

2022 Regular Session

HOUSE BILL NO. 697

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

1

AN ACT

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

20 Be it enacted by the Legislature of Louisiana:

1           Section 1. R.S. 40:1046(A)(1), (C)(1) and (2)(introductory paragraph), (G), and  
2 (H)(1), (2), (6)(a)(introductory paragraph) and (b), and (8)(a)(introductory paragraph) and  
3 (iii) are hereby amended and reenacted and R.S. 40:1046(A)(7), (B), and 1046.1 through  
4 1046.3 are hereby enacted to read as follows:

5           §1046. Recommendation and dispensing of marijuana for therapeutic use; rules and  
6 regulations of the ~~Louisiana State Board of Medical Examiners and~~  
7 Louisiana Board of Pharmacy; production facility licensing; ~~by the~~  
8 ~~Department of Agriculture and Forestry permitting by the Louisiana~~  
9 Department of Health

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

22                                 \*           \*           \*

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

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

5           C.(1) The Louisiana Board of Pharmacy shall adopt rules relating to the  
6           dispensing of recommended marijuana for therapeutic use therapeutic marijuana.  
7           Any rules published by the Louisiana Board of Pharmacy board on or before January  
8           1, 2016, that describe the pharmacist as dispensing medical marijuana based on a  
9           physician's prescription should be re promulgated to indicate that the physician is  
10          "recommending" use of therapeutic marijuana.

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

13                                 \*           \*           \*

14           G.(1) The Louisiana Board of Pharmacy shall develop an annual,  
15          nontransferable specialty license for a pharmacy to dispense recommended  
16          marijuana for therapeutic use ~~and shall limit the number of such licenses granted in~~  
17          ~~the state to no more than ten licensees. The Louisiana Board of Pharmacy shall~~  
18          ~~develop rules and regulations regarding the geographical locations of dispensing~~  
19          ~~pharmacies in Louisiana. The board shall award a minimum of one license per~~  
20          ~~region, as delineated in Paragraph (2) of this Subsection, and shall award each~~  
21          ~~license through a competitive process.~~

22           (2) For the purposes of this Subsection, the regions among which the  
23          Louisiana Board of Pharmacy shall allocate marijuana pharmacy licenses shall  
24          correspond to the sets of parishes comprising, respectively, the human services  
25          districts and authorities established by the provisions of R.S. 28:912 as those districts  
26          and authorities existed on July 1, 2022. On and after October 1, 2022, at least one  
27          licensed marijuana pharmacy shall be located in each region.

28           (3) After two thousand five hundred active, qualified patients are identified  
29          in the prescription monitoring program in a region, the Louisiana Board of Pharmacy

1       may allow the marijuana pharmacy licensee in that region to open one additional  
2       marijuana pharmacy location in that region.

3           (4) Following the issuance of a license in a region in accordance with the  
4       process provided in Paragraph (3) of this Subsection, if a total of an additional two  
5       thousand five hundred active, qualified patients are identified in the prescription  
6       monitoring program in the region, then the Louisiana Board of Pharmacy may  
7       license one additional marijuana pharmacy location in that region. In the issuance  
8       of a license as authorized in this Paragraph, the board shall consider any unserved  
9       parishes within the region when approving a location for licensure. The provisions  
10      of this Paragraph authorizing an additional license in a region shall apply each time  
11      that an additional increment of two thousand five hundred active, qualified patients  
12      identified in the prescription monitoring program is reached in the region.

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

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

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

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

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

4               H.(1)(a) The Department of Agriculture and Forestry shall develop the rules  
5               and regulations regarding the extraction, processing, and production of  
6               recommended therapeutic marijuana and the facility producing therapeutic  
7               marijuana. The rules and regulations shall require as a minimum standard that the  
8               extraction and refining process produce a product that is food-safe and capable of  
9               producing pharmaceutical-grade products. The legislature hereby recognizes and  
10               declares that both the Louisiana State University Agricultural Center and the  
11               Southern University Agricultural Center timely exercised and asserted the intent of  
12               each university to be licensed to produce recommended marijuana for therapeutic use  
13               in this state in accordance with the provisions of Act No. 261 of the 2015 Regular  
14               Session of the Legislature of Louisiana.

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

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

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

1       Center. Other than the licenses granted pursuant to Subparagraph (b) of this  
2       Paragraph, the Department of Agriculture and Forestry shall limit the number of such  
3       licenses granted in the state to no more than one licensee. The Louisiana State  
4       University Agricultural Center and the Southern University Agricultural Center shall  
5       have the right of first refusal to be licensed as the production facility, either  
6       separately or jointly. If neither of the centers exercise this option, the license shall  
7       be awarded pursuant to the requirements provided for in Paragraphs (3) through (5)  
8       of this Subsection.

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

\* \* \*

\* \* \*

8                         (8)(a) The ~~department~~ Louisiana Department of Health shall perform the  
9                         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.

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### §1046.1. Contractors; selection; minimum standards

A. The contractor selected by the licensed university through a competitive process to cultivate, extract, process, produce, and transport therapeutic

1       marijuana shall be subject to oversight and inspections by the Louisiana Department  
2       of Health as provided in this Section.

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

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

8            (a) That the contractor facility adheres to all of the following:  
9              (i) Is within a building that has a complete roof enclosure supported by  
10       connecting walls, constructed of solid materials, that extend from the ground to the  
11       roof.

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

14            (iii) Meets performance standards ensuring that cultivation and processing  
15       activities cannot be and are not reasonably perceptible from the structure in terms of  
16       common visual observation, odors, smell, fragrances, or other olfactory stimulus,  
17       light pollution, glare, brightness, adequate ventilation to prevent mold, and noise.

18            (iv) Provides complete visual screening.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25          (d) Operational alarm and video surveillance systems.

26          (e) Secure locks throughout the facility.

27          (f) Controls to limited access areas.

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

29          (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
- 11          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.

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

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          inventory:

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 the agent or 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                  Department of Health, referred to hereafter in this Section as the "department".

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 department, 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  
2               department 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 review by the department. Payment of any costs  
6               associated with access to or implementation or use of LMMTS shall be the  
7               responsibility of the 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 department.

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 department.

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 department shall  
21               ensure that the therapeutic marijuana laboratory licensee continues to meet the  
22               requirements of this Part, including but not limited to the licensee's compliance with  
23               Subsection A of this Section and its good standing with applicable requirements of  
24               the secretary of state. The department 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.

1           §1046.3. Testing; sample collection; minimum standards; reporting; remediation

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

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

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

14          B. Therapeutic marijuana shall not be used to produce any form of product  
15          until it has passed all required testing standards, including appropriate microbial and  
16          fungus limits, acceptable standards for pesticide chemical residues, appropriate  
17          residual solvent and heavy metals limits, homogeneity for concentrates and extracts,  
18          and complete active ingredient analysis or potency analysis to establish the presence  
19          of all active ingredients and their concentrations for accurate calculations of amounts  
20          needed for the production of products and to ensure accurate dosing. The  
21          administrative rules of the Louisiana Department of Health shall allow for a variance  
22          of no greater than plus fifteen percent or minus fifteen percent from the labeled  
23          amount of active ingredients in the ingredient analysis or potency analysis.

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

28          (2) A contractor may resubmit to an approved laboratory any sample that  
29          fails one or more initial tests required by this Part. The sample may be released for

1       delivery and sale only if it passes all tests conducted by an approved laboratory in  
2       duplicate. The sample may be remediated according to any reasonably acceptable  
3       industry methods if it fails one or more tests conducted by an approved laboratory.

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

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

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

11       Section 3. The Department of Agriculture and Forestry, through its agricultural  
12      chemistry laboratory, shall continue performing required testing of marijuana produced for  
13      therapeutic use according to applicable rules and regulations in effect on the effective date  
14      of this Act, subject to any overriding emergency or permanent testing rules and regulations  
15      promulgated by the Louisiana Board of Pharmacy, until at least two additional laboratories  
16      are approved by the Louisiana Board of Pharmacy and have both been operational for a  
17      minimum of six months to ensure a reliable, adequate, and uninterrupted supply of  
18      therapeutic marijuana to Louisiana patients.

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

26       Section 5. This Act shall become effective upon signature by the governor or, if not  
27      signed by the governor, upon expiration of the time for bills to become law without signature  
28      by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If

- 1 vetoed by the governor and subsequently approved by the legislature, this Act shall become  
2 effective on the day following such approval.
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## 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)]

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HB 697 Reengrossed

2022 Regular Session

Magee

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

Proposed law 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).
- (2) Transfers duties with respect to testing of medical marijuana from LDAF to LDH.
- (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.
- (5) Repeals the ten-license limit on marijuana pharmacy licenses provided in present law and provides for a system for increasing the number of licenses issued contingent upon increases in medical marijuana patient counts.

Present law provides for licensure of marijuana pharmacies by the La. Board of Pharmacy ("board"). Provides that the board shall limit the number of such licenses granted in the state to no more than ten licensees. Proposed law revises present law by requiring the board to award a minimum of one license in each of ten regions established in proposed law, to award each license through a competitive process, and to increase incrementally the number of licenses issued based upon increases in medical marijuana patient counts by region.

Proposed law provides that the regions among which the board shall allocate marijuana pharmacy licenses shall correspond to the sets of parishes comprising, respectively, the human services districts and authorities established by present law (R.S. 28:912) as those districts and authorities existed on July 1, 2022. Requires that on and after Oct. 1, 2022, at least one licensed marijuana pharmacy shall be located in each region.

Proposed law provides for the following system for incrementally increasing the number of marijuana pharmacy licenses issued by the board:

- (1) After 2,500 active, qualified patients are identified in the prescription monitoring program in a region, the board may allow the marijuana pharmacy licensee in that region to open one additional marijuana pharmacy location in that region. Requires the board to license the additional location within three months of the date on which the patient registration threshold is met.

- (2) If an additional 2,500 active, qualified patients are identified in the prescription monitoring program in a region, then the board may license one additional marijuana pharmacy location in that region. These provisions of proposed law authorizing issuance of an additional license in a region shall apply each time that an additional increment of 2,500 active, qualified patients is reached in the region.

Proposed law prohibits any marijuana pharmacy from locating within a 15-mile radius of another marijuana pharmacy, with the following exceptions:

- (1) In a region that encompasses any parish with a population of more than 350,000 persons according to the most recent federal decennial census, no marijuana pharmacy shall locate within a ten-mile radius of another marijuana pharmacy.
- (2) In a region that encompasses any municipality with a population of more than 350,000 persons according to the most recent federal decennial census, no marijuana pharmacy shall locate within a five-mile radius of another marijuana pharmacy.

Proposed law requires each marijuana pharmacy licensed in accordance with proposed law to offer home delivery to patients in each zip code within its region at least once per month.

Proposed law 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.

Proposed law provides that the licensed marijuana production facility or its contractor shall remit to the La. Department of Revenue the proceeds of the fee on gross sales of therapeutic marijuana established in present law (R.S. 40:1046(H)(8)(a)(iii)).

Proposed law requires that marijuana produced for therapeutic use be tested by a facility licensed by LDH in accordance with proposed law 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 LDH, 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 present law.

- (3) Submit to at least one on-site facility inspection conducted by LDH 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 review by LDH.
- (5) Demonstrate acceptable laboratory performance standards regarding accuracy, precision, proficiency, reportable ranges, specificity, or other quality controls required by LDH.

Proposed law 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.

Proposed law 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 proposed law, unless otherwise provided for in rules of LDH, until at least two additional laboratories are approved by LDH 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.

Proposed law requires that LDH temporarily follow existing administrative rules relative to marijuana for therapeutic use promulgated by LDAF until such time as it adopts all necessary emergency rules and permanent rules relating to cultivation, extraction, processing, production, and transportation of such product.

Proposed law authorizes the University of Louisiana at Monroe to conduct research on marijuana for therapeutic use.

Proposed law 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.

Proposed law repeals present law 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)(1), (2), (6)(a)(intro. para.) and (b), and (8)(a)(intro. para.) and (iii); Adds R.S. 40:1046(A)(7), (B), and 1046.1-1046.3; Repeals R.S. 40:1046(C)(2)(h) and (H)(3)-(5))

#### Summary of Amendments Adopted by House

The Committee Amendments Proposed by House Committee on Health and Welfare to the original bill:

1. Transfer duties with respect to testing of medical marijuana provided in proposed law from the La. Board of Pharmacy to the La. Department of Health (LDH).
2. Require that LDH temporarily follow existing administrative rules relative to medical marijuana promulgated by the Dept. of Agriculture and Forestry until such time as LDH adopts all necessary emergency rules and permanent rules

relating to cultivation, extraction, processing, production, and transportation of such product.

3. Revise the process provided for in proposed law for issuance of additional marijuana pharmacy licenses by the La. Board of Pharmacy.
4. Revise the regional structure established in proposed law for allocation of marijuana pharmacy licenses by providing that the regions shall correspond to the sets of parishes comprising, respectively, the human services districts and authorities established in present law (R.S. 28:912).
5. Revise limitations and restrictions provided in proposed law with respect to proximity of licensed marijuana pharmacies to each other.
6. Require that on and after Oct. 1, 2022, at least one licensed marijuana pharmacy shall be located in each region.
7. Authorize the University of Louisiana at Monroe to conduct research on marijuana for therapeutic use.
8. Provide that the licensed marijuana production facility or its contractor shall remit to the La. Dept. of Revenue the proceeds of the fee on gross sales of therapeutic marijuana established in present law.

The House Floor Amendments to the engrossed bill:

1. Decrease the regional patient count threshold qualifying a region for an additional marijuana pharmacy from 5,000 additional patients to 2,500 additional patients.
2. Correct references to patients registered in the prescription monitoring program to refer instead to patients identified in the prescription monitoring program.
3. Delete provisions mandating the La. Board of Pharmacy to require a marijuana pharmacy licensee to open an additional marijuana pharmacy location in certain circumstances; add in lieu thereof an authorization for the board to allow the licensee to open an additional location in those circumstances.
4. Define "active, qualified patient" for purposes of proposed law.
5. Make technical changes.