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)(a) and Section 2 of Act No. 96 of the 2016
3	Regular Session of the Legislature of Louisiana, relative to health conditions for
4	which a recommendation or prescription of medical marijuana is authorized; to
5	authorize the recommendation of or prescription for medical marijuana in treating
6	certain conditions associated with autism spectrum disorder; and to provide for
7	related matters.
8	Be it enacted by the Legislature of Louisiana:
9	Section 1. R.S. 40:1046(A)(2)(a) is hereby amended and reenacted to read as
10	follows:
11	§1046. Recommendation of marijuana for therapeutic use; rules and regulations;
12	Louisiana Board of Pharmacy and the adoption of rules and regulations
13	relating to the dispensing of recommended marijuana for therapeutic use; the
14	Department of Agriculture and Forestry and the licensure of a production
15	facility
16	А.
17	* * *
18	(2)(a) For purposes of this Subsection, "debilitating medical condition"
19	means cancer, positive status for human immunodeficiency virus, acquired immune
20	deficiency syndrome, cachexia or wasting syndrome, seizure disorders, epilepsy,

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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	* * *	
22	Section 2. Section 2 of Act No. 96 of the 2016 Regular Session of the Legislature	
23	of Louisiana is hereby amended and reenacted to read as follows:	
24	Section 2. R.S. 40:1046 is hereby amended and reenacted to read as follows:	
25	§1046. Prescription of marijuana for therapeutic use; rules and regulations;	
26	Louisiana Board of Pharmacy and the adoption of rules and	
27	regulations relating to the dispensing of prescribed marijuana for	
28	therapeutic use; the Department of Agriculture and Forestry and the	
29	licensure of a production facility	

1	A.(1) Notwithstanding any other provision of this Part, a physician
2	licensed by and in good standing with the Louisiana State Board of
3	Medical Examiners to practice medicine in this state and who is domiciled
4	in this state may prescribe, in any form as permitted by the rules and
5	regulations of the Louisiana Board of Pharmacy except for inhalation, and
6	raw or crude marijuana, tetrahydrocannabinols, or a chemical derivative of
7	tetrahydrocannabinols for therapeutic use by patients clinically diagnosed as
8	suffering from a debilitating medical condition glaucoma, symptoms
9	resulting from the administration of chemotherapy cancer treatment, and
10	spastic quadriplegia in accordance with rules and regulations promulgated by
11	the Louisiana State Board of Medical Examiners. The Louisiana State Board
12	of Medical Examiners shall submit to the Senate and House committees on
13	health and welfare on an annual basis not less than sixty days prior to the
14	beginning of the regular session of the legislature a report as to any
15	additional diseases or medical conditions that should be added to the list of
16	eligible diseases and conditions for prescription.
17	(2)(a) For purposes of this Subsection, "debilitating medical
18	condition" means cancer, positive status for human immunodeficiency
19	virus, acquired immune deficiency syndrome, cachexia or wasting
20	syndrome, seizure disorders, epilepsy, spasticity, Crohn's disease,
21	muscular dystrophy, or multiple sclerosis. any of the following:
22	(i) Cancer.
23	(ii) Positive status for human immunodeficiency virus.
24	(iii) Acquired immune deficiency syndrome.
25	(iv) Cachexia or wasting syndrome.
26	(v) Seizure disorders.
27	(vi) Epilepsy.
28	(vii) Spasticity.
29	(viii) Crohn's disease.

1	(ix) Muscular dystrophy.
2	(x) Multiple sclerosis.
3	(xi) Any of the following conditions associated with autism
4	spectrum disorder:
5	(aa) Repetitive or self-stimulatory behavior of such severity that
6	the physical health of the person with autism is jeopardized.
7	(bb) Avoidance of others or inability to communicate of such
8	severity that the physical health of the person with autism is jeopardized.
9	(cc) Self-injuring behavior.
10	(dd) Physically aggressive or destructive behavior.
11	(b) If the United States Food and Drug Administration approves
12	the use of medical marijuana in the same form provided for in this Part
13	for any debilitating medical condition specifically identified in this
14	Paragraph, that medical condition shall no longer be covered by the
	Tatagraph, that medical condition shan no longer be covered by the
15	provisions of this Part.
15	provisions of this Part.
15 16	provisions of this Part. (c) If the United States Food and Drug Administration approves
15 16 17	provisions of this Part. (c) If the United States Food and Drug Administration approves the use of medical marijuana in a form or derivative different than
15 16 17 18	provisions of this Part. (c) 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
15 16 17 18 19	provisions of this Part. (c) 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
15 16 17 18 19 20	provisions of this Part. (c) 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
 15 16 17 18 19 20 21 	provisions of this Part. (c) 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
 15 16 17 18 19 20 21 22 	provisions of this Part. (c) 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
 15 16 17 18 19 20 21 22 23 	provisions of this Part. (c) 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
 15 16 17 18 19 20 21 22 23 24 	provisions of this Part. (c) 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
 15 16 17 18 19 20 21 22 23 24 25 	provisions of this Part. (c) 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

1	(3) For purposes of this Part, "prescribe" or "prescription"	
2	means an order from a physician domiciled in Louisiana and licensed	
3	and in good standing with the Louisiana Board of Medical Examiners	
4	and authorized by the board to prescribe medical marijuana that is	
5	patient-specific and disease-specific in accordance with Paragraph (2) of	
6	this Subsection, and is communicated by any means allowed by the	
7	Louisiana Board of Pharmacy to a Louisiana-licensed pharmacist in a	
8	Louisiana-permitted dispensing pharmacy as described in Subsection G	
9	of this Section, and is preserved on file as required by Louisiana law or	
10	<u>federal law regarding medical marijuana.</u>	
11	(4) Physicians shall prescribe the use of medical marijuana for	
12	treatment of debilitating medical conditions in accordance with rules	
13	and regulations promulgated by the Louisiana State Board of Medical	
14	Examiners.	
15	(5) The Louisiana State Board of Medical Examiners shall submit	
16	to the Senate and House committees on health and welfare on an annual	
17	basis not less than sixty days prior to the beginning of the regular session	
18	of the legislature a report as to any additional diseases or medical	
19	conditions that should be added to the list of eligible diseases and	
20	conditions for recommendation.	
21	B. The Louisiana State Board of Medical Examiners shall promulgate	
22	rules and regulations authorizing physicians licensed to practice in this state	
23	to prescribe marijuana for therapeutic use by patients as described in	
24	Subsection A of this Section no later than January 1, 2016.	
25	C.(1) The Louisiana Board of Pharmacy shall adopt rules relating to	
26	the dispensing of prescribed marijuana for therapeutic use no later than	
27	December 1, 2016. The Louisiana Board of Pharmacy shall seek input from	
28	groups including but not limited to the following:	
29	(a) The Louisiana District Attorneys Association.	

1	(b) Professional law enforcement associations, organizations, and
2	commissions.
3	(2) The rules shall include but not be limited to:
4	(a) Standards, procedures, and protocols for the effective use of
5	prescribed marijuana for therapeutic use as authorized by state law and
6	related rules and regulations.
7	(b) Standards, procedures, and protocols for the dispensing and
8	tracking of prescribed therapeutic marijuana in Louisiana.
9	(c) Procedures and protocols to provide that no prescribed therapeutic
10	marijuana may be dispensed from, produced from, obtained from, sold to, or
11	transferred to a location outside of this state.
12	(d) The establishment of standards, procedures, and protocols for
13	determining the amount of usable prescribed therapeutic marijuana that is
14	necessary to constitute an adequate supply to ensure uninterrupted
15	availability for a period of one month, including amounts for topical
16	treatments.
17	(e) The establishment of standards, procedures, and protocols to
18	ensure that all prescribed therapeutic marijuana dispensed is consistently
19	pharmaceutical grade.
20	(f) The establishment of standards and procedures for the revocation,
21	suspension, and nonrenewal of licenses.
22	(g) The establishment of other licensing, renewal, and operational
23	standards which are deemed necessary by the Louisiana Board of Pharmacy.
24	(h) The establishment of standards and procedures for testing
25	prescribed therapeutic marijuana samples for levels of tetrahydrocannabinol
26	(THC) or other testing parameters deemed appropriate by the Louisiana
27	Board of Pharmacy.
28	(i) The establishment of health, safety, and security requirements for
29	dispensers of prescribed therapeutic marijuana.

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1	(j) Licensure of dispensers of prescribed therapeutic marijuana.	
2	(k) The establishment of financial requirements for applicants of	
3	therapeutic marijuana dispensing pharmacy license under which each	
4	applicant demonstrates the following:	
5	(i) The financial capacity to operate a therapeutic marijuana	
6	dispensing pharmacy.	
7	(ii) The ability to maintain an escrow account in a financial institution	
8	headquartered in Louisiana in an amount of two million dollars, if required	
9	by the Louisiana Board of Pharmacy.	
10	D. The Louisiana Board of Pharmacy shall submit a report to the	
11	legislature no later than January 1, 2016, with recommendations on possible	
12	fee amounts relative to the provisions of this Section.	
13	E. All rules shall be adopted in accordance with the provisions of the	
14	Administrative Procedure Act.	
15	F.D. Nothing in this Section shall be construed to prohibit the	
16	Louisiana State Board of Medical Examiners or the Louisiana Board of	
17	Pharmacy from adopting emergency rules as otherwise provided for in the	
18	Administrative Procedure Act.	
19	G.E. Marijuana, tetrahydrocannabinols, or a chemical derivative of	
20	tetrahydrocannabinols prescribed pursuant to this Section shall be dispensed	
21	in person from a licensed pharmacy in good standing located in Louisiana.	
22	H.F. A prescriber and dispenser of marijuana, tetrahydrocannabinols,	
23	or a chemical derivative of tetrahydrocannabinols pursuant to this Section	
24	shall review the patient's information in the Prescription Monitoring Program	
25	database prior to the prescribing and dispensing thereof.	
26	I.G. The Louisiana Board of Pharmacy shall develop an annual,	
27	nontransferable specialty license for a pharmacy to dispense prescribed	
28	marijuana for therapeutic use and shall limit the number of such licenses	
29	granted in the state to no more than ten licensees. The Louisiana Board of	

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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 provided for in rule by the Department of Agriculture and Forestry. The 5 6 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 7 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

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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.

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 Original 201	18 Regular Session	Lyons
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Abstract: Authorizes the recommendation or prescription of medical marijuana in treating certain health conditions associated with autism spectrum disorder.

Recommendation of Medical Marijuana

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

<u>Present law</u> 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.

<u>Proposed law</u> retains <u>present law</u> and <u>adds</u> 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.

Prescription of Medical Marijuana

<u>Present law</u> authorizes physicians who are domiciled in La. and licensed by and in good standing with the La. State Board of Medical Examiners to <u>prescribe</u>, 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.

<u>Proposed law</u> retains <u>present law</u> and <u>adds</u> 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.

(Amends R.S. 40:1046(A)(2)(a) and §2 of Act No. 96 of 2016 R.S.)