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HOUSE FLOOR AMENDMENTS

2019 Regular Session

Amendments proposed by Representative Dustin Miller to Engrossed House Bill No. 568
by Representative Dustin Miller

1 AMENDMENT NO. 1

2 On page 10, delete lines 26-28, delete pages 11-18, and on page 19, delete lines 1-15 all in
3 their entirety and insert in lieu thereof the following:

4 "PART X-E. THERAPEUTIC USE OF CANNABIS

5 §1046. ~~Recommendation~~ Prescription of cannabis for therapeutic use; rules and
6 regulations; Louisiana Board of Pharmacy and the adoption of rules and
7 regulations relating to the dispensing of ~~recommended~~ prescribed cannabis
8 for therapeutic use; the Louisiana Department of Health and the licensure of
9 a production facility

10 A.(1) Notwithstanding any other provision of this Part, a physician licensed
11 by and in good standing with the Louisiana State Board of Medical Examiners to
12 practice medicine in this state and who is domiciled in this state may ~~recommend~~
13 prescribe, in any form as permitted by the rules and regulations of the Louisiana
14 Board of Pharmacy except for inhalation, and raw or crude cannabis,
15 tetrahydrocannabinols, or a chemical derivative of tetrahydrocannabinols for
16 therapeutic use by patients clinically diagnosed as suffering from a debilitating
17 medical condition.

18 (2)(a) For purposes of this Subsection, "debilitating medical condition"
19 means any of the following:

- 20 (i) Cancer.
- 21 (ii) Glaucoma.
- 22 (iii) Parkinson's disease.
- 23 (iv) Positive status for human immunodeficiency virus.
- 24 (v) Acquired immune deficiency syndrome.
- 25 (vi) Cachexia or wasting syndrome.
- 26 (vii) Seizure disorders.
- 27 (viii) Epilepsy.
- 28 (ix) Spasticity.
- 29 (x) Severe muscle spasms.
- 30 (xi) Intractable pain.
- 31 (xii) Crohn's disease.
- 32 (xiii) Muscular dystrophy.
- 33 (xiv) Multiple sclerosis.
- 34 (xv) ~~Post-traumatic~~ Posttraumatic stress disorder.
- 35 (xvi) Any of the following conditions associated with autism spectrum
36 disorder:

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

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

41 (cc) Self-injuring behavior.

42 (dd) Physically aggressive or destructive behavior.

43 (b) No physician shall ~~recommend~~ prescribe therapeutic cannabis for
44 treatment of any condition associated with autism spectrum disorder for a patient

1 who is under the age of eighteen unless the physician complies with the provisions
2 of this Section and consults with a pediatric subspecialist.

3 (c) Intractable pain means a pain state in which the cause of the pain cannot
4 be removed or otherwise treated with the consent of the patient and which, in the
5 generally accepted course of medical practice, no relief or cure of the cause of the
6 pain is possible, or none has been found after reasonable efforts. It is pain so chronic
7 and severe as to otherwise warrant an opiate prescription.

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

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

23 (3) For purposes of this Part, "recommend" or "recommended" "prescribe"
24 or "prescribed" means an order from a physician domiciled in Louisiana and licensed
25 and in good standing with the Louisiana State Board of Medical Examiners and
26 authorized by the board to recommend prescribe therapeutic cannabis that is
27 patient-specific and disease-specific in accordance with Paragraph (2) of this
28 Subsection, and is communicated by any means allowed by the Louisiana Board of
29 Pharmacy to a Louisiana-licensed pharmacist in a Louisiana-permitted dispensing
30 pharmacy as described in Subsection G of this Section, and is preserved on file as
31 required by Louisiana law or federal law regarding therapeutic cannabis.

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

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

40 B. The Louisiana State Board of Medical Examiners shall promulgate rules
41 and regulations authorizing physicians licensed to practice in this state to recommend
42 prescribe cannabis for therapeutic use by patients as described in Subsection A of
43 this Section. ~~Any rules published by the Louisiana State Board of Medical~~
44 ~~Examiners on or before January 1, 2016, that describe the physician's authority to~~
45 ~~prescribe should be repromulgated to indicate that he is "recommending" use of~~
46 ~~therapeutic marijuana cannabis.~~

47 C.(1) The Louisiana Board of Pharmacy shall adopt rules relating to the
48 dispensing of recommended prescribed cannabis for therapeutic use. ~~Any rules~~
49 ~~published by the Louisiana Board of Pharmacy on or before January 1, 2016, that~~
50 ~~describe the pharmacist as dispensing medical marijuana therapeutic cannabis based~~
51 ~~on a physician's prescription should be repromulgated to indicate that the physician~~
52 ~~is "recommending" use of therapeutic marijuana cannabis.~~

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

54 (a) Standards, procedures, and protocols for the effective use of
55 recommended prescribed cannabis for therapeutic use as authorized by state law and
56 related rules and regulations.

57 (b) Standards, procedures, and protocols for the dispensing and tracking of
58 recommended prescribed therapeutic cannabis in Louisiana.

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

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

8 (e) The establishment of standards, procedures, and protocols to ensure that
 9 all ~~recommended~~ prescribed therapeutic cannabis dispensed is consistently
 10 pharmaceutical grade.

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

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

15 (h) The establishment of standards and procedures for testing ~~recommended~~
 16 prescribed therapeutic cannabis samples for levels of tetrahydrocannabinol (THC)
 17 or other testing parameters deemed appropriate by the Louisiana Board of Pharmacy.

18 (i) The establishment of health, safety, and security requirements for
 19 dispensers of ~~recommended~~ prescribed therapeutic cannabis.

20 (j) Licensure of dispensers of ~~recommended~~ prescribed therapeutic cannabis.

21 (k) The establishment of financial requirements for applicants of therapeutic
 22 cannabis dispensing pharmacy license under which each applicant demonstrates the
 23 following:

24 (i) The financial capacity to operate a therapeutic cannabis dispensing
 25 pharmacy.

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

29 D. Nothing in this Section shall be construed to prohibit the Louisiana State
 30 Board of Medical Examiners or the Louisiana Board of Pharmacy from adopting
 31 emergency rules as otherwise provided for in the Administrative Procedure Act.

32 E. Cannabis, tetrahydrocannabinols, or a chemical derivative of
 33 tetrahydrocannabinols ~~recommended~~ prescribed pursuant to this Section shall be
 34 dispensed in person from a licensed pharmacy in good standing located in Louisiana.

35 F. A person who ~~recommends~~ prescribes and a person who dispenses
 36 cannabis, tetrahydrocannabinols, or a chemical derivative of tetrahydrocannabinols
 37 pursuant to this Section shall review the patient's information in the database of the
 38 prescription monitoring program established in R.S. 40:1001 et seq. prior to the
 39 ~~recommending~~ prescribing and dispensing thereof.

40 G. The Louisiana Board of Pharmacy shall develop an annual,
 41 nontransferable specialty license for a pharmacy to dispense ~~recommended~~
 42 prescribed cannabis for therapeutic use and shall limit the number of such licenses
 43 granted in the state to no more than ten licensees. The Louisiana Board of Pharmacy
 44 shall develop rules and regulations regarding the geographical locations of
 45 dispensing pharmacies in Louisiana.

46 H.(1)(a) The Louisiana Department of Health shall develop the rules and
 47 regulations regarding the extraction, processing, and production of ~~recommended~~
 48 prescribed therapeutic cannabis and the facility producing therapeutic cannabis. The
 49 rules and regulations shall include but not be limited to both of the following
 50 minimum standards:

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

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

55 (b) The rules and regulations shall also include but not be limited to the
 56 procedures for application, qualifications, eligibility, background checks, and
 57 standards for suitability for a license and penalties for violations of the rules and
 58 regulations.

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

11 (b) Prior to September 1, 2016, the Louisiana State University Agricultural
12 Center and the Southern University Agricultural Center shall each provide written
13 notice to the secretary of the Louisiana Department of Health of their intent to be
14 licensed as a production facility, either separately or jointly.

15 (c) The Louisiana State University Agricultural Center or the Southern
16 University Agricultural Center may conduct research on cannabis for therapeutic use
17 if the center is licensed as a production facility pursuant to this Section. Effective
18 January 1, 2020, and annually thereafter, the Louisiana State University Agricultural
19 Center and the Southern University Agricultural Center shall submit a report to the
20 Senate and House committees on health and welfare, to include data and outcomes
21 of the research conducted pursuant to this Paragraph.

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

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

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

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

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

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

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

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

1 value that is expressed in the contract, memorandum of understanding, or
2 cooperative endeavor agreement.

3 (6)(a) The Louisiana Department of Health shall collect the following
4 information from each licensee:

5 (i) The amount of gross cannabis produced by the licensee during each
6 calendar year.

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

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

11 (iv) The amount of therapeutic chemicals produced resulting from the
12 cannabis grown pursuant to this Section.

13 (v) The amounts paid each year to the licensee related to the licensee's
14 production of therapeutic cannabis pursuant to this Section.

15 (vi) The amount of therapeutic cannabis distributed to each pharmacy
16 licensed to dispense therapeutic cannabis in this state during each calendar year.

17 (b) The Louisiana Department of Health shall provide the information
18 collected pursuant to this Paragraph for the previous calendar year in the form of a
19 written report to the Louisiana Legislature no later than February first of each year.
20 The department shall also make a copy of the report required by this Subparagraph
21 available to the public on the ~~Internet~~ internet.

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

27 (8)(a) The department shall perform the following:

28 (i) Establish and collect an annual license fee of one hundred thousand dollars
29 and an annual permit fee of one hundred dollars for administrative and inspection
30 costs.

31 (ii) Collect a nonrefundable application fee of ten thousand dollars.

32 (b) All fees collected by the department shall be used to fund the expenses
33 relating to the regulation and control of prescribed cannabis for therapeutic use.

34 I. The levels of THC in any cannabis produced pursuant to this Section shall
35 be reduced to the lowest acceptable therapeutic levels available through scientifically
36 accepted methods.

37 J. Notwithstanding any other provision of law to the contrary, employers and
38 their worker's compensation insurers shall not be obliged or ordered to pay for
39 therapeutic cannabis in claims arising under Title 23 of the Louisiana Revised
40 Statutes of 1950, the Louisiana Workers' Compensation Law.

41 K. The provisions of this Section shall terminate on January 1, 2025."