall be effective for one
12	year and shall be renewed on or before December 31 annually.
13	(2) Each therapeutic marijuana laboratory licensee shall apply for license
14	renewal on or before October 31 each year on a form and in a manner prescribed by
15	the board.
16	(3) Any therapeutic marijuana laboratory license not timely renewed as
17	required by this Subsection shall expire on December 31 at midnight. Upon
18	expiration of the license, the laboratory shall cease all operations and destroy all
19	marijuana or marijuana products physically remaining at its location.
20	(4) Prior to granting a license renewal application, the board shall ensure that
21	the therapeutic marijuana laboratory licensee continues to meet the requirements of
22	this Part, including but not limited to the licensee's compliance with Subsection A
23	of this Section and its good standing with applicable requirements of the secretary
24	of state. The board or its designee shall conduct an out-of-cycle inspection of the
25	therapeutic marijuana laboratory licensee if necessary to ensure acceptable lab
26	performance standards, accuracy, precision, proficiency, reportable ranges,
27	specificity, or other quality controls and assurances necessary to protect Louisiana
28	patients.
29	§1046.3. Testing; sample collection; minimum standards; reporting; remediation

A.(1) Each contractor permitted to cultivate, extract, process, production	luce, and
transport therapeutic marijuana pursuant to this Part shall comply with a	approved
minimum standards by making each batch of therapeutic marijuana su	ubject to
random selection, sampling, and analysis conducted by an independent a	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 deli	ivered to
the Louisiana Board of Pharmacy and contractor permitted to cultivate,	, extract,
process, produce, and transport therapeutic marijuana within twenty-four	hours of
test completion.	
B. Therapeutic marijuana shall not be used to produce any form of	f product
until it has passed all required testing standards, including appropriate micro	obial and
fungal limits, acceptable standards for pesticide chemical residues, app	propriate
residual solvent and heavy metals limits, homogeneity for concentrates and	extracts,
and complete active ingredient analysis or potency analysis to establish the	presence
of all active ingredients and their concentrations for accurate calculations of	amounts
needed for the production of products and to ensure accurate dosing.	
C.(1) Neither a contractor nor an approved laboratory authorized	pursuant
to this Part shall release or approve a therapeutic marijuana product for de	elivery or
sale until a sample from the applicable product batch has complied with all	required
testing standards.	
(2) A contractor may resubmit to a second approved laboratory any	y 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 the second a	approved
laboratory in duplicate. The sample may be remediated according to any re-	asonably
acceptable industry methods if it fails one or more tests conducted by the	e second
approved laboratory.	

1 (3) Any remediated sample shall pass remediation testing in duplicate prior 2 to approval for delivery and sale. 3 (4) A product may be remediated only once, and any product failing 4 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 5 6 Section 2. R.S. 40:1046(H)(3) through (5) are hereby repealed in their entirety. 7 Section 3. The Department of Agriculture and Forestry, through its agricultural 8 chemistry laboratory, shall continue performing required testing of marijuana produced for 9 therapeutic use according to applicable rules and regulations in effect on the effective date 10 of this Act, subject to any overriding emergency or permanent testing rules and regulations 11 promulgated by the Louisiana Board of Pharmacy, until at least two additional laboratories 12 are approved by the Louisiana Board of Pharmacy and have both been operational for a 13 minimum of six months to ensure a reliable, adequate, and uninterrupted supply of 14 therapeutic marijuana to Louisiana patients. 15 Section 4. This Act shall become effective upon signature by the governor or, if not 16 signed by the governor, upon expiration of the time for bills to become law without signature 17 by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If 18 vetoed by the governor and subsequently approved by the legislature, this Act shall become 19 effective on the day following such approval.

DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

HB 697 Original

2022 Regular Session

Magee

Abstract: Revises laws establishing and providing for a regulatory system for medical marijuana.

<u>Proposed law</u> revises laws establishing and providing for a regulatory system for marijuana for therapeutic use, known commonly as medical marijuana, in the following ways:

(1) Transfers duties for licensure and regulation of medical marijuana production facilities from the La. Dept. of Agriculture and Forestry (LDAF) to the La. Dept. of Health (LDH).

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CODING: Words in struck through type are deletions from existing law; words underscored are additions.

- (2) Transfers duties with respect to testing of medical marijuana from LDAF to the La. Board of Pharmacy (board).
- (3) Provides requirements and standards for laboratories that conduct testing of medical marijuana.
- (4) Provides for selection of marijuana production contractors by licensed producers of medical marijuana and for oversight and regulation of such contractors.

<u>Proposed law</u> requires the board to reserve one marijuana pharmacy permit for each of the nine public health regions of the state identified in <u>proposed law</u>. Stipulates that within three months after the registration of 5,000 qualified patients within any region, the board shall issue to an existing marijuana pharmacy licensed and operating in that region one additional marijuana pharmacy permit for a location in the region. Provides that thereafter, the board shall issue an additional marijuana pharmacy permit after the registration of each additional increment of 5,000 qualified patients, within any region.

<u>Proposed law</u> provides requirements and standards for marijuana production contractors of licensed producers of medical marijuana, including requirements and standards with respect to all of the following:

- (1) Initial inspections of contractor facilities.
- (2) Inspections of contractor facilities subsequent to initial inspections.
- (3) Security at contractor facilities.
- (4) Visitors at contractor facilities.
- (5) Data management by contractors.
- (6) Contractors' inventory.
- (8) Material safety data sheet requirements.
- (9) Transportation of therapeutic marijuana by contractors.

<u>Proposed law</u> requires that marijuana produced for therapeutic use be tested by a facility licensed by the board in accordance with <u>proposed law</u> as a therapeutic marijuana laboratory. Requires that applicants for licensure as a therapeutic marijuana laboratory meet all of the following requirements in order to qualify for a license:

- (1) 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 board, which accreditation shall be maintained in active and good standing or other substantially similar status for the duration of licensure.
- (2) Employ or hire a laboratory director or other qualifying individual who meets certain suitability requirements provided in <u>present law</u>.
- (3) Submit to at least one on-site facility inspection conducted by the board or its designee prior to licensure.
- (4) Implement and utilize the Louisiana Medical Marijuana Tracking System computerized inventory tracking system to post accurate analyses and results, which shall be subject to board review.

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

<u>Proposed law</u> stipulates that the LDAF agricultural chemistry laboratory shall be exempt from the application process and deemed approved as a therapeutic marijuana laboratory; requires, however that such laboratory shall comply with the requirements of paragraphs (4) and (5) above.

<u>Proposed law</u> requires LDAF to continue to conduct laboratory testing of marijuana produced for therapeutic use according to applicable rules and regulations in effect on the effective date of <u>proposed law</u>, unless otherwise provided for in rules of the board, until at least two additional laboratories are approved by the board 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.

<u>Proposed law</u> recognizes and declares that both the Louisiana State University Agricultural Center (LSU Ag Center) and the Southern University Agricultural Center (SU Ag Center) timely exercised and asserted their intent 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 RS.

<u>Proposed law</u> repeals <u>present law</u> providing procedures for selection and licensing of a therapeutic marijuana producer in the event that neither the LSU Ag Center nor the SU Ag Center is licensed as a production facility.

Effective upon signature of governor or lapse of time for gubernatorial action.

(Amends R.S. 40:1046(A)(1), (C)(1) and (2)(intro. para.), (g), and (h), (G), and (H)(1), (2), and (6)(a)(intro. para.) and (b); Adds R.S. 40:1046(A)(7), (B), and 1046.1-1046.3; Repeals R.S. 40:1046(H)(3)-(5))