EXCEP PERSON/DEV DISABLE: Authorizes the recommendation of medical marijuana for treating certain health conditions of persons with autism

AN ACT

To amend and reenact R.S. 40:1046(A)(2) and Section 2 of Act No. 96 of the 2016 Regular Session of the Legislature of Louisiana, relative to health conditions for which a recommendation or prescription of medical marijuana is authorized; to authorize the recommendation of or prescription for medical marijuana in treating certain conditions associated with autism spectrum disorder; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 40:1046(A)(2) is hereby amended and reenacted to read as follows:

§1046. Recommendation of marijuana for therapeutic use; rules and regulations;

Louisiana Board of Pharmacy and the adoption of rules and regulations relating to the dispensing of recommended marijuana for therapeutic use; the Department of Agriculture and Forestry and the licensure of a production facility

A.

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(2)(a) For purposes of this Subsection, "debilitating medical condition" means cancer, positive status for human immunodeficiency virus, acquired immune deficiency syndrome, cachexia or wasting syndrome, seizure disorders, epilepsy,
spasticity, Crohn's disease, muscular dystrophy, or multiple sclerosis. any of the following:

(i) Cancer.

(ii) Positive status for human immunodeficiency virus.

(iii) Acquired immune deficiency syndrome.

(iv) Cachexia or wasting syndrome.

(v) Seizure disorders.

(vi) Epilepsy.

(vii) Spasticity.

(viii) Crohn's disease.

(ix) Muscular dystrophy.

(x) Multiple sclerosis.

(xi) 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.

(b) No physician 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 physician is a pediatric subspecialist licensed by the Louisiana State Board of Medical Examiners and credentialed by the Louisiana Board of Pharmacy.

(c) If the United States Food and Drug Administration approves the use of medical marijuana in the same form provided for in this Part for any debilitating medical condition specifically identified in this Paragraph, that medical condition shall no longer be covered by the provisions of this Part.
(c) (d) If the United States Food and Drug Administration approves the use of medical marijuana in a form or derivative different than provided for in this Part for any debilitating medical condition specifically identified in this Paragraph, the disease state shall remain covered by the provisions of this Part. The patient shall first be treated by the approved form or derivative of medical marijuana through utilization of step therapy or fail first protocols. If, after use of the United States Food and Drug Administration approved form or derivative of medical marijuana, the physician determines that the preferred treatment required under step therapy or fail first protocol has been ineffective in the treatment of the patient's debilitating medical condition, he may recommend the form of medical marijuana provided for in this Part for use by the patient as medically necessary.

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Section 2. Section 2 of Act No. 96 of the 2016 Regular Session of the Legislature of Louisiana is hereby amended and reenacted to read as follows:

Section 2. R.S. 40:1046 is hereby amended and reenacted to read as follows:

§1046. Prescription of marijuana for therapeutic use; rules and regulations; Louisiana Board of Pharmacy and the adoption of rules and regulations relating to the dispensing of prescribed marijuana for therapeutic use; the Department of Agriculture and Forestry and the licensure of a production facility

A.(1) Notwithstanding any other provision of this Part, a physician licensed by and in good standing with the Louisiana State Board of Medical Examiners to practice medicine in this state and who is domiciled in this state may prescribe, in any form as permitted by the rules and regulations of the Louisiana Board of Pharmacy except for inhalation, and raw or crude marijuana, tetrahydrocannabinols, or a chemical derivative of tetrahydrocannabinols for therapeutic use by patients clinically diagnosed as suffering from a debilitating medical condition glaucoma, symptoms resulting from the administration of chemotherapy cancer treatment, and
spastic quadriplegia in accordance with rules and regulations promulgated by
the Louisiana State Board of Medical Examiners. The Louisiana State Board
of Medical Examiners shall submit to the Senate and House committees on
health and welfare on an annual basis not less than sixty days prior to the
beginning of the regular session of the legislature a report as to any
additional diseases or medical conditions that should be added to the list of
eligible diseases and conditions for prescription.

(2)(a) For purposes of this Subsection, "debilitating medical
condition" means cancer, positive status for human immunodeficiency
virus, acquired immune deficiency syndrome, cachexia or wasting
syndrome, seizure disorders, epilepsy, spasticity, Crohn's disease,
muscular dystrophy, or multiple sclerosis, any of the following:

(i) Cancer.
(ii) Positive status for human immunodeficiency virus.
(iii) Acquired immune deficiency syndrome.
(iv) Cachexia or wasting syndrome.
(v) Seizure disorders.
(vi) Epilepsy.
(vii) Spasticity.
(viii) Crohn's disease.
(ix) Muscular dystrophy.
(x) Multiple sclerosis.
(xi) 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.

(b) No physician 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 physician is a pediatric subspecialist licensed by the Louisiana State Board of Medical Examiners and credentialed by the Louisiana Board of Pharmacy.

(c) If the United States Food and Drug Administration approves the use of medical marijuana in the same form provided for in this Part for any debilitating medical condition specifically identified in this Paragraph, that medical condition shall no longer be covered by the provisions of this Part.

(d) If the United States Food and Drug Administration approves the use of medical marijuana in a form or derivative different than provided for in this Part for any debilitating medical condition specifically identified in this Paragraph, the disease state shall remain covered by the provisions of this Part. The patient shall first be treated by the approved form or derivative of medical marijuana through utilization of step therapy or fail first protocols. If, after use of the United States Food and Drug Administration approved form or derivative of medical marijuana, the physician determines that the preferred treatment required under step therapy or fail first protocol has been ineffective in the treatment of the patient's debilitating medical condition, he may prescribe the form of medical marijuana provided for in this Part for use by the patient as medically necessary.

(3) For purposes of this Part, "prescribe" or "prescription" means an order from a physician domiciled in Louisiana and licensed and in good standing with the Louisiana Board of Medical Examiners and authorized by the board to prescribe medical marijuana that is patient-specific and disease-specific in accordance with Paragraph (2) of
this Subsection, and is communicated by any means allowed by the
Louisiana Board of Pharmacy to a Louisiana-licensed pharmacist in a
Louisiana-permitted dispensing pharmacy as described in Subsection G
of this Section, and is preserved on file as required by Louisiana law or
federal law regarding medical marijuana.

(4) Physicians shall prescribe the use of medical marijuana for
treatment of debilitating medical conditions in accordance with rules
and regulations promulgated by the Louisiana State Board of Medical
Examiners.

(5) The Louisiana State Board of Medical Examiners shall submit
to the Senate and House committees on health and welfare on an annual
basis not less than sixty days prior to the beginning of the regular session
of the legislature a report as to any additional diseases or medical
conditions that should be added to the list of eligible diseases and
conditions for recommendation.

B. The Louisiana State Board of Medical Examiners shall promulgate
rules and regulations authorizing physicians licensed to practice in this state
to prescribe marijuana for therapeutic use by patients as described in
Subsection A of this Section no later than January 1, 2016.

C.(1) The Louisiana Board of Pharmacy shall adopt rules relating to
the dispensing of prescribed marijuana for therapeutic use no later than
December 1, 2016. The Louisiana Board of Pharmacy shall seek input from
groups including but not limited to the following:
   (a) The Louisiana District Attorneys Association;
   (b) Professional law enforcement associations, organizations, and
       commissions.

(2) The rules shall include but not be limited to:
(a) Standards, procedures, and protocols for the effective use of prescribed 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 prescribed therapeutic marijuana in Louisiana.

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

(d) The establishment of standards, procedures, and protocols for determining the amount of usable prescribed therapeutic marijuana that is necessary to constitute an adequate supply to ensure uninterrupted availability for a period of one month, including amounts for topical treatments.

(e) The establishment of standards, procedures, and protocols to ensure that all prescribed therapeutic marijuana dispensed is consistently pharmaceutical grade.

(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) The establishment of standards and procedures for testing prescribed therapeutic marijuana samples for levels of tetrahydrocannabinol (THC) or other testing parameters deemed appropriate by the Louisiana Board of Pharmacy.

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

(j) Licensure of dispensers of prescribed 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.

D. The Louisiana Board of Pharmacy shall submit a report to the legislature no later than January 1, 2016, with recommendations on possible fee amounts relative to the provisions of this Section.

E. All rules shall be adopted in accordance with the provisions of the Administrative Procedure Act.

F. 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.

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

H. A prescriber and dispenser of marijuana, tetrahydrocannabinols, or a chemical derivative of tetrahydrocannabinols pursuant to this Section shall review the patient’s information in the Prescription Monitoring Program database prior to the prescribing and dispensing thereof.

I. The Louisiana Board of Pharmacy shall develop an annual, nontransferable specialty license for a pharmacy to dispense prescribed marijuana for therapeutic use and shall limit the number of such licenses granted in the state to no more than ten licensees. The Louisiana Board of
Pharmacy shall develop rules and regulations regarding the geographical locations of dispensing pharmacies in Louisiana.

+++ H.1(a) The Department of Agriculture and Forestry shall develop the rules and regulations regarding the extraction, processing, and production of prescribed therapeutic marijuana and the facility producing therapeutic marijuana. The rules and regulations shall include but not be limited to both of the following minimum standards:

(i) In order to mitigate the risk of bacterial contamination, food-grade ethanol extraction shall be used.

(ii) The extraction and refining process shall produce a product that is food safe and capable of producing pharmaceutical-grade products.

(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.

(2)(a) The Department of Agriculture and Forestry shall develop an annual, nontransferable specialty license for the production of prescribed marijuana for therapeutic use. 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.

(3) The license shall be limited to one geographic location as
provided for in rule by the Department of Agriculture and Forestry. The
geographic location shall be a public record subject to disclosure under the
Public Records Law, R.S. 44:1 et seq. The licensee shall permit inspection
of the production facility by any elected member of the Louisiana Legislature
upon request after receipt of reasonable notice.

(4)(a) The Department of Agriculture and Forestry shall grant the
license pursuant to a contract awarded through a competitive sealed bid or a
competitive sealed proposal as provided for in R.S. 39:1594 and 1595. The
contract for the license shall be subject to the Louisiana Procurement Code
and shall not be subject to any exceptions to or other variances from the
Louisiana Procurement Code. The contract shall not be awarded under the
sole source procurement provisions provided for in R.S. 39:1597.

(b) Any contract for the license awarded pursuant to this Subsection
shall not exceed five years.

(c) Any contract, memorandum of understanding, or cooperative
endeavor agreement entered into pursuant to this Section shall be a public
record subject to disclosure under the Public Records Law, R.S. 44:1 et seq.

(d) Any contract, memorandum of understanding, or cooperative
endeavor agreement entered into for services for the cultivation or processing
in any way of marijuana pursuant to this Section shall be a public record
subject to disclosure under the Public Records Law, R.S. 44:1 et seq.

(e) No person licensed pursuant to this Subsection shall subcontract
for services for the cultivation or processing in any way of marijuana if the
subcontractor, or any of the service providers in the chain of subcontractors,
is owned wholly or in part by any state employee or member of a state
employee's immediate family, including but not limited to any legislator, statewide public official, university or community or technical college employee, Louisiana State University Agricultural Center employee, or Southern University Agricultural Center employee. For the purposes of this Paragraph, "immediate family" has the same meaning as provided in R.S. 42:1102.

(f) Any bid for the license awarded pursuant to this Subsection shall include proof of the financial capability of the bidder to operate a therapeutic marijuana production facility including but not limited to a net worth of not less than one million dollars.

(5) No person licensed pursuant to this Subsection shall give or receive anything of value in connection with any contract, memorandum of understanding, or cooperative endeavor agreement executed pursuant to this Subsection except the value that is expressed in the contract, memorandum of understanding, or cooperative endeavor agreement.

(6)(a) The Department of Agriculture shall collect 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 Department of Agriculture and Forestry shall provide the information collected pursuant to this Paragraph for the previous calendar year in the form of a written report to the Louisiana 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) The Department of Agriculture and Forestry shall submit a report to the legislature no later than January 1, 2016, with recommendations on possible fee amounts relative to the provisions of this Section.

K.-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.

L.-J. The provisions of this Section shall terminate on January 1, 2020.

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 627 Engrossed 2018 Regular Session Lyons

Abstract: Authorizes the recommendation or prescription of medical marijuana in treating certain health conditions associated with autism spectrum disorder.
Recommendation of Medical Marijuana

Present law authorizes physicians who are domiciled in La. and licensed by and in good standing with the La. State Board of Medical Examiners to recommend tetrahydrocannabinols (commonly referred to as "medical marijuana"), or chemical derivatives thereof, for therapeutic use by patients clinically diagnosed as suffering from a debilitating medical condition. Defines "debilitating medical condition" to mean cancer, positive status for human immunodeficiency virus, acquired immune deficiency syndrome, cachexia or wasting syndrome, seizure disorders, epilepsy, spasticity, Crohn's disease, muscular dystrophy, or multiple sclerosis.

Proposed law retains present law and adds the following conditions associated with autism spectrum disorder as conditions for which physicians may recommend treatment with medical marijuana:

1. Repetitive or self-stimulatory behavior of such severity that the physical health of the person with autism is jeopardized.
2. Avoidance of others or inability to communicate of such severity that the physical health of the person with autism is jeopardized.
4. Physically aggressive or destructive behavior.

Proposed law stipulates that no physician shall recommend medical marijuana for treatment of any condition associated with autism spectrum disorder for a patient who is under the age of 18 unless the physician is a pediatric subspecialist licensed by the La. State Board of Medical Examiners and credentialed by the La. Board of Pharmacy.

Prescription of Medical Marijuana

Present law authorizes physicians who are domiciled in La. and licensed by and in good standing with the La. State Board of Medical Examiners to prescribe, rather than recommend, medical marijuana for therapeutic use by patients clinically diagnosed as suffering from a debilitating medical condition if and when the U.S. Drug Enforcement Administration reclassifies marijuana from a Schedule I drug to a Schedule II drug, thereby allowing the drug to be legally prescribed. Defines "debilitating medical condition" to mean cancer, positive status for human immunodeficiency virus, acquired immune deficiency syndrome, cachexia or wasting syndrome, seizure disorders, epilepsy, spasticity, Crohn's disease, muscular dystrophy, or multiple sclerosis.

Proposed law retains present law and adds the following conditions associated with autism spectrum disorder as conditions for which physicians may prescribe treatment with medical marijuana if and when such prescribing becomes legal:

1. Repetitive or self-stimulatory behavior of such severity that the physical health of the person with autism is jeopardized.
2. Avoidance of others or inability to communicate of such severity that the physical health of the person with autism is jeopardized.
4. Physically aggressive or destructive behavior.

Proposed law stipulates that no physician shall prescribe medical marijuana for treatment of any condition associated with autism spectrum disorder for a patient who is under the age of 18 unless the physician is a pediatric subspecialist licensed by the La. State Board of Medical Examiners and credentialed by the La. Board of Pharmacy.
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(Amends R.S. 40:1046(A)(2) and §2 of Act No. 96 of 2016 R.S.)

Summary of Amendments Adopted by House

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

1. Stipulate that no physician shall recommend or prescribe medical marijuana for treatment of any condition associated with autism spectrum disorder for a patient who is under the age of 18 unless the physician is a pediatric subspecialist licensed by the La. State Board of Medical Examiners and credentialed by the La. Board of Pharmacy.

2. Make technical changes.