

2018 Regular Session

HOUSE BILL NO. 627

BY REPRESENTATIVE LYONS

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

1 AN ACT

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

8 Be it enacted by the Legislature of Louisiana:

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

10 §1046. Recommendation of marijuana for therapeutic use; rules and regulations;  
11 Louisiana Board of Pharmacy and the adoption of rules and regulations  
12 relating to the dispensing of recommended marijuana for therapeutic use; the  
13 Department of Agriculture and Forestry and the licensure of a production  
14 facility

15 A.

16 \* \* \*

17 (2)(a) For purposes of this Subsection, "debilitating medical condition"  
18 means ~~cancer, positive status for human immunodeficiency virus, acquired immune~~  
19 ~~deficiency syndrome, cachexia or wasting syndrome, seizure disorders, epilepsy,~~

1 ~~spasticity, Crohn's disease, muscular dystrophy, or multiple sclerosis; any of the~~  
2 following:

3 (i) Cancer.

4 (ii) Positive status for human immunodeficiency virus.

5 (iii) Acquired immune deficiency syndrome.

6 (iv) Cachexia or wasting syndrome.

7 (v) Seizure disorders.

8 (vi) Epilepsy.

9 (vii) Spasticity.

10 (viii) Crohn's disease.

11 (ix) Muscular dystrophy.

12 (x) Multiple sclerosis.

13 (xi) Any of the following conditions associated with autism spectrum  
14 disorder:

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

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

19 (cc) Self-injuring behavior.

20 (dd) Physically aggressive or destructive behavior.

21 (b) No physician shall recommend medical marijuana for treatment of any  
22 condition associated with autism spectrum disorder for a patient who is under the age  
23 of eighteen unless the physician is a pediatric subspecialist licensed by the Louisiana  
24 State Board of Medical Examiners and credentialed by the Louisiana Board of  
25 Pharmacy.

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

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

\* \* \*

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

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

16           §1046. Prescription of marijuana for therapeutic use; rules and regulations;  
17           Louisiana Board of Pharmacy and the adoption of rules and  
18           regulations relating to the dispensing of prescribed marijuana for  
19           therapeutic use; the Department of Agriculture and Forestry and the  
20           licensure of a production facility

21           A.(1) Notwithstanding any other provision of this Part, a physician  
22           licensed **by and in good standing with the Louisiana State Board of**  
23           **Medical Examiners** to practice medicine in this state **and who is domiciled**  
24           **in this state** may prescribe, in any form as permitted by the rules and  
25           regulations of the Louisiana Board of Pharmacy except for inhalation, and  
26           raw or crude marijuana, tetrahydrocannabinols, or a chemical derivative of  
27           tetrahydrocannabinols for therapeutic use by patients clinically diagnosed as  
28           suffering from **a debilitating medical condition** ~~glaucoma, symptoms~~  
29           ~~resulting from the administration of chemotherapy cancer treatment, and~~

1 spastic quadriplegia in accordance with rules and regulations promulgated by  
 2 the Louisiana State Board of Medical Examiners. The Louisiana State Board  
 3 of Medical Examiners shall submit to the Senate and House committees on  
 4 health and welfare on an annual basis not less than sixty days prior to the  
 5 beginning of the regular session of the legislature a report as to any  
 6 additional diseases or medical conditions that should be added to the list of  
 7 eligible diseases and conditions for prescription.

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

13 (i) Cancer.

14 (ii) Positive status for human immunodeficiency virus.

15 (iii) Acquired immune deficiency syndrome.

16 (iv) Cachexia or wasting syndrome.

17 (v) Seizure disorders.

18 (vi) Epilepsy.

19 (vii) Spasticity.

20 (viii) Crohn's disease.

21 (ix) Muscular dystrophy.

22 (x) Multiple sclerosis.

23 (xi) Any of the following conditions associated with autism  
 24 spectrum disorder:

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

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

29 (cc) Self-injuring behavior.

1                    (dd) Physically aggressive or destructive behavior.

2                    (b) No physician shall recommend medical marijuana for  
3                    treatment of any condition associated with autism spectrum disorder for  
4                    a patient who is under the age of eighteen unless the physician is a  
5                    pediatric subspecialist licensed by the Louisiana State Board of Medical  
6                    Examiners and credentialed by the Louisiana Board of Pharmacy.

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

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

25                   (3) For purposes of this Part, "prescribe" or "prescription"  
26                   means an order from a physician domiciled in Louisiana and licensed  
27                   and in good standing with the Louisiana Board of Medical Examiners  
28                   and authorized by the board to prescribe medical marijuana that is  
29                   patient-specific and disease-specific in accordance with Paragraph (2) of

1           this Subsection, and is communicated by any means allowed by the  
2           Louisiana Board of Pharmacy to a Louisiana-licensed pharmacist in a  
3           Louisiana-permitted dispensing pharmacy as described in Subsection G  
4           of this Section, and is preserved on file as required by Louisiana law or  
5           federal law regarding medical marijuana.

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

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

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

20                 C.(1) The Louisiana Board of Pharmacy shall adopt rules relating to  
21                 the dispensing of prescribed marijuana for therapeutic use ~~no later than~~  
22                 ~~December 1, 2016.~~ The Louisiana Board of Pharmacy shall seek input from  
23                 groups including but not limited to the following:

24                         ~~(a) The Louisiana District Attorneys Association.~~

25                         ~~(b) Professional law enforcement associations, organizations, and~~  
26                         ~~commissions.~~

27                         (2) The rules shall include but not be limited to:

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

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

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

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

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

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

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

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

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

27 (j) Licensure of dispensers of prescribed therapeutic marijuana.

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

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

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

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

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

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

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

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

25 I.G. The Louisiana Board of Pharmacy shall develop an annual,  
26 nontransferable specialty license for a pharmacy to dispense prescribed  
27 marijuana for therapeutic use and shall limit the number of such licenses  
28 granted in the state to no more than ten licensees. The Louisiana Board of



1 Pharmacy shall develop rules and regulations regarding the geographical  
2 locations of dispensing pharmacies in Louisiana.

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

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

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

13 **(b) The rules and regulations shall also include but** not be limited  
14 to the procedures for application, qualifications, eligibility, background  
15 checks, and standards for suitability for a license and penalties for violations  
16 of the rules and regulations.

17 (2)**(a)** The Department of Agriculture and Forestry shall develop an  
18 annual, nontransferable specialty license for the production of prescribed  
19 marijuana for therapeutic use, ~~and~~ **Other than the licenses granted**  
20 **pursuant to Subparagraph (b) of this Paragraph, the Department of**  
21 **Agriculture and Forestry** shall limit the number of such licenses granted in  
22 the state to no more than one licensee. The Louisiana State University  
23 Agricultural Center and the Southern University Agricultural Center shall  
24 have the right of first refusal to be licensed as the production facility, either  
25 separately or jointly. If neither of the centers exercise this option, the license  
26 shall be awarded pursuant to the requirements provided for in Paragraphs (3)  
27 through (5) of this Subsection.

28 **(b) Prior to September 1, 2016, the Louisiana State University**  
29 **Agricultural Center and the Southern University Agricultural Center**

1           **shall each provide written notice to the commissioner of agriculture and**  
2           **forestry of their intent to be licensed as a production facility, either**  
3           **separately or jointly.**

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

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

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

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

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

26          (e) No person licensed pursuant to this Subsection shall subcontract  
27          for services for the cultivation or processing in any way of marijuana if the  
28          subcontractor, or any of the service providers in the chain of subcontractors,  
29          is owned wholly or in part by any state employee or member of a state

1 employee's immediate family, including but not limited to any legislator,  
2 statewide public official, university or community or technical college  
3 employee, Louisiana State University Agricultural Center employee, or  
4 Southern University Agricultural Center employee. For the purposes of this  
5 Paragraph, "immediate family" has the same meaning as provided in R.S.  
6 42:1102.

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

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

16 (6)(a) The Department of Agriculture shall collect the following  
17 information from each licensee:

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

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

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

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

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

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

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

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

15 ~~(8) The Department of Agriculture and Forestry shall submit a report~~  
16 ~~to the legislature no later than January 1, 2016, with recommendations on~~  
17 ~~possible fee amounts relative to the provisions of this Section.~~

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

21 ~~L.J.~~ The provisions of this Section shall terminate on January 1,  
22 2020.

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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 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.
- (3) Self-injuring behavior.
- (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.
- (3) Self-injuring behavior.
- (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.

(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.