



Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov



Board Meeting

March 14, 2017

NOTE: Pursuant to the Open Meetings Law at La. R.S. 42:16, the Board may, upon 2/3 affirmative vote of those members present and voting, enter into executive session for the limited purposes of (1) discussion of the character, professional competence, or physical or mental health of a licensee, (2) investigative proceedings regarding allegations of misconduct, (3) strategy sessions or negotiations with respect to litigation, (4) discussions regarding personnel matters, or other purposes itemized at La. R.S. 42:17.



Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov



NOTICE IS HEREBY GIVEN that a special meeting of the Board has been ordered and called for 12:00 p.m. on Tuesday, March 14, 2017 at the Board office, for the purpose to wit:

AGENDA

NOTE: This agenda is tentative until 24 hours in advance of the meeting, at which time the most recent revision becomes official.

Revised 01-25-2017

1. Call to Order
2. Invocation & Pledge of Allegiance
3. Quorum Call
4. Call for Additional Agenda Items & Adoption of Agenda
5. Opportunity for Public Comment
6. Consideration of Comments & Testimony from Public Hearings
 - *Regulatory Project 2015-9 ~ Pharmacy Technicians*
 - Project Timeline 003
 - Proposed Rule 005
 - Summary of Comments & Testimony 008
 - Comment Documents 011
 - Staff Notes re Comments 032
 - *Regulatory Project 2016-4 ~ Standing Orders for Distribution of Naloxone*
 - Project Timeline 037
 - Proposed Rule 038
 - Summary of Comments & Testimony 040
 - *Regulatory Project 2016-5 ~ Reinstatement of CDS Licenses*
 - Project Timeline 041
 - Proposed Rule 042
 - Summary of Comments & Testimony 043
 - *Regulatory Project 2016-6 ~ Marijuana Pharmacy*
 - Project Timeline 044
 - Proposed Rule 045
 - Summary of Comments & Testimony 065
 - Comment Documents 071
 - Staff Notes re Comments 085
 - Enabling Legislation 102
7. Consideration of *Legislative Proposal 2017-C ~ Pharmacy Benefit Managers (Draft #2)* 107
8. Announcements 108
9. Adjourn

NOTE: Pursuant to the Open Meetings Law at La. R.S. 42:16, the Board may, upon 2/3 affirmative vote of those members present and voting, enter into executive session for the limited purposes of (1) discussion of the character, professional competence, or physical or mental health of a licensee, (2) investigative proceedings regarding allegations of misconduct, (3) strategy sessions or negotiations with respect to litigation, (4) discussions regarding personnel matters, or other purposes itemized at La. R.S. 42:17.



Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov



MEMORANDUM

To: Board Members
From: Malcolm Broussard
Date: March 14, 2017
Re: Regulatory Project 2015-9 ~ Pharmacy Technicians

Project Timeline

- 11-30-2015 > Board adopted *Emergency Rule #1* for the purpose of delaying the implementation date in the current rule (§905.A.3.b), which requires applicants for the pharmacy technician certificate submitting their applications to document their successful completion of a nationally-accredited and board-approved pharmacy technician training program, from January 1, 2016 to January 1, 2017.
- > Board directed the Regulation Revision Committee to revise the current rule to shift the requirement of national accreditation of the training program FROM completion of such program as a qualification for the pharmacy technician certificate TO enrollment in such a program as a qualification for the pharmacy technician candidate registration; and further, to update the CE requirements to include CPE Monitor; and further, to update the scope of practice for technicians by removing the compounding restriction.
- 03-24-2016 Re-issued original *Emergency Rule #2*.
- 05-04-2016 Board approved Regulatory Proposal 2015-J (Draft #4) for promulgation.
- 07-22-2016 Re-issued original *Emergency Rule #3*.
- 11-17-2016 Board adopted *Revised Emergency Rule #4* for the purpose of further delaying the implementation date, from January 1, 2017 to January 1, 2018.
- 01-09-2017 Submitted Notice of Intent to Joint Legislative Oversight Committee on Health & Welfare.
- 01-20-2017 Notice of Intent published in *Louisiana Register*.

Regulatory Project 2015-9
Project Timeline
Page 2 of 2

- | | |
|------------|--|
| 03-01-2017 | Public hearing to receive comments and testimony on proposed rule. |
| 03-14-2017 | Board meeting to consider comments and testimony on proposed rule. |
| 03-15-2017 | Scheduled to re-issue <i>Revised Emergency Rule #5</i> . |
| 07-10-2017 | Scheduled to re-issue <i>Revised Emergency Rule #6</i> . |

1 Louisiana Administrative Code

2
3 Title 46 – Professional and Occupational Standards

4
5 Part LIII: Pharmacists

6
7 Chapter 9. Pharmacy Technicians

8
9 §901. Definitions

10 A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section:

11 ...
12 CPE Monitor – a collaborative service from the National Association of Boards of Pharmacy
13 (NABP) and the Accreditation Council for Pharmacy Education (ACPE) that provides an
14 electronic system for pharmacists and pharmacy technicians to record and track their
15 completed CPE activities.

16 ...
17 Pharmacy Technician Candidate – an individual ~~not yet certified as a pharmacy technician by the~~
18 ~~board who is,~~ registered by the board, training to become a pharmacy technician, who assists
19 in the practice of pharmacy under the direct and immediate supervision of a Louisiana-
20 licensed pharmacist.

21 a. ~~an individual who possesses a valid registration and is working under the~~
22 ~~supervision of a pharmacist for the purpose of obtaining practical experience for~~
23 ~~certification as a pharmacy technician by the board; or~~

24 b. ~~an individual who possesses a valid registration and is awaiting examination.~~

25 Structured Training Program – ~~Repealed a pharmacy technician training program that is currently~~
26 ~~nationally-accredited and has been approved by the board.~~

27
28 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

29 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2485
30 (November 2004), effective January 1, 2005, amended LR 39:1777 (July 2013), amended LR

31
32 §903. Pharmacy Technician Candidates

33 A. Registration

34 1. All pharmacy technician candidates shall obtain a registration from the board prior to
35 performing any professional functions in a pharmacy; failure to do so may result in
36 disciplinary action by the board.

37 2. Qualifications

38 a. ~~All pharmacy technician candidates shall register with the board; failure to do so~~
39 ~~may result in disciplinary action by the board.~~

40 b. The candidate applicant shall be at least 18 years of age, as evidenced by a valid
41 and legible copy of a birth certificate or other appropriate credential.

42 c. The candidate applicant shall be of good moral character and non-impaired.

43 d. ~~The candidate shall be a graduate from a high school approved by a state~~
44 ~~department of education, or shall possess an equivalent degree of education, as~~
45 ~~evidenced by a valid and legible copy of a diploma, transcript, or other appropriate~~
46 ~~credential;~~

47 c. The applicant shall satisfy one of the following eligibility criteria:

48 i. Proof of enrollment in a nationally-accredited and board-approved
49 pharmacy technician training program; or

50 ii. Proof of successful completion of the board-approved technician
51 certification examination, and further, proof of successful completion of a
52 high school approved by a state department of education or an equivalent
53 degree of education, as evidenced by a valid and legible copy of a diploma,
54 transcript, or other appropriate credential; or

55 iii. Proof of credentialing as a pharmacy technician by another state board of
56 pharmacy as well as evidence of practice as a pharmacy technician for at
57 least one year in that state, and further, proof of successful completion of
58 the board-approved technician certification examination.

59
60
61
62
63
64
65
66
67
68
69
70
71
72
73
74
75
76
77
78
79
80
81
82
83
84
85
86
87
88
89
90
91
92
93
94
95
96
97
98
99
100
101
102
103
104
105
106
107
108
109
110
111
112
113
114
115
116

- e. Exceptions: ...
- 3. Issuance and Maintenance
 - a – b ...
 - c. The registration shall expire ~~18~~ 24 months after the date of issuance, and it shall not be renewable.
 - d – e ...

B. Training Programs

- 1. All training programs approved by the board shall maintain their national accreditation.
- 2. The training program shall notify the board when a pharmacy technician candidate is no longer satisfactorily progressing in the program. Evidence of a program's failure to comply with this rule shall constitute sufficient basis for the withdrawal of the board's approval for the program.
- 3. The training program shall provide an appropriate credential to the pharmacy technician candidate who has successfully completed the program, provided, however, that such credential shall not be formatted in such a manner to lead anyone to believe that credential resembles a document providing legal authority to practice as a pharmacy technician.

C. Practical Experience

- 1. The candidate shall possess a registration prior to performing any permitted professional function or earning any practical experience in a pharmacy.
- ~~2. The candidate's registration shall be conspicuously displayed in the prescription department.~~
- ~~3 – 4 ...~~
- 5. The candidate's registration shall evidence his authority to earn ~~a minimum of 600 hours of~~ practical experience in a pharmacy, under the supervision of a pharmacist, in satisfaction of the requirements for pharmacy technician certification.
 - a. In the event the registration was issued to an applicant enrolled in a nationally-accredited and board-approved training program, the candidate shall earn the amount of experience prescribed by the curriculum of that program; or
 - b. In the event the registration was issued to an applicant by any other method, the candidate shall earn at least 600 hours of practical experience in a pharmacy in Louisiana, provided however, that a candidate may receive board credit for a maximum of 50 hours per week.
- ~~3. A candidate may receive board credit for a maximum of 50 hours per week.~~
- 4. Hours of practical experience earned by a candidate shall expire ~~one~~ two years after the expiration date of the registration.

D. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, repromulgated LR 19:1025 (August 1993), amended LR 23:1307 (October 1997), LR 30:2485 (November 2004), effective January 1, 2005, amended LR 39:1777 (July 2013), amended LR

§905. Pharmacy Technician Certificate

A. Qualifications

- 1 – 2 ...
- 3. An applicant shall demonstrate one of the following educational competencies:
 - ~~a. shall be a graduate from a high school approved by a state department of education, or shall possess an equivalent degree of education, as evidenced by a valid and legible copy of a diploma, transcript, or other appropriate credential; and~~
 - ~~b. For those applicants submitting applications on or after January 1, 2016, the applicant shall demonstrate successful completion of a nationally-accredited and board-approved pharmacy technician training program, as evidenced by a valid and legible copy of the appropriate credential from that program.~~
 - a. In the event the applicant obtained their technician candidate registration on the basis of their enrollment in a nationally-accredited and board-approved pharmacy technician training program, the applicant shall demonstrate successful completion

117 of that training program, or in the alternative, another nationally-accredited and
118 board-approved pharmacy technician training program.
119 b. In the event the applicant obtained their technician candidate registration by any
120 other method, the applicant shall demonstrate the acquisition of at least 600 hours
121 of practical experience under the supervision of a pharmacist, using a form
122 supplied by the board.

123 ~~2. An applicant shall demonstrate evidence of at least 600 hours of practical experience under~~
124 ~~the supervision of a pharmacist, using a form supplied by the board.~~

125 3. ...

126 B. Issuance and Maintenance

127 1. Upon receipt of a properly completed and notarized application, ~~properly executed preceptor~~
128 ~~affidavit(s)~~, copies of valid and legible credentials, and the appropriate fee, and any other
129 documentation required by the board, and following verification that all requirements have
130 been satisfied, the board may issue a pharmacy technician certificate to the applicant for the
131 current renewal period.

132 2 - 6 ...

133

134 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

135 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
136 (October 1988), effective January 1, 1989, repromulgated LR 19:1025 (August 1993), LR 30:2486 (November
137 2004), effective January 1, 2005, amended LR 38:1235 (May 2012), amended LR 39:1777 (July 2013), amended LR
138

139 **§907. Scope of Practice**

140 A - B.5 ...

141 C. Pharmacy technicians shall not:

142 1 - 2 ...

143 3. ~~compound high-risk sterile preparations, as defined by the United States Pharmacopeia~~
144 ~~(USP), or its successor;~~

145 4. ...

146

147 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

148 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2486
149 (November 2004), effective January 1, 2005, amended LR 32:1049 (June 2006), amended LR
150

151 **§909. Continuing Education**

152 A. ...

153 B. Certified pharmacy technicians shall maintain copies of their individual records of personal CPE
154 activities ~~at their primary practice site for at least 2 years with CPE Monitor and shall authorize the~~
155 board's access to their file by recording their Louisiana pharmacy technician certificate number within
156 that file, and shall present them a copy of their CPE Monitor transcript when requested by the board.

157 C - D.3 ...

158

159 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

160 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
161 (October 1988), effective January 1, 1989, amended LR 17:779 (August 1991), repromulgated LR 19:1025 (August
162 1993), amended LR 23:1308 (October 1997), LR 30:2487 (November 2004), effective January 1, 2005, amended
163 LR 39:1778 (July 2013), amended LR
164

164

165 ...



Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov



Summary of Testimony & Public Comments
re
Regulatory Project 2015-9 ~ Pharmacy Technicians
at
March 1, 2017 Public Hearing

1. February 27, 2017 letter from David Dubose (PST) on behalf of PassAssured

Opposes the requirement for national accreditation of training programs; recommends retention of high school and employer-based programs. Noted that 23 accredited programs are located in 13 parishes, leaving 51 parishes without any accredited programs. Recommends approval of ExCPT examination in addition to PTCB.

2. February 27, 2017 email from Susan Brunet (PST) on behalf of an un-named pharmacy

Indicated the pass rate for technicians she has trained is better than technicians trained at Unitech Training Academy.

3. February 27, 2017 email from Angelle Billiot (PTC) at Wolfe's Pharmacy

Working in pharmacy; has failed test twice. Values on-the-job training. Could not afford cost of formal training.

4. February 27, 2017 email from Geraldine LeBoeuf (CPT) at Wolfe's Pharmacy

Indicated she has been a technician for 22 years. Trained at Wolfe's Pharmacy and passed test without attending a school for tech training. Has worked with some techs who attended school and appeared to be 'lost' in the pharmacy.

5. February 28, 2017 email from Peter Wolfe, Sr. (PST) at Wolfe's Pharmacy

Has trained many techs in his pharmacy. Excellent pass rate until a few years ago when test 'got more difficult.' Most of his technician candidates cannot afford to pay for formal training because they are family wage earners.

6. February 28, 2017 letter from Mary Staples on behalf of NACDS

(1) If the board moves forward with accreditation requirement, suggest the programs be either accredited or board-approved, but not both. Offered specific suggested revisions to accomplish that objective. (2) Questions the need for the board to be notified when the candidate is no longer satisfactorily progressing in a training program. Term is not well-defined and is unnecessary micromanagement by the board, with no real benefit to the board or public safety; recommend clarification or removal.

7. February 27, 2017 letter from Lyndsey McDonald on behalf of National Healthcareer Association (NHA)

NHA is the provider of the Examination for the Certification of Pharmacy Technicians (ExCPT). Supportive of the three eligibility options for the candidate registration described in §903.A.2.c; however, they request that the option described in (ii) of that paragraph be modified to indicate the certification examination shall be accredited by the National Commission of Certifying Agencies (NCCA) or board-approved. Similarly, requested a change at §905.A.4 to indicate the certification examination would be any such examination accredited by NCCA.

8. March 1, 2017 email from Meghan McEachern (CPT) at Wolfe's Pharmacy

Trained at the pharmacy, but failed the first test because questions didn't pertain to what she had learned. Passed the test on the second try; nothing like the first test. Would not be able to afford formal training program.

9. March 1, 2017 email from Courtney Battise (PTC) at Wolfe's Pharmacy

Has trained at Wolfe's Pharmacy. Failed first test even though questions appeared to relate to what she was taught. Failed second test because questions didn't appear to relate to what she was taught. Wouldn't attend an accredited school because she wouldn't get the experience she's getting in the pharmacy.

10. March 1, 2017 letter from Anne LaVance (CPT) at Delgado Community College

Serves as director of technician training program which is accredited. Indicated tuition cost at her program is \$7500 – 8000; she related information from a major retailer indicating on-the-job (OJT) costs approximated \$8700. Indicated her program's pass rate for PTCB is 93% on first attempt and 100% on second attempt. 95% of graduates are employed within 60 days, with 80% of those hired by their preceptor. An additional 6 graduates have continued, graduating from a college of pharmacy. Indicated her research of other accredited programs across the state reflected none of them are operating at full capacity. Working on two innovative solutions – collaboration with other technical colleges without a program to develop a hybrid online solution, and developing challenge examination pathways for students with prior experience but have not yet passed the PTCB test.

11. Testimony from Lisa LaCour (PST) on behalf of 7 pharmacies: Albany Drugs, Bernard's Family Pharmacy, Channell Drugs, Dutchtown Pharmacy, Greensburg Pharmacy, Pete's Pharmacy, and Ponchatoula Family Pharmacy

Opposes accreditation requirement. Questions whether programs can supply sufficient manpower for pharmacies.

12. Testimony from Andre Stolier on behalf of La. Independent Pharmacies Association (LIPA)

Opposes accreditation requirement. Will adversely impact their members in rural areas without access to accredited programs in urban areas. Wish to continue current permission to train their own technicians. If proposed rule is modified to allow that current option, their objection would be withdrawn.

13. Testimony from Aurdie Bellard (PST) on behalf of Bellard's Family Pharmacy as well as LSU-A and LSU-E

Serves as instructor in LSU-A's 18-month accredited program via teleconference on the LSU-E campus. Supports the proposed rule as written. Opposes any further delay. Working on an associate degree option for the program. Introduced seven technician students in attendance.

14. Testimony from Charles Feucht (PST) on behalf of Acadiana Consultant Pharmacy Service (ACPS) as well as LSU-A and LSU-E

Serves as instructor in LSU-A's accredited program via teleconference on the LSU-E campus. Supports the proposed rule as written, but requests consideration for non-permitted pharmacy practice sites to be included in permissible sites for practical experience. Related his consultant pharmacy practice, where there are no drugs stored or dispensed, as a valuable practice site for technician training. Opposes any further delay. Recalling the previous comment

that the 23 accredited programs are found in 13 parishes, leaving 51 parishes without any accredited programs, and the resulting concern for the production of enough manpower, he noted there are only two schools of pharmacy in 2 parishes, leaving 62 parishes without any schools of pharmacy, but there doesn't seem to be any manpower supply issues. Would support current model of on-the-job training (OJT) if the Board developed and enforced standards that are comparable to those of accredited programs. Finally, the low pass rate for the PTCB test raises concern not only for the OJT programs but also the accredited programs. Suggested more oversight and compliance checking by the Board.

15. Further testimony from Andre Stolier on behalf of LIPA

Returned to comment on previous commentator's testimony. LIPA has no objection to Board exercising oversight of OJT programs, and does not advocate any particular set of standards as long as those standards permit OJT to continue in their members' pharmacies.

16. Chelsea Carmouche (PTC) at LSU-E

Current technician student at LSU-E. Related her mother's technician education, and how she helped her mother with the mathematics portion. Believes her education at multiple practice sites is better for her career options when she finishes.

17. Further testimony from Charles Feucht (PST) on behalf of ACPS, LSU-A and LSU-E

Recalled previous case of Emily Jerry, the two-year old child who died in 2006 as the result of a compounding error by a pharmacy technician. Suggested public safety requires adequately educated pharmacy technicians.

18. Conversation between Lisa LaCour, Aurdie Bellard, Charles Feucht, and Andre Stolier

Pharmacists are responsible for checking their technicians' work. Given the 3:1 ratio, the requirement for accredited education will create a shortage of technicians. If the two schools of pharmacy graduate 300 pharmacists per year then the technician programs need to graduate 900 technicians per year. If they do not, the shortage will worsen.

Most OJT programs in community pharmacies train only for community pharmacy settings; that places the technician at a disadvantage when the technician needs to leave that practice site. If the education and training is focused on one practice site, then the technician's license needs to be restricted to that practice site.

The following letter arrived after the 12:00 pm deadline, but is included in the compilation:

19. March 1, 2017 letter from Randal Johnson on behalf of LIPA

Expressed concern for proposed rule; will make it more difficult and burdensome for pharmacies to find qualified technicians or to certify potential candidates. Suggests pursuing an alternative pathway rather than requiring accreditation for technician training programs.

Louisiana
Nationally-accredited and Board-approved
Pharmacy Technician Training Program

David Dubose, R.Ph.
1504 West Park Avenue
Orange, TX 77630

Office: 409.883.4041
Cell: 409.670.3631
Email: davidd@passassured.com



Executive Summary

1. Records indicate that there are 500 to 600 new Technicians each year.
2. Records indicate that Louisiana has 23 schools that are Nationally-accredited by ASHP. These 23 schools are located in 13 parishes, leaving 51 Parishes without schools.
3. 16 of the schools' tuition runs between \$12,000 and \$20,000, 5 schools run between \$4,000 and \$9,000 with 2 schools under \$3,000. This does not include room and board.
4. The Louisiana Department of Education, Career and Technical Education section, (CTE) strives to provide all students a challenging, relevant, meaningful, and seamless education that will help them become lifelong learners and productive citizens of the 21st Century. High schools cannot afford the cost of becoming ASHP nationally accredited. This would eliminate all CTE programs leading to national certification as a Pharmacy Technician after passing the National exam approved by the BOP.
5. Louisiana State Board of Pharmacy could recognize both the Exam for Certification of Pharmacy Technicians (ExCPT) given by NHA (National Healthcareer Association) and the Pharmacy Technician Certification Exam (PTCE) given by the PTCB (Pharmacy Technician Certification Board)
6. Both exams are *ACCREDITED* by the NCCA (National Commission for Certifying Agencies)
7. Texas State Board of Pharmacy had the exams evaluated by two 3rd party evaluators:
 - i. NHA (ExCPT) average 95% (2017 results)
 - ii. PTCB (PTCE) average 96% (2014 results)
8. Having the didactic training either in High Schools, home study or employee based training allows local pharmacies to draw from their communities. The candidate shall still earn at least 600 hours of practical experience in a pharmacy in Louisiana.
9. Board could approve a program that meets the requirements set by the Board.
10. The BOP dropping the nationally-accredited requirements for schools levels the playing field for all 62 Parishes.

Nationally-accredited and Board-approved Pharmacy Technician Training Program

Why this could be a problem:

- A. Records indicate that Louisiana has 6,969 Pharmacy Technicians
- B. Records indicate that there are 500 to 600 new Technicians each year.
- C. Records indicate that Louisiana has 23 schools that are Nationally-accredited by AHSP (American Society of Health-System Pharmacists).
 - a. These 23 schools are located in 13 parishes leaving 51 Parishes without schools. (See Exhibit A)
 - b. The cost of attending one of the 23 AHSP schools for 9 Months:
 - 9 Schools with cost of over \$20,000
 - 3 schools with cost over \$15,000
 - 2 schools over \$14,000
 - 2 schools over \$12,000
 - 1 over \$9,000
 - 3 over \$7,000
 - 1 over \$4,000
 - 1 at \$2,920
 - 1 at \$1,720

**This does not include room and board for 9 months (none have dormitories).

The big question is: where will the 51 Parishes without schools train their Technicians?

- A. The Board of Pharmacy could drop the proposed rule requiring the training program selected by the pharmacy technician candidate to be accredited by a national accreditation organization approved by the board. (AHSP) (The PTCB has dropped their requirements for AHSP schools before sitting for their exam.)

- B. Louisiana State Board of Pharmacy could recognize both the Exam for Certification of Pharmacy Technicians (ExCPT) given by NHA (National Healthcareer Association) and the Pharmacy Technician Certification Exam (PTCE) given by the PTCB (Pharmacy Technician Certification Board)
 - 1. Both the Pharmacy Technician Certification Exam (PTCE) and Exam for Certification of Pharmacy Technicians (ExCPT) are *ACCREDITED* by the NCCA (National Commission for Certifying Agencies)
 - 2. Texas State Board of Pharmacy had the exams evaluated by two 3rd party evaluators:
 - a. NHA (ExCPT) average 95% (2017)
 - b. PTCB (PTCE) average 96% (2014)
 - 3. Passing of either test earns the designation of a nationally Certified Pharmacy Technician (CPhT)
 - 4. Home or employee based training allows local pharmacies to draw from their communities
- C. Board could approve a program that meets the requirements set by the Board.

The chain stores will have to develop AHSP training centers.

Accreditation Fee Schedule for Retail Chain Based Pharmacy Technician Training Programs

- 1. Please note that annual assessment fees are assessed from the date of ASHP's receipt of the application for accreditation. ASHP's billing is based on the calendar year.
- 2. The Annual Assessment Fee and Application Fee are subject to change yearly.
- 3. 2016 Initial application fee was \$10,000.
- 4. Independent pharmacies and small chains with less than ten stores would not be able to train technicians.

Number of Stores	Annual Assessment 2016
10-100	\$8,500
101-1,000	\$16,500
1,001-3,000	\$28,800
3,001-5,000	\$39,800
5,000 or more	\$52,100

An interesting fact:

Pharmacy Technician Certification Board (PTCB) exam pays royalties to:

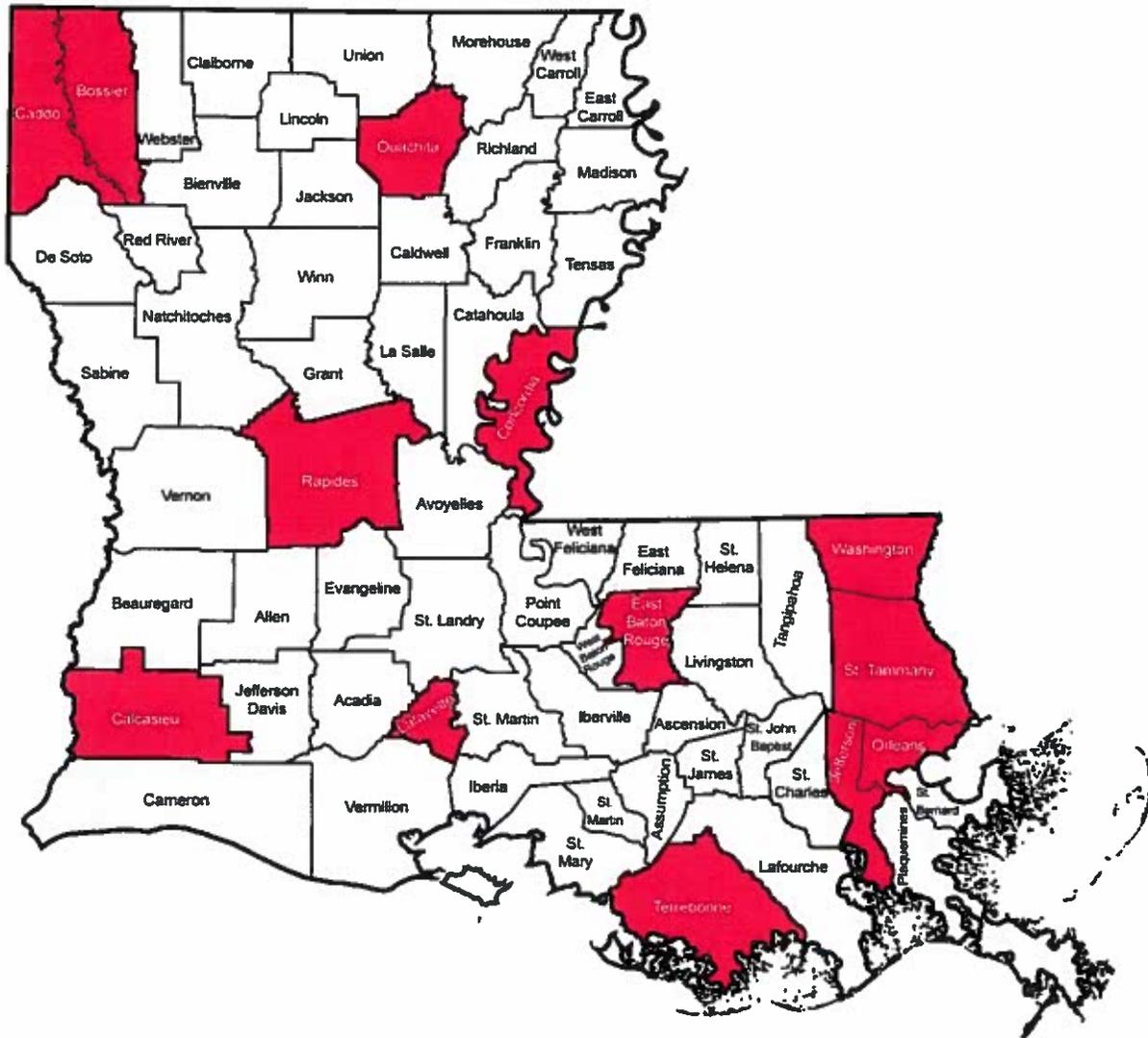
1. ASHP (American Society of Health-System Pharmacists)
2. APhA (American Pharmaceutical Association)
3. NABP (National Association of Boards of Pharmacy)

* The PTCB 990 Forms indicate that the PTCB has paid \$2.5 million in royalties to the NABP (National Association of Boards of Pharmacy) and to ASHP (American Society of Health System Pharmacists) from the years 2011 to 2014, or approximately \$700,000 annually.

Other states' requirements

- A. 33 states approve both the ExCPT and PTCE (includes Washington D.C.)
 - Ex. California has a Board approved training program also.
- B. 9 states do not require certification at all (no approval process) – Alaska, Arkansas, Hawaii, Maine, Missouri, New Hampshire, New York, Oklahoma, Wisconsin, Florida has a board approved employee based training program.
- C. 6 states recognize the PTCB ONLY
 1. 3 of these 6 require certification for all technicians – Louisiana, North Dakota, Wyoming
 2. 3 of these 6 require certification only to increase tech to pharmacist ratios – South Carolina, North Carolina, Colorado

Exhibit A – Map of Louisiana Parishes with ASHP Accredited Schools



- | | |
|---------------------------------|--|
| 1. Caddo Parish – 2 Schools | 8. East Baton Rouge Parish – 5 Schools |
| 2. Bossier Parish – 2 Schools | 9. Terrebonne Parish – 1 School |
| 3. Ouachita Parish – 1 School | 10. Jefferson Parish – 2 Schools |
| 4. Concordia Parish – 1 School | 11. Orleans Parish – 1 School |
| 5. Rapides Parish – 2 Schools | 12. St. Tammany Parish – 1 School |
| 6. Calcasieu Parish – 1 School | 13. Washington Parish – 1 School |
| 7. Lafayette Parish – 3 schools | |

Exhibit B – List of Schools by Parish and cost of the school:

- A. Caddo Parish – 2 Schools
 - 1. Ayers Career College (\$15,900)
 - 2. Remington college (\$20,500)
- B. Bossier Parish – 2 Schools
 - 1. Bossier Parish Community College (\$2,920)
 - 2. Virginia College (\$12,775)
- C. Ouachita – 1 School
 - 1. Unitech Training Academy (\$22,484)
- D. Concordia – 1 School
 - 1. Central Louisiana Technical Community College (\$7,996)
- E. Rapides – 2 Schools
 - 1. Louisiana State University At Alexandria (\$4,484)
 - 2. Unitech Training Academy (\$22,484)
- F. Calcasieu – 1 School
 - 1. Unitech Training Academy (22,484)
- G. Lafayette – 3 Schools
 - 1. Infinity college (\$9,600)
 - 2. Remington College (\$20,520)
 - 3. Unitech Training Academy (\$22,484)
- H. East Baton Rouge – 5 schools
 - 1. Baton Rouge Community College (\$6,500)
 - 2. Fortis College Baton Rouge (\$16,000)
 - 3. Medical Training College (\$145,200)
 - 4. Unitech Training Academy (\$22,484)
 - 5. Virginia College (\$12,775)
- I. Terrebonne – 1 School
 - 1. Unitech Training Academy (\$22,484)
- J. Jefferson – 2 Schools
 - 1. Healthcare Training Institute (\$16,500)
 - 2. Unitech Training Academy (\$22,484)
- K. Orleans – 1 School
 - 1. Delgado Community College (\$1,720)
- L. St. Tammany – 1 School
 - 1. Delta College (\$14,200)
- M. Washington – 1 School
 - 1. Northshore Technical Community College (\$7,200)

Malcolm J. Broussard

From: ANDRE BRUNET [jacesjaces@bellsouth.net]
Sent: Monday, February 27, 2017 1:57 PM
To: Malcolm J. Broussard
Subject: Pharmacy Techs

Mr. Broussard,

I just wanted to give my input into the tech training. We have had several technicians from Uni-Tech apply to our pharmacy and none of them were able to pass the certification test. All but one of the technicians that I have trained in our program have passed the test. I think that speaks volumes against the formal training in our area.

Susan Brunet



Malcolm J. Broussard

From: peter wolfe [wolfespharmacy@gmail.com]
Sent: Monday, February 27, 2017 4:50 PM
To: Malcolm J. Broussard
Subject: pharmacy technician on the job training

I am writing concerning the rule that has been changed that you have to attend a pharmacy tech training program to become a licensed technician. I have been working in a pharmacy and i have taken the pharmacy technician test. I failed twice, many of the questions were about hospital settings and material we don't use in the pharmacy. i studied the material given and i also know alot of what goes on in the pharmacy, medications, rules, laws, ect. As an older single mother i could not afford the schooling. working two jobs raising kids at my age there's not really the same opportunity as someone just getting out of high school. i work along side of some amazing technicians that have trained on the job. Training on the job gives you the experience of learning whats really going on in this field. please reconsider this rule.

Sincerely,
Angelle Billiot

Malcolm J. Broussard

From: Larry LeBoeuf [lgleboeuf@yahoo.com]
Sent: Monday, February 27, 2017 9:33 PM
To: Malcolm J. Broussard
Subject: Pharmacy Technician Training

I have been a Pharmacy Technician for 22 years. I received my training at Wolfe's Pharmacy, passed my test and even though I have never attended a school for tech training, I feel very confident in my profession. Over the years most of the techs I've worked with and still do, received their tech license by training at the pharmacy like I did. I have also worked with a couple of techs who attended schools and passed their tests but were very lost in the pharmacy surroundings. We were surprised at their lack of knowledge of medications and insurance. I am now working with a couple of techs in training who have found that some questions on the tech exam were on subject matter that a tech would never be asked to handle. These young people are very knowledgeable and would be an asset as a tech to any pharmacy. It's sad the tests are so hard to pass. Living in a rural community, we see a lot of young people who want to work in a pharmacy but can't imagine having to invest such large sums of money to get their training needed to become a tech. They depend on the training programs offered by their pharmacy. Please consider these young people when making your decision to continue to allow in house training for pharmacy technicians.

Malcolm J. Broussard

From: peter wolfe [wolfespharmacy@gmail.com]
Sent: Tuesday, February 28, 2017 10:31 AM
To: Malcolm J. Broussard
Subject: Pharmacy technicians

Hello Malcomb and Pharmacy Board ,

First let me thank you for serving tirelessly on the board and helping to regulate the practice of Pharmacy, I appreciate your responsibility and thank you. Pharmacy is very dependent on having hard working well trained Pharmacy Techs, having been a pharmacist since 1961 I have vast amount of experience with Techs. I trained my first four techs over 20 years ago when the regulation was adopted, and have trained many more over the years since then. Up until a few years ago all of my techs passed the test on their first attempt.

Then for some reason the test got more difficult, covered a lot of information that tech do not need to know to practice retail, Our failure rate increased, have very capable techs in training that have taken the test 2 to 3 times and are not passing. The tests I am told have questions that are not at all about what a techs duties entail.

Many of my best techs would not enroll in a costly nationally accredited program if they were not able to be trained on site. Most of my techs in training would not enroll in such a program, they are the wage earners for their family and are in need of the income in light of the job market in this area.

This regulation IMO will create a huge shortage of Pharmacy tech in the not to distant future. I have hired two techs that were trained by nationally accredited program and they were very much lacking the ability to function in my pharmacy with out further in store training. One tech was totally uninformed about common every day medication.

We are a very busy pharmacy 75% of my practice is in Rx Sync and compliance packaging we serve over 700 patients a month and are helping patients to take their medication as ordered by their MDs and have improved outcomes. Pharmacy has changed over the years and all must embrace the changes and stay in business in spite of the greedy PBMs that refuse to reimburse us for the service and value that we add to the medication to improve outcomes.

Thank you for allowing this old country druggist and opportunity to express my opinion.

Peter H. Wolfe Sr
Wolfe's Pharmacy
5458 Hwy 56
Chauvin, La, 70344
985-594-5821



February 28, 2017

Malcolm J. Broussard
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700

Via email: mbroussard@pharmacy.la.gov

RE: Proposed Regulation for Pharmacy Technicians

Dear Mr. Broussard:

On behalf of our members that operating in the state of Louisiana, the National Association of Chain Drug Stores (NACDS) is writing to convey some concerns with proposed regulation 46-LIII-9, regarding requirements for pharmacy technician training (Proposed Regulation).

To optimize the delivery of high quality and timely patient care, NACDS supports a practice environment that utilizes and promotes well-qualified pharmacy technicians as essential members of the pharmacy care team. Pharmacy technicians are paraprofessionals that perform non-judgmental tasks to assist pharmacists in preparing and dispensing prescription medications and performing related pharmacy care services.

Section 901: Definition of "Training Programs"

If a program **must be** nationally accredited based on the above language, then we believe it is unnecessary to go through the process of also becoming board approved. Instead, we recommend that either the board cite the accrediting bodies that approve programs and strike the board approval requirement or we would recommend the following revision providing an option to have one or the other:

Training Program – a pharmacy technician training program that is currently nationally-accredited **and or** has been approved by the board.

This language appears throughout the regulation and we recommend the following revisions to ensure uniformity:

Section 903(A)(2)(c)(i): Proof of enrollment in a nationally-accredited **and or** board-approved pharmacy technician training program;

Section 903(B)(1): All **accredited** training programs ~~approved by the board~~ shall maintain their national accreditation.

Section 905(A)(3)(a): In the event the applicant obtained their technician candidate registration on the basis of their enrollment in a nationally-accredited ~~and or~~ board-approved pharmacy technician training program, the applicant shall demonstrate successful completion of that training program, or in the alternative, another nationally-accredited ~~and or~~ board-approved pharmacy technician training program.

Section 903(2): Training Programs

We believe that the requirement for a training program to notify the Board when a technician candidate is no longer satisfactorily progressing in the program is highly concerning and frankly, unnecessary micromanagement by the Board. We request the Board to clarify the intent of this section and the intended use of the information. Additionally, the phrase "satisfactorily progressing" is alarmingly vague. We urge you to consider the following questions when clarifying this section:

- Does a technician candidate need to fail the program to be reported or is progressing "slowly" enough to warrant a report to the Board? If the latter, how would "slowly" be measured?
- In a scenario where the technician candidate is reported, but then rehabilitates and finishes the program, will the notification be a mark on the technician's record?
- Will the Board take any steps to help candidates who are reported to finish the program?
- Does the Board need to be notified of candidates who drop out of the program? With the amount of turnover with pharmacy technicians, this requirement will likely put a strain on employers and training schools to maintain the documentation necessary.

Overall, we believe that these notification requirements put the entire training program at risk with seemingly no real benefit to the board or public safety and urge the Board to clarify this Section or remove it altogether.

We thank you for the opportunity to comment on this important Regulation we look forward to working with you to develop policy to recognize the value of pharmacy technicians. Please do not hesitate to contact me with any questions or concerns at mstaples@nacds.org or 817-442-1155.

Sincerely,



cc: Nick Cahanin, The Picard Group
Nic Walts, The Picard Group
Bud Courson, Courson Nickel

February 22, 2017

Executive Director Malcolm Broussard
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809

Dear Executive Director Broussard and Pharmacy Board Members,

We appreciate your consideration of the following written comment from National Healthcareer Association (NHA) concerning the Proposed Rule to amend Title 46, Part LIII ("Proposed Rule"). NHA is the provider of the Examination for the Certification of Pharmacy Technicians (ExCPT). The ExCPT is a nationally accredited pharmacy technician certification exam of equal rigor and quality to the certification examination offered by PTCB.

We write specifically to comment upon the section of the Proposed Rule found at §903(A)(2)(c). We support the Board's approach in offering three eligibility options for pharmacy technician candidates applying for registration with the State. Technician training comes in many forms and we agree that it's important to provide technician candidates with access to multiple pathways to a pharmacy technician career all the while, demonstrating their competency either through an accredited or approved training program or through certification. For example, pharmacy technician candidates who are trained in the military would not meet the requirements of §903(A)(2)(c)(i), enrollment in an accredited training program, but by completing a national certification pursuant to section (c)(ii), the service member would be eligible for registration as a pharmacy technician candidate.

Comments concerning §903(A)(2)(c)(ii)

NHA respectfully requests that §903(A)(2)(c)(ii) of the Proposed Rule be modified to address two concerns: (1) as written, section (c)(ii) suggests that only one certification examination will be available in Louisiana; and (2) while it is clear that the Board recognizes the value of accreditation with respect to training programs (*see* section (c)(i)), the Board has not availed itself or the citizens of Louisiana of the benefits inherent in requiring that certification examination programs also be accredited.

1. Section (c)(ii) provides that a pharmacy technician candidate applicant can satisfy the eligibility criteria, in part, by providing "[p]roof of successful completion of *the* board-approved technician certification examination . . ." (emphasis added). As with training programs, consumers should have a choice of certification examinations. The ExCPT and the PTCE have undergone significant evaluations conducted by two states, Texas and California. Both exams were deemed

psychometrically sound by both states, each achieving near identical scores.¹ California also conducted an occupational analysis where the ExCPT performed significantly better than the PTCE. NHA would be happy to share this information with the Board. Additionally, each certification provider offers different levels of customer service, preparation materials and data analytics, all factors that are important to consumers in choosing a certification provider. Accordingly, we recommend that, at a minimum, the Board revises section (c)(ii) to reflect that more than one certification choice will be made available to Louisiana educators, employers and pharmacy technician candidates.

2. Both the ExCPT and PTCE are nationally accredited by the lead accreditor for certification programs, the National Commission of Certifying Agencies (“NCCA”). NCCA sets rigorous guidelines for certification programs including requiring regular practice analysis studies, adherence to psychometric principles and exam security standards. NCCA-accredited certification program providers are required to set eligibility criteria, impose continuing education requirements and investigate complaints from any stakeholder of misconduct by certified pharmacy technicians and, if after due process has been provided, take disciplinary action, including revocation of the certification, when appropriate. As with educational accreditation, NCCA accreditation requires that the certification provider performs at the highest standards, enhancing public safety and consumer protection.

Accordingly, NHA believes that the Board and the citizens of Louisiana would be well served if section (c)(ii) was revised as follows: “Proof of successful completion of a certification program accredited by the National Commission of Certifying Agencies or a board-approved technician certification examination. . . .”

Comment concerning §905(A)(3)(a)

Although our comment is particularly directed at §903(A)(2)(c)(ii), we would be remiss if we did not raise a potential strengthening of §905(A)(3)(a). Applicants for a pharmacy technician certificate who obtained their candidate registration on the basis of having enrolled in an accredited training program, in addition to providing evidence of completion of such training, should demonstrate that they have the necessary core competencies by successfully completing a certification program accredited by the NCCA. We would suggest that this section of the Proposed Rule be revised as follows:

In the event the applicant obtained their technician candidate registration on the basis of their enrollment in a nationally-accredited and board-approved pharmacy technician training program, the applicant shall demonstrate (1) successful completion of that training program, or in the alternative, another nationally-accredited and board-approved pharmacy technician training program; and (2) successful completion of a

¹ In the most recent analysis conducted by Texas of each exam, PTCE scored 96% in 2014 and the ExCPT scored 95% in 2017.

certification program accredited by the National Commission of Certifying Agencies or a board-approved technician certification examination.

Thank you for your consideration of these proposed revisions to Sections 903(A)(2)(c)(ii) and 905(A)(3)(a) of the Proposed Rule.

Sincerely,

A handwritten signature in black ink that reads "Lyndsey McDonald". The signature is written in a cursive, flowing style.

Lyndsey McDonald

ExCPT Strategic Partnerships

Malcolm J. Broussard

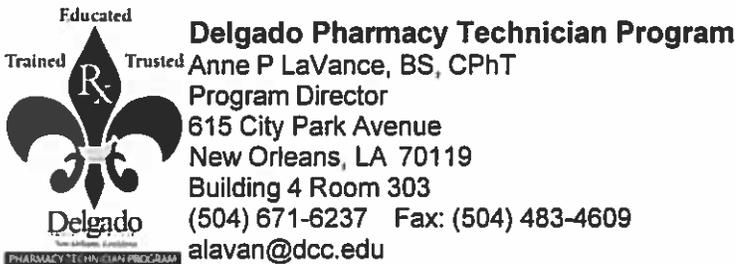
From: peter wolfe [wolfespharmacy@gmail.com]
Sent: Wednesday, March 01, 2017 9:48 AM
To: Malcolm J. Broussard
Subject: Regulation Revision

Hello i'm Meghan, a pharmacy tech at Wolfes Pharmacy in Chauvin, La. I have been a tech here for about a year now. I started at the pharmacy as a cashier out of high school and then started the training program through the pharmacy. When I was beginning my training it was just at the time when the Board wanted to end the in-store pharmacy training. I felt really pressured and stressed during my training because I felt as though I would not be able to test past December 2015. I studied very hard every night up until my testing date as well as training in the pharmacy everyday at work. It was very convenient for me to work and train at the same time, I got to become familiar with the ways that this store is run along with learning how to be a technician. I felt very confident as I went into my first test but unfortunately I did not pass. I did not feel like the questions were even pertaining to anything I have been practicing in the pharmacy. It was very difficult to find the material to study for the questions I had seen on my first test. Fortunately, I was able to pass the 2nd test, which was very easy in my opinion. It was nothing like my fist test and I knew the answers to question from working in the pharmacy and studying the same material I had for my first test. I feel like if this law goes through and people are not able to train in a pharmacy, we will have a major shortage of technicians. I would not be interested in paying for the schooling in this field of work, when it is just a training program with the same test that I was able to pass from the knowledge I've obtained from working in the pharmacy. It would take a very long time to pay back the loan I would have to take out to afford this certification. It is very discouraging for others looking into becoming a technician when they look at the time and money they are going to have to spend when the technicians before them were able to train on the job. Thank for your time and consideration.

Malcolm J. Broussard

From: peter wolfe [wolfespharmacy@gmail.com]
Sent: Wednesday, March 01, 2017 11:24 AM
To: Malcolm J. Broussard
Subject: Regulation Revision Committee

Hello I'm Courtney Battise, I currently work at Wolfe's Pharmacy in Chauvin, La. When I was in high school I came speak to Mr. Peter about becoming a pharmacy technician, and he told me to come back after I graduated and he would help me to achieve my goal of becoming a technician by training me while I worked here as a cashier. As of now, It's almost been a year that I have been working and training here. When I first started I was rushed into taking the PTCE with not a lot a time and knowledge under my belt because the law was soon to be passed that we could no longer train in the pharmacy, and we would have to go to a accredited school. I definitely did not feel I needed to go to a school to obtain a certification that others over the course of years before me who work here and other pharmacies had trained on the job and passed the test. I knew it was a great opportunity for me as well, and knowing that I could not afford to go to the school to train for this career, I studied as hard as I could with the material I could find and took in all the training that I could get before we were sent to test. I felt so confident going into the test and I felt I knew all the material and was well prepared from working in the pharmacy seeing and learning what goes on rather than if I would have just went to a school and not seen the actual process that goes on in the pharmacy. As I took the test I felt I knew majority of the questions and felt it was very easy because it was stuff I had used or seen in the pharmacy where I work, however I was shocked when I found out that I failed the test, and when I received my scores I could not believe I failed it by only 30 points. I was very upset because I was afraid I lost my opportunity, however after many calls we were informed I could take the test again so I studied even more and went back for my second time feeling even more confident, and as I started to take the test I was so discouraged because I felt I knew almost nothing on it, and that the material I had studied and trained doing all this time wasn't even on it, it was like I was taking a whole different test. When I received my scores the second time I was informed I came 70 points away from passing. Even though I did not pass the test yet, I strongly feel if I did not work in a pharmacy and train in this environment there would be no way I would understand the information that is being asked on the PTCE. Working here I'm not only learning or just memorizing material out of a book, I'm getting hands on training and actually doing what I am reading which makes everything easier to comprehend, I honestly don't think any accredited school could make me truly understand what this career really handles, the importance of it all, and give me the help I need to pass this test. Thank you for your time and consideration.



Louisiana State Board of Pharmacy
Comments on intent to amend Chapter 9, Pharmacy Technician.

I am writing today in support of the proposed changes to LAC46:LIII.Chapter 9.

I am writing both as a Pharmacy Technician, and as an Educator. I have been a CPhT for nearly 19 years, completing an ASHP accredited program and becoming PTCB certified in 1998. I have been Certified in LA since 2005.

There are several points I would like to address in this letter:

- Trust and Patient Safety
- Employability and employer cost savings
- PTCB pass rates

Patient safety is the primary edict for health care. To provide patient safety, I feel it is paramount to have an educated and well trained healthcare team. Accredited education provides a standard on which to build that team. I do find it somewhat ironic that the hearing today is also the anniversary of the tragic death of Emily Jerry, who died as a result of a technician error.

As the roles of the pharmacist has continued to advance into more patient-focused practice, there is the creation of a gap in the traditional 'task-oriented' responsibilities once relegated to the pharmacist that can be met by technicians. For the technician to step perform these tasks, the Board of Pharmacy, the Pharmacists, and the public should have trust that the technicians have been educated and trained to perform the tasks effectively. I personally have experienced the effect of trust on my potential to advance as a Pharmacy Technician. Because I was able to prove my abilities and my knowledge to my Pharmacists in the workplace, I was often given the opportunity to advance more quickly than my co-workers who were not educated through a Pharmacy Technician education and training program. This allowed my Pharmacist more time for their duties. To this day, one of my proudest moments as a technician was when I a Pharmacist, that my co-workers perceived as 'difficult' because they 'didn't let the tech do anything', thanked me for making their job easier. When my co-workers asked why that pharmacist let me do things they asked other technicians not to do, my response was trust. I had earned the trust of the pharmacist by showing them I could apply my knowledge. By providing a standard (accredited education), pharmacists will be better able to assess the base abilities of a technician.

As educated technicians enter the workforce, the employers are able to get an employee who has made an investment in the position. This can result in a lower turn-over rate in the workforce, which results in a cost savings for the employer. Additionally, it can reduce training dollars spent in the length of 'getting the technician up to speed' and the overall investment the employer has to spend on training. I was recently told by a major retail employer that the estimated cost of an OTJ trained technician is approximately \$8700 and there is no guarantee that the trainee will be successful in passing the PTCB. Speaking from the prospective of the director of an accredited program, my students currently require only an additional 5 weeks (200 hours under the current statute) to meet the requirements to be Pharmacy Technician in Louisiana. This is a cost savings for the employer. My students often only need to train on the 'pharmacy system' where they become employed, where as

an OJT technician candidate must learn all areas of 'pharmacy'. In the 2015 National Pharmacy Technician Workforce Study¹ sponsored by the Pharmacy Technician Accreditation Commission, Pharmacy Technician Certification Board, and Pharmacy Workforce Center found that CPhTs have a higher job satisfaction rate and most plan to stay at least 10 years in the profession.

Speaking from the prospective as an educator. I have been with Delgado Community College in New Orleans since 2003. To date, our program completers have a 93% pass rate on the PTCE (1st attempt), with 100% pass rate on 2nd attempt. Approximately 95% of our program completers are employed within 60 days, with 80% being hired by their preceptor. Of our program completers, 6 have graduated from a College of Pharmacy.

Education is an investment. The student does generally incur some level of debt through tuition and fees. Although program costs can range from <\$2,000 - \$30,000, the average Community College program costs approximately \$7,500 – 8,000. Most Community College students are eligible for some type of federal grant or student loans. I have had a discussion with a representative from the Louisiana Community and Technical College System as to how to address areas of the state where a Community College program may not be currently readily available to potential students wishing to pursue pharmacy technician education and have been actively working on a hybrid/online solution to help meet the needs for the state. In order to meet the needs in the New Orleans area, I have had discussion with employers as to their anticipated annual needs and I have revised my program to allow for more flexibility in program participants so that we can help provide well trained candidates for those employers. We are also trying to address potential students who have OJT experience, but have not been successful in passing the PTCE and may have to meet the new requirement of completing an accredited program to maintain their currently position by allowing challenge exams for prior experience to receive credit toward program classes.

In 2015 there were 23 accredited programs in Louisiana. There are currently 23 accredited/pending accreditation throughout the state. To me, this shows the ability to provide the educational requirement outlined in the proposed changes to Chapter 9. Currently, no program is operating at full capacity, which means that when the need arises, there is room to accommodate influx of students.

As previously stated, my program pass rate is 93%. This has remained constant, even after the update of the PTCE in 2014. In fact, I had 9 students take the exam within one month of the new 'more challenging' exam was implemented, with a 100% pass rate. My perspective is that although many employers have 'training programs' the technician candidate is left to 'self-educate', and for many they are not successful. Although PTCE pass rate is not a requirement for maintaining accreditation, I feel that it reflects the success of an accredited program. Even looking at the previous requirement of a 'board approved' program (2005 – 2013), the pass rate was higher than the current pass rate. The challenge with the previous requirement was there was no tracking to ensure the 'board approved program' was successful with maintaining the educational guidelines submitted the Board. With the requirement of an accredited program, there is a level of accountability. Although not all programs may achieve the pass rate of my program, some may actually perform with a higher pass rate, I believe that overall, the state pass rate will quickly pass the national pass rate. Unfortunately, before that occurs, I feel the state pass rate may decline even more as poorly prepared prospective technicians 'try to pass' prior to the implementation of the change to Chapter 9.

Thank you for your time and consideration of my comments.

Respectfully,

Anne P LaVance, BS, CPhT
Pharmacy Technician Program Director
alavan@dcc.edu
504-671-6237

¹Desselle and Holmes; 2015 National Pharmacy Technician Workforce Study; Retrieved from URL: <http://www.aaco.org/advocacy/WhatDoesAACPAAdvocateFor/BudgetandAppropriations/Documents/Final%20Report%20Pharmacv%20Technician>



BOARD OFFICERS

*Richard "Andy" Soileau, RPh
Chairman*

*Pat Boggs, RPh
Vice Chairman*

*Allen Cassidy, RPh
Secretary*

*David Osborn, RPh
Treasurer*

BOARD OF DIRECTORS

*District 1:
Diane Milano, RPh*

*District 2:
Blake Pitre, RPh*

*District 3:
David Osborn, RPh*

*District 4:
T. J. Woodard Jr., RPh*

*District 5:
David Darce, RPh*

*District 6:
Allen Cassidy, RPh*

*District 7:
Nick LeBas, RPh*

*District 8:
Marty McKay, RPh*

*District 9:
Patrick Boggs, RPh*

*District 10:
Charles Jones, RPh*

*District 11:
Kenny Wilson, RPh*

*At Large:
Richard "Andy" Soileau, RPh
Greg Poret, RPh*

*Randal Johnson
President*



March 1, 2017

Malcolm Broussard
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809

Dear Mr. Broussard:

The Louisiana Independent Pharmacies Association (LIPA), on behalf of our membership, wishes to express concerns regarding implementation of Regulatory Project 2015-9 on January 1st, 2018 of the rule changes to certification for pharmacy technicians under Title 46 Part LIII Chapter 9 of the Louisiana Administrative Code.

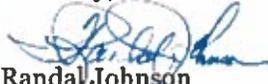
The status quo enables independent community pharmacies, particularly those in rural areas, to train and certify technicians who are a crucial component of the pharmacy practice. The proposed rule change would make it more difficult and burdensome for pharmacies to find qualified technicians or to certify potential candidates. Sending potential technicians to nationally accredited programs outside of their area is cost and regionally prohibitive.

We also suggest the Board of Pharmacy consider under the proposed rule change the effect it would have on individuals in these communities who are interested in becoming or are seeking a career as a pharmacy technician. Current rule allows them that opportunity as many of these individuals do not have the means themselves to attend one of these programs as suggested under proposed rule.

While LIPA understands the board's concerns with the current dynamic, we believe the potential loss of pharmacy technicians under this rule change could have an adverse effect on our pharmacies and ultimately harm patients and community healthcare.

The Louisiana Board of Pharmacy currently has oversight authority over in-house pharmacy technician training programs. LIPA believes the board should continue exercising this authority and could pursue an alternative other than requiring nationally accredited training programs which are few and far in-between.

Sincerely,


Randal Johnson
President & CEO



Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov



MEMORANDUM

To: Board Members
From: Malcolm Broussard
Date: March 14, 2017
Re: Regulatory Project 2015-9 ~ Staff Notes re Comments & Testimony

Item 1 – Mr. Dubose

§903. Pharmacy Technician Candidates (PTC)

A. Registration

1. ...

2. Qualifications

c. The applicant shall satisfy one of the following eligibility criteria:

- i. Proof of enrollment in a nationally-accredited and board-approved pharmacy technician training program; or
- ii. Proof of successful completion of the board-approved technician certification examination, and further, proof of successful completion of a high school approved by a state department of education or an equivalent degree of education, as evidenced by a valid and legible copy of a diploma, transcript, or other appropriate credential; or
- iii. Proof of credentialing as a pharmacy technician by another state board of pharmacy as well as evidence of practice as a pharmacy technician for at least one year in that state, and further, proof of successful completion of the board-approved technician certification examination.

Staff Note: Commentator has apparently overlooked the option available to his clients at §903.A.2.c.ii, which requires a high school diploma and a passing PTCB score. His client high schools across the state offer the PassAssured software program to the high school seniors. The students are typically less than 18 years of age, so they cannot earn any hours until they reach that required age. The requirements established for that program requires the graduating students to complete the PTCB test prior to July 1 of the year they graduate. With that passing PTCB score and their high school diploma, they can apply for the PTC registration and then earn their hours at any pharmacy, then apply for and receive their technician certificate.

With respect to the board-approved technician certification examination, the Board has approved the examination offered by PTCB. With respect to the alternative examination offered by National Healthcareer Association (NHA) – the ExCPT test, the

Board previously considered the approval of that examination during its August 2009 meeting. The Board deferred further consideration of their request for approval pending receipt of results from a psychometric evaluation of the test to be administered by a competent firm mutually agreeable with the test administrator and NABP. The rationale for that decision was that NABP had performed such an evaluation of the PTCB test prior to its later affiliation with that organization, and that because of that affiliation, NABP could no longer perform such an evaluation. However, since the Board relies on NABP's professional guidance for psychometric evaluation of all its licensing examinations, the Board was willing to accept a report from a third party evaluator acceptable to NABP and the test administrator. The test administrator has never responded to that offer.

Item 2 – Ms. Brunet

No specific amendments requested.

Item 3 – Ms. Billiot

No specific amendments requested.

Item 4 – Ms. LeBoeuf

No specific amendments requested.

Item 5 – Mr. Wolfe

No specific amendments requested.

Item 6 – NACDS

§901. Definitions

Training Program – a pharmacy technician training program that is currently nationally-accredited ~~and~~ or has been approved by the board.

§903. Pharmacy Technician Candidates

A. Registration

2. Qualifications

c. The applicant shall satisfy one of the eligibility criteria:

i. Proof of enrollment in a nationally-accredited ~~and~~ or board-approved pharmacy technician training program; or

B. Training Programs

1. All accredited training programs ~~approved by the board~~ shall maintain their national accreditation.

§905. Pharmacy Technician Certificate

A. Qualifications

3. An applicant shall demonstrate one of the following educational competencies:

a. In the event the applicant obtained their technician candidate registration on the basis of their enrollment in a nationally-accredited ~~and~~ or board-approved pharmacy technician training program, the applicant shall demonstrate successful completion of that training program, or in the alternative, another nationally-accredited ~~and~~ or board-approved pharmacy technician training program.

Staff Note: The Board's requirement for both national accreditation and board approval of the pharmacy technician training program is intentional. It follows the same requirement used for colleges and schools of pharmacy. Those schools must be accredited by ACPE and approved by the Board. The Board has already adopted an approval process, by composing a roster of accredited programs and re-confirming your approval on an annual basis. Given the length of time between accreditation decisions, it is possible the Board may need to act more quickly in the event something happens between such accreditation decisions. The requirement for Board approval preserves the Board's ability to respond relatively quickly to an adverse event.

§903. Pharmacy Technician Candidates

B. Training Programs

2. The training program shall notify the board when a pharmacy technician candidate is no longer ~~satisfactorily progressing~~ enrolled in the program. Evidence of a program's failure to comply with this rule shall constitute sufficient basis for the withdrawal of the board's approval for the program.

Staff Note: Commentator objects to requiring programs notify the Board when their students are not 'satisfactorily progressing.' We agree the term is not well-defined, and suggest replacing the term with 'enrolled'. The rationale for this rule is that PTC registrations are issued on the basis of enrollment in programs, and when they leave the program, for any reason other than graduation, they no longer meet the eligibility criteria to retain the registration. The proposed rule infers that, but we agree the proposed rule should state that explicitly. Therefore, we propose the addition of the following language:

§903. Pharmacy Technician Candidates

A. Registration

2. Issuance and Maintenance

a – c. ...

d. (i) In the event the candidate is no longer enrolled in a nationally-accredited and board-approved pharmacy technician training program for any reason other than graduation, the candidate no longer meets the eligibility criteria to possess the registration, and the candidate shall relinquish the registration to the board, giving notice of their last day of enrollment in the program.

(ii) In the event a candidate fails to relinquish their registration when required to do so, or when notified by the board office of that requirement, the board staff shall inactivate the registration and refer the matter to the board for its consideration of disciplinary action against the candidate.

(iii) In the event the candidate should re-enroll in the original program or a different program, and gives proof of that enrollment to the board, the board may re-issue the registration with the original expiration date preserved.

(iv) In its discretion, the board may grant an exception to the original expiration date upon request by the candidate demonstrating unusual circumstances.

d – e. ...

Item 7 – NHA

§903. Pharmacy Technician Candidates

A. Registration

2. Qualifications

c. The applicant shall satisfy one of the following eligibility criteria:

- ii. Proof of successful completion of a certification program accredited by the National Commission of Certifying Agencies or a board-approved technician certification examination; and further, proof of successful completion of a high school approved by a state department of education or an equivalent degree of education, as evidenced by a valid and legible copy of a diploma, transcript, or other appropriate credential; or

Staff Note: With respect to the ExCPT examination and the question of board approval of that examination, see the notes in Item 1. In addition, as written, the proposed revision requires a certification, as opposed to a certification examination. The maintenance of certification requires continuing education, not all of which must be accredited by ACPE. Since the Board requires CE for technician renewal, all of which must be accredited by ACPE, the Board has never imposed the requirement to maintain a certification but only to pass the certification examination.

Item 8 – Ms. McEachern

No specific amendment requested, but wishes to preserve current rule for training.

Item 9 – Ms. Battise

No specific amendment requested, but wishes to preserve current rule for training.

Item 10 – Delgado

No specific amendment requested.

Item 11 – Ms. LaCour

No specific amendment requested, but wishes to preserve current rule for training.

Item 12 – Mr. Stolier (LIPA)

No specific amendment requested, but wishes to preserve current rule for training.

Item 13 – Mr. Ballard

No specific amendment requested.

Item 14 – Dr. Feucht

§903. Pharmacy Technician Candidates

C. Practical Experience

5. The candidate's registration shall evidence his authority to earn practical experience in a pharmacy, under the supervision of a pharmacist, in satisfaction of the requirements for pharmacy technician certification.

- a. In the event the registration was issued to an applicant enrolled in a nationally-accredited and board-approved training program, the candidate shall earn the amount of experience prescribed by the curriculum of that program, which may include hours earned in a

consultant pharmacy practice which does not hold a pharmacy permit;
or

Staff Note: We have no objection to that allowance. The Board's proposed rule for pharmacy interns will have a similar allowance.

Item 15 – Mr. Stolier (LIPA)

No specific amendments requested, but supports adoption of approval standards for current training programs.

Item 16 – Ms. Carmouche

No specific amendments requested.

Item 17 – Dr. Feucht

No specific amendments requested.

Item 18 – (Multiple)

No specific amendments requested. Some of the commentators preferred maintaining current rule for training. Some commentators suggested if the current training rule is maintained, then the license issued to those technicians should be limited to the practice site where the training was obtained.

Item 19 – LIPA

No specific amendment requested, but wishes to preserve current rule for training.



Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov



MEMORANDUM

To: Board Members
From: Malcolm Broussard
Date: March 14, 2017
Re: Regulatory Project 2016-4 ~ Standing Orders for Distribution of Naloxone

Project Timeline

08-10-2016 Board approved Regulatory Proposal 2016-G (Draft #1) for promulgation, and further, adopted *Emergency Rule #1* for the purpose of immediately implementing the provisions of Act 370 of the 2016 Legislature.

12-07-2016 Re-issued original *Emergency Rule #2*.

01-09-2017 Submitted Notice of Intent to Joint Legislative Oversight Committee on Health & Welfare.

01-20-2017 Notice of Intent published in *Louisiana Register*.

03-01-2017 Public hearing to receive comments and testimony on proposed rule.

03-14-2017 Board meeting to consider comments and testimony on proposed rule.

04-05-2017 Scheduled to re-issue original *Emergency Rule #3*.

08-02-2017 Scheduled to re-issue original *Emergency Rule #4*.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

...
Subchapter D. Prescription Drugs

§2541. Standing Orders for Distribution of Naloxone and Other Opioid Antagonists

- A. Given the current public health emergency relative to the misuse and abuse of opioid derivatives, public health officials have strongly recommended the widespread availability of naloxone and other opioid antagonists to addicts and their caregivers as well as first responders in the community.
- B. For as long as naloxone and other opioid antagonists remain classified as prescription drugs by the federal Food and Drug Administration, pharmacists must secure a prescription or order from a prescriber with the legal authority to prescribe the drug product in order to dispense or distribute the drug product.
- C. The Louisiana Legislature has adopted a number of laws designed to facilitate the distribution and dispensing of naloxone and other opioid antagonists beyond the person who would need the medication on an emergent basis to manage an opioid-related drug overdose, more specifically to first responders as well as caregivers and family and friends of potential patients.
 - 1. Act 253 of the 2014 Legislature authorized prescribers to issue prescriptions for naloxone and other opioid antagonists to first responders, and further, authorized pharmacists to recognize such prescriptions as legitimate orders for the dispensing and distribution of naloxone and other opioid antagonist drug products, and further, authorized first responders to have and hold those drug products ready for administration in emergent conditions to manage opioid-related drug overdoses.
 - 2. Act 192 of the 2015 Legislature authorized medical practitioners to prescribe naloxone or another opioid antagonist without having previously examined the individual to whom the medication would be administered, but only under certain conditions specified in the legislation, including the requirement for the prescriber to provide the recipient of the drug with all training and education required for the safe and proper administration of the drug product.
 - 3. Act 370 of the 2016 Legislature authorized medical practitioners to issue nonpatient-specific standing orders to pharmacists authorizing the distribution of naloxone and other opioid antagonists to anyone who might be in a position to assist a patient in the emergent management of an opioid-related drug overdose, but only in compliance with these rules.
 - a. A nonpatient-specific standing order for the facilitated distribution of naloxone or other opioid antagonist issued by a medical practitioner licensed by the State of Louisiana shall expire one year after the date of issuance.
 - b. A Louisiana-licensed pharmacist may distribute naloxone or other opioid antagonist according to the terms of the nonpatient-specific standing order issued by a Louisiana-licensed medical practitioner until the expiration date of the standing order. No pharmacist shall distribute naloxone or other opioid antagonist pursuant to a standing order more than one year after the date of issuance of the standing order.
 - c. Before releasing the naloxone or other opioid antagonist drug product to the recipient, the pharmacist shall verify the recipient's knowledge and understanding of the proper use of the drug product, including, at a minimum:
 - i. Techniques on how to recognize signs of an opioid-related drug overdose;
 - ii. Standards and procedures for the storage and administration of the drug product; and
 - iii. Emergency follow-up procedure including the requirement to summon emergency

54
55
56
57
58
59
60
61
62
63

- services either immediately before or immediately after administering the drug product to the individual experiencing the overdose.
- d. To comply with the recordkeeping requirements found elsewhere in the Board's rules, the pharmacist shall attach a copy of the standing order to the invoice or other record of sale or distribution, and further, shall store these transaction documents with the other distribution records in the pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR



Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov



Summary of Testimony & Public Comments
re
Regulatory Project 2016-4 ~ Standing Orders for Distribution of Naloxone
at
March 1, 2017 Public Hearing

No comments or testimony were received for this regulatory project.



Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov



MEMORANDUM

To: Board Members
From: Malcolm Broussard
Date: March 14, 2017
Re: Regulatory Project 2016-5 ~ Reinstatement of CDS License

Project Timeline

11-16-2016	Board approved Regulatory Proposal 2016-H (Draft #1) for promulgation, and further, adopted <i>Emergency Rule #1</i> for the purpose of immediately implementing its provisions.
01-09-2017	Submitted Notice of Intent to Joint Legislative Oversight Committee on Health & Welfare.
01-20-2017	Notice of Intent published in <u>Louisiana Register</u> .
03-01-2017	Public hearing to receive comments and testimony on proposed rule.
03-14-2017	Board meeting to consider comments and testimony on proposed rule.
03-15-2017	Scheduled to re-issue original <i>Emergency Rule #2</i> .
07-10-2017	Scheduled to re-issue original <i>Emergency Rule #3</i> .

1 Louisiana Administrative Code

2
3 Title 46 – Professional and Occupational Standards

4
5 Part LIII: Pharmacists

6
7
8 Chapter 27. Controlled Dangerous Substances

9
10 ...
11
12 Subchapter B. Licenses

13
14 ...
15
16 §2707. Licensing Procedures

17 A. – C.3 ...

- 18 4. An application for the reinstatement of a CDS license for a pharmacy which was suspended or revoked by
19 the board may only be approved by the full board following a hearing to determine whether the
20 reinstatement of the license is in the public's best interest. For all other CDS licenses, the reinstatement
21 may be approved by the joint consent of the chair of the reinstatement committee and the board president
22 without the necessity of a hearing; when such approvals are issued, staff shall prepare a reinstatement order
23 for the president's signature.

24 C.5 – D.5.e ...

25
26 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

27 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2131
28 (October 2008), amended LR

29
30 ...
31
32



Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov



Summary of Testimony & Public Comments
re
Regulatory Project 2016-5 ~ Reinstatement of CDS License
at
March 1, 2017 Public Hearing

No comments or testimony were received for this regulatory project.



Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov



MEMORANDUM

To: Board Members
From: Malcolm Broussard
Date: March 14, 2017
Re: Regulatory Project 2016-6 ~ Marijuana Pharmacy

Project Timeline

08-10-2016	Board approved Regulatory Proposal 2016-A (Draft #4) for promulgation.
01-09-2017	Submitted Notice of Intent to Joint Legislative Oversight Committee on Health & Welfare.
01-20-2017	Notice of Intent published in <u>Louisiana Register</u> .
03-01-2017	Public hearing to receive comments and testimony on proposed rule.
03-14-2017	Board meeting to consider comments and testimony on proposed rule.

1 Louisiana Administrative Code

2
3 Title 46 – Professional and Occupational Standards

4
5 Part LIII: Pharmacists

6
7 Chapter 24. Limited Service Providers

8
9 Subchapter E. Marijuana Pharmacy

10
11 §2440. Preamble; warning; consultation suggested

- 12 A. Pursuant to Act 261 of the Regular Session of the 2015 Louisiana Legislature as well as the subsequent
13 amendment found in Act 96 of the Regular Session of the 2016 Louisiana Legislature, the Louisiana
14 Board of Pharmacy was directed to:
- 15 1. Develop an annual, nontransferable specialty license for a pharmacy to dispense recommended
16 marijuana for therapeutic use, to limit the number of such licenses to a maximum of ten, and to
17 adopt rules regarding the geographical locations of dispensing pharmacies in the state; and
 - 18 2. Adopt rules relating to the dispensing of recommended marijuana for therapeutic use, with such
19 rules to include, at a minimum, the following:
 - 20 a. Standards, procedures, and protocols for the effective use of recommended marijuana for
21 therapeutic use as authorized by state law and related rules;
 - 22 b. Standards, procedures, and protocols for the dispensing and tracking of recommended
23 therapeutic marijuana;
 - 24 c. Procedures and protocols to provide that no recommended therapeutic marijuana may be
25 dispensed from, produced from, obtained from, sold to, or transferred to a location outside of
26 this state;
 - 27 d. Standards, procedures, and protocols for determining the amount of usable recommended
28 therapeutic marijuana that is necessary to constitute an adequate supply to ensure
29 uninterrupted availability for a period of one month, including amount for topical treatments;
 - 30 e. Standards, procedures, and protocols to ensure all recommended therapeutic marijuana
31 dispensed is consistently pharmaceutical grade;
 - 32 f. Standards and procedures for the revocation, suspension, and nonrenewal of licenses;
 - 33 g. Other licensing, renewal, and operational standards deemed necessary by the Louisiana Board
34 of Pharmacy;
 - 35 h. Standards and procedures for testing recommended therapeutic marijuana samples for levels
36 of tetrahydrocannabinols (THC) or other testing parameters deemed appropriate by the
37 Louisiana Board of Pharmacy;
 - 38 i. Standards for the protection of health, safety, and security for dispensers of recommended
39 therapeutic marijuana;
 - 40 j. Standards for the licensure of dispensers of recommended therapeutic marijuana; and
 - 41 k. Standards for financial capacity to operate a marijuana pharmacy.
- 42 B. Marijuana is classified as a Schedule I controlled substance by the U.S. Department of Justice, Drug
43 Enforcement Administration.
- 44 1. As provided by the federal Controlled Substances Act, the procurement, possession, prescribing,
45 distribution, dispensing, or administering of any Schedule I controlled substance, including
46 marijuana, is a violation of federal law.
 - 47 2. Neither Louisiana law nor the board's rules can preempt federal law. Therefore, the provisions of
48 this Subchapter notwithstanding, persons engaged in the activities described herein remain subject
49 to the full force of federal law enforcement, including arrest and prosecution of criminal charges,
50 the assessment of civil fines and forfeitures, as well as administrative consequences such as
51 forfeiture of federal controlled substance registrations and exclusion from Medicare and other
52 federal payer programs.
- 53 C. For the foregoing reasons, pharmacists and other persons credentialed by the board may wish to
54 consult with their own legal counsel as well as any health care facility, private or governmental payor
55 with which they are affiliated, professional liability insurers, and financial institutions with which they
56 maintain depository relationships before engaging in the activities described herein.
- 57

58 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

§2441. Definitions

- A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section:
 - 1. *Administer* means the direct application of marijuana to the body of a qualifying patient by ingestion or any other means.
 - 2. *Advertisement* means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of marijuana.
 - 3. *Agent* means an authorized person who acts on behalf of or at the direction of another person. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.
 - 4. *Approved safe* means a safe which conforms to or exceeds all of the following standards:
 - a. Shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;
 - b. If it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way it cannot be readily removed; and
 - c. Depending upon the quantities stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the licensee, or such other protection as the board or its designee may approve.
 - 5. *Approved vault* means:
 - a. A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or
 - b. A vault constructed after September 1, 1971:
 - i. The walls, floors, and ceilings of which are constructed of at least eight inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with one-half inch steel rods tied six inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;
 - ii. The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;
 - iii. Which vault, if operations require it to remain open for frequent access, is equipped with a "day gate" which is self-closing and self-locking or the equivalent, for use during the hours of operation in which the vault door is open;
 - iv. The walls or perimeter of which are equipped with an alarm which, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or a local or state police agency which has a legal responsibility to respond, or a 24-hour control station operated by the licensee, or such other protection as the board or its designee may approve, and if necessary, alarm buttons at strategic points of entry to the perimeter area of the vault;
 - v. The door of which shall be equipped with one or more contact switches; and
 - vi. Which vault has one of the following:
 - (a) Complete electrical lacing of the walls, floor and ceiling;
 - (b) Sensitive ultrasonic equipment within the vault;
 - (c) Sensitive sound accumulator system; or
 - (d) Such other device designed to detect illegal entry as may be approved by the board.
 - 6. *Board* means the Louisiana Board of Pharmacy.
 - 7. *CFR* means Code of Federal Regulations.
 - 8. *Deliver or delivery* means the actual, constructive or attempted transfer from one person to another of marijuana, whether or not there is an agency relationship.
 - 9. *Financial interest* means any actual, or a future right to, ownership or investment, either directly or indirectly, through business, investment or immediate family. Financial interest does not include ownership of investment securities in a publicly-held corporation that is traded on a

- 117 national exchange or over-the-counter market, provided the investment securities held by such
118 person do not exceed five per cent of the total number of shares issued by the corporation.
- 119 10. *Immediate family* shall have the same meaning as provided in La. R.S. 42:1102, i.e., his children
120 and the spouses of his children, his brothers and their spouses, his sisters and their spouses, his
121 parents, his spouse, and the parents of his spouse.
- 122 11. *LDAF* means the Louisiana Department of Agriculture and Forestry.
- 123 12. *LDH* means the Louisiana Department of Health.
- 124 13. *Louisiana Medical Marijuana Tracking System (LMMTS)* means the required seed-to-sale tracking
125 system that tracks medical marijuana from either the seed or immature plant stage until the
126 product is sold to a pharmacy or is destroyed.
- 127 14. *Marijuana* means all parts of plants of the genus *Cannabis*, whether growing or not, the seeds
128 thereof, the resin extracted from any part of such plant, and every compound, manufacture, salt,
129 derivative, mixture, or preparation of such plant, its seeds or resin, but shall not include the mature
130 stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such
131 plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature
132 stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant
133 which is incapable of germination.
- 134 15. *Marijuana pharmacy* means that area within a facility where marijuana is stored, dispensed, and
135 sold. If a facility does not offer any products or services other than marijuana and/or related
136 supplies, the entire facility is a marijuana pharmacy for the purposes of this Subchapter.
- 137 16. *Marijuana pharmacy owner* means any person with an ownership interest in a marijuana
138 pharmacy, except the term does not include a person with an investment interest through a
139 publicly-held company provided the interest held by such person does not exceed five per cent of
140 the total ownership or interest rights in such pharmacy and such person does not participate
141 directly or indirectly in the control, management, or operation of the pharmacy.
- 142 17. *Marijuana product* means any product containing marijuana, including raw materials, that requires
143 no further processing and that is packaged for sale to pharmacies, qualifying patients and primary
144 caregivers.
- 145 18. *Owner's managing officer* means the person designated by the organization owning the pharmacy
146 to be responsible to the board for the proper operation of the pharmacy in compliance with all
147 applicable laws and regulations.
- 148 19. *Pharmaceutical grade marijuana* means marijuana or marijuana products that are not adulterated
149 and are:
- 150 a. Processed, packaged and labeled according to the United States Food & Drug
151 Administration's "Current Good Manufacturing Practice in Manufacturing, Packaging,
152 Labeling, or Holding Operations for Dietary Supplements" as found in 21 CFR 111 or its
153 successor;
- 154 b. Labeled with the results of an active ingredient analysis, a microbiological contaminants
155 analysis, a mycotoxin analysis, a heavy metal analysis, and a pesticide chemical residue
156 analysis which have been completed on a batch basis by a laboratory; and
- 157 c. Where each step of the production, cultivating, trimming, curing, manufacturing, processing,
158 and packaging method has been documented by using standard operation procedures
159 approved by the Commissioner of the Louisiana Department of Agriculture and Forestry.
- 160 20. *Pharmacist* means an individual currently licensed by the board to engage in the practice of
161 pharmacy.
- 162 21. *Pharmacy technician* means an individual who assists in the practice of pharmacy under the direct
163 and immediate supervision of a licensed pharmacist and is currently certified to do so by the
164 board.
- 165 22. *Physician* means an individual currently licensed by the Louisiana State Board of Medical
166 Examiners to engage in the practice of medicine.
- 167 23. *Prescription monitoring program (PMP)* means the electronic prescription drug monitoring
168 program established by La. R.S. 40:1001 *et seq.*
- 169 24. *Producer* means a person licensed by the Louisiana Department of Agriculture and Forestry to
170 cultivate marijuana for therapeutic use.
- 171 25. *Production or produce* means the manufacture, planting, preparation, cultivation, growing,
172 harvesting, propagation, compounding, conversion or processing of marijuana, either directly or
173 indirectly by extraction from substances of natural origin, or independently by means of chemical
174 synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging
175 or repackaging of the substance or labeling or relabeling of its container, except that this term does

- 176 not include the preparation or compounding of marijuana by a patient or caregiver for the patient's
177 use.
178 26. *Production facility* means a secure facility where the production of marijuana occurs and that is
179 operated by a person to whom the Louisiana Department of Agriculture and Forestry has issued a
180 producer license.
181 27. *Sale* is any form of delivery, which includes barter, exchange or gift, or offer therefor, and each
182 such transaction made by any person whether as principal, proprietor, agent, servant, or employee.
183 28. *Usable marijuana* means the dried leaves and flowers of the marijuana plant, and any mixtures or
184 preparations of such leaves and flowers, that are appropriate for the therapeutic use of marijuana,
185 but does not include the seeds, stalks, and roots of the marijuana plant.
186

187 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

188 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR
189

190 §2443. Marijuana products

191 A. Exclusive Source.

- 192 1. The exclusive source of marijuana products shall be the producer licensed for that activity by the
193 Louisiana Department of Agriculture and Forestry (LDAF).
194 2. That producer shall prepare pharmaceutical grade marijuana products for distribution to the
195 marijuana pharmacies licensed by the board.
196 3. Marijuana products from any other source shall be deemed misbranded and/or adulterated and
197 shall not be distributed to any marijuana pharmacy, nor may such misbranded and/or adulterated
198 products be dispensed by any marijuana pharmacy.

199 B. Laboratory Testing.

- 200 1. Prior to manufacturing any marijuana product, the producer shall segregate all harvested
201 marijuana into homogenized batches.
202 2. A producer shall make available each such batch at the production facility for testing by a
203 laboratory approved by LDAF. The laboratory employee shall select a random sample from each
204 batch. The laboratory shall test each sample for microbiological contaminants, mycotoxins, heavy
205 metals, pesticide chemical residue, residual solvents, homogeneity, and for the purpose of
206 conducting an active ingredient analysis.
207 3. From the time that a batch of marijuana has been homogenized for sample testing and eventual
208 packaging and sale to a pharmacy until the laboratory provides the results from its tests and
209 analyses, the producer shall segregate and withhold from use the entire batch with the exception of
210 the samples removed by the laboratory for testing. During this period of segregation, the producer
211 shall maintain the marijuana batch in a secure, cool and dry location so as to prevent the marijuana
212 from becoming contaminated or losing its efficacy. Under no circumstances shall a producer
213 include marijuana in a marijuana product or sell it to a pharmacy prior to the time the laboratory
214 has completed its testing and analysis and provided those results, in written or electronic form, to
215 the producer or the producer's designated employee.
216 4. The laboratory shall immediately return or dispose of any marijuana upon the completion of any
217 testing, use, or research. When the laboratory disposes of marijuana, the laboratory shall comply
218 with the marijuana disposal rules promulgated by LDAF.
219 5. In the event a sample of marijuana does not pass the microbiological, mycotoxin, heavy metal,
220 pesticide chemical residue, residual solvent, or homogeneity test based on the standards set forth
221 in this Section, the producer shall dispose of the entire batch from which the sample was taken, in
222 compliance with the marijuana disposal rules promulgated by LDAF.
223 a. With respect to the microbiological test, a marijuana sample shall be deemed to have passed if
224 it satisfies the standards set forth in *Chapter 1111 – Microbiological Examination of*
225 *Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances*
226 *for Pharmaceutical Use of the United States Pharmacopeia (USP)*, available at www.usp.org.
227 b. With respect to the mycotoxins test, a marijuana sample shall be deemed to have passed if it
228 meets the following standards:
229 i. Aflatoxin B1 < 20 parts per billion (ppb);
230 ii. Aflatoxin B2 < 20 ppb;
231 iii. Aflatoxin G1 < 20 ppb;
232 iv. Aflatoxin G2 < 20 ppb; and
233 v. Ochratoxin A < 20 ppb.

- 234
235
236
237
238
239
240
241
242
243
244
245
246
247
248
249
250
251
252
253
254
255
256
257
258
259
260
261
262
263
264
265
266
267
268
269
270
271
272
273
274
275
276
277
278
279
280
281
282
283
284
285
286
287
288
289
290
291
292
- c. With respect to the heavy metals test, a marijuana sample shall be deemed to have passed if it meets the following standards:
 - i. Arsenic < 10 parts per million (ppm);
 - ii. Cadmium < 4.1 ppm;
 - iii. Lead < 10 ppm; and
 - iv. Mercury < 2 ppm
 - d. With respect to the pesticide chemical residue test, a marijuana sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the United States Environmental Protection Agency's "Tolerances and Exemptions for Pesticide Chemical Residues in Food", as found in 40 CFR 180 or its successor.
 - e. With respect to the residual solvent test, a marijuana sample shall be deemed to have passed if the following solvents are below the listed limits:
 - i. Butanes < 800 ppm;
 - ii. Heptanes < 500 ppm;
 - iii. Benzene < 1 ppm;
 - iv. Toluene < 1 ppm;
 - v. Hexanes < 10 ppm; and
 - vi. Total Xylenes < 1 ppm.
 - f. With respect to the test for homogeneity, a marijuana sample shall be deemed to have failed if ten percent of the sample contains more than twenty percent of the total active ingredient.
 - g. With respect to the analysis of active ingredients, the following substances, when present, shall be identified and measured. The maximum variance permitted is fifteen percent from the labeled amount. For example, a product labeled as containing 10 milligrams of tetrahydrocannabinol (THC) shall contain no less than 8.5 milligrams THC and no more than 11.5 milligram THC.
 - i. THC (tetrahydrocannabinol);
 - ii. THCA (tetrahydrocannabinolic acid);
 - iii. CBD (cannabidiol); and
 - iv. CBDA (cannabidiolic acid).
6. If a sample of marijuana passes the microbiological, mycotoxin, heavy metal, pesticide chemical residue, residual solvent, and homogeneity tests, the laboratory shall release the entire batch for immediate manufacturing, packaging, and labeling for sale to a marijuana pharmacy.
 7. In the event of any test failure, the laboratory shall transmit to LDAF an electronic copy of such test result at the same time it transmits those results to the producer.
 8. The laboratory shall comply with all rules applicable to the testing of marijuana promulgated by LDAF.
 9. A producer shall provide the laboratory test results to the marijuana pharmacy for each batch of marijuana used in a product acquired by the marijuana pharmacy. The pharmacy shall make such testing results available upon request to their patients, caregivers, and physicians who recommended such marijuana products dispensed to their patients.
- C. Product Dosage Forms.
1. The producer shall limit their production of pharmaceutical grade marijuana products to the following dosage forms:
 - a. Oils, extracts, tinctures, or sprays;
 - b. Solid oral dosage forms, e.g., capsules or pills;
 - c. Liquid oral dosage forms, e.g., solutions or suspensions;
 - d. Edible dosage forms;
 - e. Topical applications, oils or lotions;
 - f. Transdermal patches; or
 - g. Suppositories.
 2. No marijuana product shall:
 - a. Include alcoholic liquor, dietary supplements, or any drug, except for pharmaceutical grade marijuana. For purposes of this provision, alcoholic liquor does not include any liquid or solid containing less than one-half of one percent of alcohol by volume, or ethanol-based tinctures;
 - b. Be manufactured or sold as a beverage;
 - c. Be manufactured or sold in a form or with a design that:
 - i. Is obscene or indecent;

- 293 ii. May encourage the use of marijuana for recreational purposes;
294 iii. May encourage the use of marijuana for a condition other than a debilitating medical
295 condition; or
296 iv. Is customarily associated with persons under the age of eighteen; or
297 d. Have had pesticide chemicals or organic solvents used during the production or
298 manufacturing process other than those which may be approved by the Commissioner of
299 LDAF.

- 300 3. Any marijuana product not in compliance with the provisions of this Paragraph shall be deemed
301 adulterated.

302 D. Packaging and Labeling Requirements.

303 1. Packaging.

- 304 a. The producer shall ensure every product intended for dispensing to a patient is placed within a
305 child-resistant, light-resistant, tamper-evident container prior to sale or transport to the
306 pharmacy.
307 i. A package shall be deemed child-resistant if it satisfies the standard for 'special
308 packaging' as set forth in the United States Consumer Product Safety Commission's
309 *Poison Prevention Packaging* as found in 16 CFR 1700.1(b)(4) or its successor.
310 ii. A package shall be deemed light-resistant if it satisfies the standard set forth in *Chapter*
311 *671 – Containers: Performance Testing of the United States Pharmacopeia (USP)*.
312 iii. A package shall be deemed tamper-evident if it clearly indicates prior access to the
313 container.
314 b. Any product containing pharmaceutical grade marijuana or its principal psychoactive
315 constituent tetrahydrocannabinol (THC) shall be packaged so that one dose contains no more
316 than 10 milligrams of THC.
317 c. If it is not intended for the entire product to be used at a single time, the packaging must be re-
318 sealable in a manner that maintains its child-resistant property for multiple openings. Single
319 doses may be placed in a package with other single doses; however, the total amount of active
320 THC contained within the larger packaging shall not exceed 100 milligrams.
321 d. No single container shall contain more than a one month supply of marijuana.
322 e. Packaging selected by the producer shall be subject to the following restrictions.
323 i. Shall not specifically target individuals under the age of 21 years;
324 ii. Shall not bear any resemblance to a trademarked, characteristic or product-specialized
325 packaging of any commercially available candy, snack, baked good or beverage;
326 iii. Shall not use the words "candy" or "candies";
327 iv. Shall not use a cartoon, color scheme, image, graphic or feature that might make the
328 package attractive to children; and
329 v. Shall not use a seal, flag, crest, coat of arms or other insignia that could reasonably lead
330 any person to believe the product has been endorsed, manufactured by, or used by any
331 state, parish, municipality, or any agent thereof.

332 2. Labeling.

- 333 a. Each product shall be labeled by the producer prior to its sale to the marijuana pharmacy.
334 Each label shall be securely affixed to the package and shall include, at a minimum:
335 i. The batch or lot number assigned by the producer to the marijuana plant(s) from which
336 the marijuana used in the product was harvested;
337 ii. A complete list of solvents, chemicals, and pesticides used in the creation of any
338 marijuana concentrate;
339 iii. A complete list of all ingredients used to manufacture the product, which may include a
340 list of any potential allergens contained within, or used in the manufacture of, a product;
341 iv. The potency of the THC and CBD in the product, expressed in milligrams for each
342 cannabinoids;
343 v. The net weight, using a standard of measure compatible with the LMMTS, of the
344 product prior to its placement in the shipping container;
345 vi. A product expiration date, upon which the product will no longer be fit for use. Once a
346 label with an expiration date has been affixed to a product, the producer shall not
347 alter that date or affix a new label with a later date; and
348 vii. A statement the product has been tested for contaminants, that there were no adverse
349 findings, and the date of such testing.

- 350 b. The labeling text on any marijuana product shall not make any false or misleading statements
351 regarding health or physical benefits to the consumer. Further, each label shall include all of
352 the following statements:
353 i. "Contains Marijuana. For Medical Use Only. KEEP OUT OF THE REACH OF
354 CHILDREN."
355 ii. "Marijuana can impair concentration, coordination, and judgment. Do not operate a
356 vehicle or machinery under the influence of this drug."
357 iii. "There may be additional health risks associated with the consumption of this product
358 for women who are pregnant, breastfeeding, or planning to become pregnant."
359 iv. A statement that it is illegal for any person to possess or consume the contents of the
360 package other than the patient for whom it was recommended.
361 c. The labeling text required by this Section shall be no smaller than 1/16 of an inch, shall be
362 printed in English, and must be unobstructed and conspicuous.
363 E. Distribution of Marijuana Products to Marijuana Pharmacies.
364 1. The producer shall maintain complete inventory records in the Louisiana Medical Marijuana
365 Tracking System (LMMTS), as required and delineated in rules promulgated by LDAF.
366 2. The producer shall maintain comprehensive records in LMMTS of all marijuana products
367 distributed to the marijuana pharmacies, whether by transport and delivery to the pharmacy or by
368 transfer to the agent of the pharmacy at the production facility.
369 3. In the event the producer delivers the products to the pharmacy, such activities must be in
370 compliance with the rules for that activity promulgated by LDAF.
371 4. In the event the pharmacy elects to send an agent to the production facility to retrieve products
372 ordered by the pharmacy, the personnel at the production facility shall verify the identity and
373 credentials of the pharmacy's agent before releasing the products to the agent.
374 a. The producer shall provide a copy of the transport manifest generated by LMMTS, which
375 shall contain the following information:
376 i. The name and address of the producer selling the product;
377 ii. The name and address of the pharmacy purchasing the product;
378 iii. The name and quantity (by weight or unit) of marijuana products included in the
379 delivery;
380 iv. The date of transport and time of departure from the production facility;
381 v. The make, model, and license plate number of the delivery vehicle;
382 vi. The date and time of arrival at the pharmacy; and
383 vii. The name and signature of the pharmacy's agent.
384 b. The pharmacy's agent shall compare the transport manifest to the products transferred to his
385 possession, and when correct, shall return a signed copy of the manifest to the producer before
386 departing from the production facility.
387 c. The pharmacy's agent shall place the products in a locked, safe, and secure storage
388 compartment that is part of the motor vehicle, or in the alternative, in a locked storage
389 container that has a separate key or combination pad, and further, the product shall not visible
390 or recognizable from outside the vehicle, and further, the vehicle shall not bear the name of
391 the pharmacy or any markings to indicate the vehicle contains marijuana
392 d. The pharmacy's agent shall maintain physical control of the vehicle at all times during the
393 transport, and shall not leave the vehicle unattended at any time.
394 e. The pharmacy's agent shall have access to a secure form of communication with the
395 pharmacy as well as the ability to contact law enforcement through the 911 emergency
396 system.
397 f. Upon arrival at the pharmacy, the pharmacy's agent shall deliver the product to a pharmacist
398 for verification of receipt; the pharmacist shall time, date, and sign the delivery manifest.
399

400 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

401 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR

402 §2445. Marijuana pharmacy permit

- 403 A. The board shall develop and configure a pharmacy permit designated as a marijuana pharmacy permit.
404 B. The dispensing of marijuana for therapeutic purposes shall be restricted to those pharmacies holding a
405 marijuana pharmacy permit issued by the board, and only when that permit is in active or restricted
406 status.
407

- 408
409
410
411
412
413
414
415
416
417
418
419
420
421
422
423
424
425
426
427
428
429
430
431
432
433
434
435
436
437
438
439
440
441
442
443
444
445
446
447
448
449
450
451
452
453
454
455
456
457
458
459
460
461
462
463
464
465
466
- C. When issued to a successful applicant, the permit will authorize the operation of a marijuana pharmacy in compliance with the provisions of this Subchapter.
 - D. When the permit is issued, it shall be valid only for the owner and the specific location noted on the application and recorded on the permit.
 - E. A marijuana pharmacy permit is non-transferable from one owner to another owner, and moreover, in the event the ownership of the organization that acquired the permit changes by fifty percent or more, then the ownership will be deemed sufficiently different as to require a new marijuana pharmacy permit. A marijuana pharmacy permit owner continuing to operate a marijuana pharmacy after its ownership has changed by fifty percent or more without obtaining a new marijuana pharmacy permit shall be deemed guilty of operating a pharmacy without a valid permit, in violation of R.S. 37:1221.
 - F. Although a change of ownership of less than fifty percent shall not require a new pharmacy permit, any proposed change of ownership shall require prior notice to the board, and further, approval by the board.
 - G. The board shall not have more than ten active marijuana pharmacy permits at any given time. To facilitate compliance with that legislative restriction, the board recognizes the nine regions previously declared by the Department of Health, to wit:
 1. *Metropolitan*, composed of the parishes of Jefferson, Orleans, Plaquemines, and St. Bernard;
 2. *Capitol*, composed of the parishes of Ascension, East Baton Rouge, East Feliciana, Iberville, Pointe Coupee, West Baton Rouge, and West Feliciana;
 3. *Teche*, composed of the parishes of Assumption, Lafourche, St. Charles, St. James, St. John, St. Mary, and Terrebonne;
 4. *Acadian*, composed of the parishes of Acadia, Evangeline, Iberia, Lafayette, St. Landry, St. Martin, and Vermilion;
 5. *Southwest*, composed of the parishes of Allen, Beauregard, Calcasieu, Cameron, and Jefferson Davis;
 6. *Central*, composed of the parishes of Avoyelles, Catahoula, Concordia, Grant, LaSalle, Rapides, Vernon, and Winn;
 7. *Northwest*, composed of the parishes of Bienville, Bossier, Caddo, Claiborne, DeSoto, Natchitoches, Red River, Sabine, and Webster;
 8. *Northeast*, composed of the parishes of Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union, and West Carroll; and
 9. *Southeast*, composed of the parishes of Livingston, St. Helena, St. Tammany, Tangipahoa, and Washington.
 - H. To achieve an equitable distribution of the marijuana pharmacy permits across the state, the board shall reserve one marijuana pharmacy permit for each of the nine regions identified above. In the event the board is convinced of the need for a second permit in one region, it may issue that permit following the procedures identified in this Subchapter. Further expansion will require a legislative amendment of the original restriction.
 - I. When the board is prepared to receive and process applications for and issue marijuana pharmacy permits, it shall publish on its internet web site, and in such other places as the board deems appropriate, a notice to that effect. Such notice shall include, but not be limited to:
 1. The maximum number of permits to be awarded;
 2. Information on how to obtain an application;
 3. The deadline for receipt of applications;
 4. Acceptable methods for submitting an application;
 5. The preferred locations, if any, for the marijuana pharmacy permits; and
 6. The criteria that shall be considered in awarding the marijuana pharmacy permits.
 - J. Following the deadline for receipt of applications, the board shall evaluate each complete and timely submitted application and award marijuana pharmacy permits on a competitive basis based on the criteria set out in the notice for applications. In the event the board determines there are an insufficient number of qualified applicants to award all of the marijuana pharmacy permits the board has determined are desirable, the board may republish, in accordance with this section, a notice of open applications for marijuana pharmacy permits.
 - K. The board shall have the right to amend the notice of open applications prior to the deadline for submitting an application. Such amended notice shall be published in the same manner as the original notice of open applications.
 - L. The board shall have the right to cancel a notice of open applications prior to the award of a marijuana pharmacy permit.

467 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
468 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR
469

470 **§2447. Licensing procedures**

471 A. Application for Initial Issuance of Permit

- 472 1. The board shall develop an application form suitable for the marijuana pharmacy permit. The
473 board may revise that application form on its own initiative in order to collect the information it
474 deems necessary to properly evaluate an applicant.
- 475 2. The board shall not process applications received by facsimile, or that are incomplete, or
476 submitted with the incorrect fee.
- 477 3. The applicant shall fully disclose the ownership of the entity that will own the permit as well as
478 any additional holding companies that may exist, such that any natural person with any ownership
479 interest shall be fully identified.
- 480 4. In the event any person holding any ownership interest in the entity submitting an application for a
481 marijuana pharmacy permit has engaged in any of the following activities, the entity shall be
482 disqualified and the board shall not issue a marijuana pharmacy permit to that applicant:
- 483 a. Within the two year period preceding the date of the application, has made a contribution to a
484 candidate in a Louisiana election for a statewide elected official or state legislative election
485 governed by the provisions of the Campaign Finance Disclosure Act [R.S. 14:1481]; or
- 486 b. Within the two year period preceding the date of the application, the person or any member of
487 the person's immediate family held a position in state service in Louisiana, including but not
488 limited to, a legislator, statewide public official, state employee, or member of the board.
- 489 5. The applicant shall provide a complete street address reflecting the location at which the applicant
490 proposes to operate the marijuana pharmacy.
- 491 6. The applicant shall provide the following information and records in the application process:
- 492 a. A detailed description of any other services or products to be offered by the marijuana
493 pharmacy;
- 494 b. Details regarding the applicant's plans to maintain adequate control against the diversion,
495 theft, or loss of marijuana;
- 496 c. Documents or information sufficient to establish the applicant is authorized to conduct
497 business in Louisiana and that all applicable state and local building, fire and zoning
498 requirements, and local ordinances will be met;
- 499 d. Text and graphic materials showing the exterior appearance of the proposed marijuana
500 pharmacy and its site compatibility with commercial or residential structures already
501 constructed or under construction within the immediate neighborhood;
- 502 e. A blueprint of the proposed marijuana pharmacy which shall, at a minimum, show and
503 identify:
- 504 i. The square footage of the area which will constitute the prescription department;
- 505 ii. The square footage of the overall marijuana pharmacy;
- 506 iii. The square footage and location of areas used as storerooms or stockrooms;
- 507 iv. The size of the counter that will be used for the dispensing and sale of marijuana;
- 508 v. The location of the marijuana pharmacy sink and refrigerator, if any;
- 509 vi. The location of all approved safes and vaults that will be used to store marijuana;
- 510 vii. The location of the toilet facilities;
- 511 viii. The location of the break room and location of lockers for personal belongings;
- 512 ix. The location and size of the patient counseling area(s);
- 513 x. The location(s) where any other products or services will be offered; and
- 514 xi. The location of all areas that may contain marijuana showing the location of walls,
515 partitions, counters, and all areas of ingress and egress.
- 516 f. Such other documents and information reasonably required by the board to determine the
517 applicant's suitability for permitting or to protect the public's health and safety.
- 518 7. The owner's managing officer and the pharmacist-in-charge shall be fully identified within the
519 application and they both shall sign and date the application form.
- 520 8. The applicant shall direct the following persons to submit to the criminal history record check
521 process used by the board, at the applicant's expense:
- 522 a. The owner's managing officer;
- 523 b. The pharmacist-in-charge; and

- 524 c. Any person holding any share of ownership in the entity; provided however that any person
525 not holding any share of ownership but holding a corporate officer position in the entity may
526 be required to submit to the criminal history record check.
- 527 9. The requirement for a criminal history record check may be waived by the board in the event the
528 person has already completed that process for the board within the two year period prior to the
529 date of the application.
- 530 10. The applicant shall supplement the application form with sufficient documentation of the
531 applicant's financial capacity to properly operate a marijuana pharmacy, including but not limited
532 to, evidence of his escrow account, letter of credit, or surety bond of at least one million dollars in
533 a financial institution headquartered in Louisiana.
- 534 a. The pharmacy's one million dollar escrow account, letter of credit, or surety bond shall be
535 payable to the board in the event the board determines after a due process hearing that the
536 pharmacy has failed to timely and successfully complete the construction of the pharmacy or
537 to operate such pharmacy in compliance with the provisions of this Subchapter.
- 538 b. The board shall permit the pharmacy's escrow account, letter of credit, or surety bond to be
539 reduced by two hundred fifty thousand dollars upon the successful achievement of each of the
540 following milestones:
- 541 i. A determination by the board that the pharmacy is fully operational and able to commence
542 and has begun dispensing of marijuana as provided in this Subchapter;
- 543 ii. A determination by the board that the pharmacy remained operational and without
544 substantial interruption and without any violation of law or regulation for a one year
545 period; and
- 546 iii. A determination by the board that the pharmacy remained operational and without
547 substantial interruption and without any violation of law or regulation for a second one
548 year period.
- 549 iv. The pharmacy shall maintain the escrow account, letter of credit, or surety bond for a
550 minimum of two hundred fifty thousand dollars for the remainder of its operation.
- 551 c. In the event a pharmacy voluntarily chooses not to renew the pharmacy permit and follows
552 proper closure procedures, the board shall extinguish the obligations under the escrow
553 account, letter of credit, or surety bond at the end of the permit's term.
- 554 11. In the event any information contained in the application or accompanying documents changes
555 after being submitted to the board, the applicant shall immediately notify the board in writing and
556 provide corrected information in a timely manner so as not to disrupt the application processing or
557 permit selection process.
- 558 12. The board may verify information contained in each application and accompanying documentation
559 in order to assess the applicant's character and fitness to operate a marijuana pharmacy. The
560 board may verify the information and assess the applicant's character and fitness by, among other
561 actions:
- 562 a. Contacting the applicant by telephone, electronic mail, mail, or such other means as is
563 reasonable under the circumstances;
- 564 b. Conducting one or more on-site visits of the location for the proposed marijuana pharmacy, or
565 other pharmacies associated with the applicant or any of the applicant's owners;
- 566 c. Conducting background checks or contacting references of the applicant, its managing officer,
567 any of the corporate officers, or any shareholder, as well as the pharmacist-in-charge;
- 568 d. Contacting state regulators in any other states where the applicant, the applicant's owners or
569 corporate officers, or its pharmacist-in-charge are engaged in, or have sought to be engaged
570 in, any aspect of that state's medical marijuana program; or
- 571 e. Requiring a personal meeting with the owner's managing officer and the pharmacist-in-charge
572 and the submission of additional information or documents.
- 573 13. The application shall be accompanied by payment of the permit fees and administrative hearing
574 fee authorized by La. R.S. 37:1184 and 40:1013.
- 575 14. When the staff has determined an entity's application package is complete, the application shall be
576 referred to the board's Application Review Committee, and further, the applicant shall be properly
577 notified at least thirty days prior to the committee's hearing during which their application will be
578 considered.
- 579 15. During the hearing held by the board's Application Review Committee, the members shall
580 consider, but are not limited to, the following criteria when evaluating an application for a
581 marijuana pharmacy permit:

- 582
583
584
585
586
587
588
589
590
591
592
593
594
595
596
597
598
599
600
601
602
603
604
605
606
607
608
609
610
611
612
613
614
615
616
617
618
619
620
621
622
623
624
625
626
627
628
629
630
631
632
633
634
635
636
637
638
639
- a. The character and fitness of the owner's managing officer, the pharmacist-in-charge, any of the owners and any other person who may have control or influence over the operation of the proposed marijuana pharmacy;
 - b. The location for the proposed marijuana pharmacy including, but not limited to:
 - i. Its proximity to previously approved marijuana pharmacies or locations of proposed marijuana pharmacies with pending applications;
 - ii. Whether the patient population in the area proposed by the marijuana pharmacy permit applicant justifies the need for a marijuana pharmacy, or an additional marijuana pharmacy, in that area;
 - iii. Whether the proximity of the proposed marijuana pharmacy will have a detrimental effect upon any place used primarily for religious worship, public or private school, convent, charitable institution, whether supported by private or public funds, hospital or veterans' home or any camp or military establishment; or
 - iv. Whether the number of marijuana pharmacies in the locality is such that the granting of a permit is detrimental to the public interest. In reaching a conclusion in this respect, the board may consider the population of, the number of like permits and number of all - permits existent in, the particular municipality and the immediate neighborhood concerned, the effect that a new permit may have on such town or neighborhood or on like permits existent in such municipality or neighborhood.
 - c. The applicant's ability to maintain adequate control against the diversion, theft and loss of marijuana;
 - d. The applicant's ability to maintain the knowledge, understanding, judgment, procedures, security controls and ethics to ensure optimal safety and accuracy in the dispensing and sale of marijuana; and
 - e. The extent to which the applicant or any of the applicant's owners have a financial interest in any other permittee, licensee, registrant, or other applicant currently or previously credentialed by the board; and
 - f. Any other reason provided by any federal law or rule or state law or rule that is not inconsistent with the Act.
16. Following their evaluation of the applications for a marijuana pharmacy permit, the committee shall develop a recommendation for presentation to the board at the board's next meeting. The board may accept the committee's recommendation, select an alternative applicant, reject all of the applicants, or return all the applicants to the committee for their reconsideration.
17. The board may disqualify any applicant who:
- a. Submits an incomplete, false, inaccurate, or misleading application;
 - b. Fails to submit an application by the published deadline; or
 - c. Fails to pay all applicable fees.
18. The decision of the board to award or not to award a marijuana pharmacy permit to an applicant shall be final.
19. Upon the approval of an application, the board shall issue the marijuana pharmacy permit and state controlled dangerous substance license to the applicant.
20. If an applicant has been awarded a marijuana pharmacy permit and has not commenced operation of such pharmacy within 180 days of being notified of the marijuana pharmacy permit award, the board may, in the board's discretion, rescind such marijuana pharmacy permit, unless such delay was caused by force majeure. A marijuana pharmacy shall be deemed to have commenced operation if the pharmacy is capable of operating in accordance with the applicant's approved application. In the event a marijuana pharmacy permit is rescinded pursuant to this subsection, the board shall award a marijuana pharmacy permit by selecting among the qualified applicants who applied for the marijuana pharmacy permit that was rescinded. If no other qualified applicant applied for such marijuana pharmacy permit or satisfied the criteria for awarding a permit, the board shall publish, in accordance with this section, a notice of open applications for marijuana pharmacy permits.
- B. Application for Renewal of Permit**
1. All marijuana pharmacy permits expire at midnight on December 31 of every year, regardless of the date of its initial issuance.
 2. The owner's managing officer and pharmacist-in-charge of the marijuana pharmacy permit shall complete, sign and date a permit renewal application form supplied by the board, and further, shall include all information requested on the form and include the pharmacy permit renewal fee and

- 640 state controlled dangerous substance license renewal fee authorized in R.S. 37:1184 prior to the
641 expiration the pharmacy permit.
- 642 3. The board shall not process applications received by facsimile, or that are incomplete, or
643 submitted with the incorrect fees.
 - 644 4. In the event the pharmacy does not submit a properly completed renewal application form and fee
645 to the board prior to the expiration of the permit, the permit shall be rendered null and void. A
646 marijuana pharmacy shall not operate with an expired permit. Evidence it has done so will
647 provide sufficient basis for the board to discipline the permit for violation of R.S. 37:1241(12).
 - 648 5. An application for the late renewal of an expired (lapsed) marijuana pharmacy permit that is
649 received in the board office no later than thirty days after the expiration date of the permit may be
650 processed by the board staff, provided the appropriate delinquent fee authorized in R.S. 37:1184 is
651 included with the application.
 - 652 6. A marijuana pharmacy permit not renewed by thirty days after the expiration date shall be
653 automatically terminated by the board.
 - 654 7. An application for the reinstatement of a terminated marijuana pharmacy permit shall be referred
655 to the board's Reinstatement Committee for its consideration.
- 656 C. Application for Reinstatement of Terminated, Suspended, or Revoked Marijuana Pharmacy Permits
- 657 1. The applicant shall complete an application form for this specific purpose supplied by the board;
658 the application shall require the inclusion of the annual renewal fee, the delinquent fee, the
659 administrative hearing fee, and the reinstatement fees authorized in R.S. 37:1184 and the program
660 fee authorized in R.S. 40:1013.
 - 661 2. An application for the reinstatement of a marijuana pharmacy permit previously terminated,
662 suspended or revoked by the board may only be approved following a preliminary hearing to
663 determine whether the reinstatement of the permit is in the public's best interest.
- 664 D. Maintenance of Marijuana Pharmacy Permit
- 665 1. A marijuana pharmacy permit is valid only for the entity or person to whom it is issued and shall
666 not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall the permit
667 be valid for any premises other than the business location recorded thereon.
 - 668 2. A duplicate or replacement permit shall be issued upon the written request of the licensee and
669 payment of the fee authorized in R.S. 37:1184. A duplicate or replacement license shall not serve
670 or be used as an additional or second license.
 - 671 3. Prior to any person affiliating with a marijuana pharmacy, including any change in the ownership
672 of the permit, such person shall comply with the credentialing requirements of the board. No
673 person shall commence their affiliation with a marijuana pharmacy until approved by the board.
 - 674 4. Prior to making any change in the marijuana pharmacy's name or trade name, the owner of the
675 permit shall notify the board and request approval of the contemplated name or trade name. The
676 board shall reasonably accommodate such requests, unless there is cause not to do so, e.g.,
677 duplicative or misleading names. The marijuana pharmacy shall not change its name or trade
678 name until approved by the board.
 - 679 5. Prior to any modification, remodeling, expansion, reduction, other physical, non-cosmetic
680 alteration of the marijuana pharmacy, the owner of the permit shall notify the board and request
681 approval of the contemplated change(s). The board shall reasonably accommodate such request,
682 unless there is cause not to do so, e.g., inconsistent with operating requirements. The marijuana
683 pharmacy shall not make such changes until approved by the board.
 - 684 6. Prior to any change in the location of a marijuana pharmacy, the owner of the permit shall submit
685 an application form for that purpose supplied by the board and pay the appropriate fee authorized
686 in R.S. 37:1184. The board may require an inspection of the new location prior to the issuance of
687 the permit for the new location. No marijuana pharmacy shall commence operation in a new
688 location until approved by the board.
 - 689 7. The owner of the pharmacy permit shall notify the board no later than ten days following a change
690 in the pharmacist-in-charge for the marijuana pharmacy permit.
 - 691 8. The owner of the pharmacy permit shall notify the board no later than ten days following a change
692 in the owner's managing officer for the marijuana pharmacy permit.
 - 693 9. In the event a marijuana pharmacy contemplates permanent closure, the pharmacist-in-charge shall
694 notify the board in accordance with the rules governing the permanent closure of a pharmacy as
695 described in Chapter 11 of the board's rules.

696
697 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

698 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR

699
700
701
702
703
704
705
706
707
708
709
710
711
712
713
714
715
716
717
718
719
720
721
722
723
724
725
726
727
728
729
730
731
732
733
734
735
736
737
738
739
740
741
742
743
744
745
746
747
748
749
750
751
752
753
754
755
756

§2449. Marijuana pharmacy personnel; therapeutic marijuana designation

- A. No person shall be employed by, or affiliated with, a marijuana pharmacy prior to their eighteenth birthday.
- B. The owner's managing officer and all persons holding a professional credential from the board shall first obtain a Therapeutic Marijuana (TM) designation from the board before affiliating with a marijuana pharmacy.
- C. The board may issue a TM designation to a person who has filed the application for that designation supplied by the board and has completed a criminal background check for the board within the two year period prior to the date of the application for the TM designation, and that person:
 - 1. Has been listed as an owner's managing officer on an application for a marijuana pharmacy permit, or on a request to become a replacement owner's managing officer for an existing marijuana pharmacy permit; or
 - 2. Holds one of the following professional credentials issued by the board – pharmacist, pharmacy intern, or certified pharmacy technician – and further, that professional credential was issued by the board at least two years prior to the date of the application for the TM designation, is in active status and has not been disciplined by the board within the two year period prior to the date of the application for the TM designation.
- D. The board may restrict, suspend, or revoke a TM designation for cause, but only pursuant to the Administrative Procedure Act.
- E. No pharmacist, pharmacy intern, or certified pharmacy technician may practice within a marijuana pharmacy in the absence of an active professional credential, an active TM designation, as well as access privileges to the state prescription monitoring program. A pharmacist may elect to not allow a pharmacy intern or pharmacy technician to function as his delegate with respect to access privileges to the state prescription monitoring program, but the pharmacist shall have such access. A pharmacy technician candidate shall not practice in a marijuana pharmacy.
- F. A pharmacist shall first acquire a Pharmacist-in-Charge (PIC) privilege, as described in §1105 of the board's rules, and the TM designation, as described in this Section, before accepting an appointment as the PIC of a marijuana pharmacy.
 - 1. The PIC of the marijuana pharmacy shall comply with the requirements of §1105 of the board's rules.
 - 2. The PIC shall be responsible for notice to the board of all pharmacists, pharmacy interns, and pharmacy technicians practicing at the marijuana pharmacy. The PIC shall cause such notice to be received in the board office in written form (mail, fax, or electronic mail) no later than ten days after the arrival or departure of the pharmacist, pharmacy intern, or pharmacy technician.
- G. The PIC shall insure and document the initial and continuing competency of the entire professional staff to provide the pharmacy care services rendered at the marijuana pharmacy. At a minimum, the PIC shall provide access to education and training in the following domains:
 - 1. Policies and procedures of the pharmacy, especially those relating to the tasks and functions that employee is expected to perform;
 - 2. Professional conduct, ethics, and patient confidentiality; and
 - 3. Developments in the therapeutic use of marijuana.Further, the PIC shall document such education and training, provide such records to the board when requested, and retain such records for at least two years after the employee disassociates with the pharmacy.
- H. The PIC shall comply with the professional supervision rules and ratios found in Chapter 7 (pharmacy interns) and Chapter 9 (pharmacy technicians) of the board's rules.
- I. In addition to the scope of practice limitations found in Chapter 9 of the board's rules, pharmacy technicians practicing in a marijuana pharmacy shall not:
 - 1. Consult with a patient or the patient's caregiver regarding marijuana or other drugs, either before or after marijuana has been dispensed, or regarding any medical information contained in a patient medication record;
 - 2. Consult with the physician who issued the recommendation/prescription/order for marijuana to the patient, or the physician's agent, regarding a patient or any medical information pertaining to the patient's marijuana or any other drug the patient may be taking;
 - 3. Interpret the patient's clinical data or provide medical advice;
 - 4. Perform professional consultations with physicians, nurses, or other health care professionals or their authorized agents; or

- 757
758
759
760
5. Determine whether a different brand or formulation of marijuana should be dispensed for the marijuana product or formulation recommended/prescribed/ordered by the physician or requested by the patient or his caregiver.

761 AUHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

762 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR

763

764 **§2451. Operation of marijuana pharmacy**

- 765
766
767
768
769
770
771
772
773
774
775
776
777
778
779
780
781
782
783
784
785
786
787
788
789
790
791
792
793
794
795
796
797
798
799
800
801
802
803
804
805
806
807
808
809
810
811
812
813
- A. No person may operate a marijuana pharmacy without a marijuana pharmacy permit issued by the board, and further, that permit shall be in active or restricted status. A pharmacist shall be on duty at all times during the regular open hours of the marijuana pharmacy.
 - B. A marijuana pharmacy shall not dispense marijuana from, obtain marijuana from, or transfer marijuana to, a location outside of the state of Louisiana.
 - C. A marijuana pharmacy shall not obtain, cultivate, deliver, transfer, transport, sell or dispense marijuana except:
 - 1. It may acquire marijuana from an authorized producer pursuant to the provisions of R.S. 40:1046; and
 - 2. It may dispense and sell marijuana to a patient with a recommendation/prescription/order for such marijuana or the patient's caregiver.
 - D. No person at a marijuana pharmacy shall provide marijuana samples.
 - E. A marijuana pharmacy shall sell marijuana products only in the original sealed containers or packaging as delivered by the producer, except that a pharmacist may remove the marijuana product from the producer's child-resistant container or package and place the marijuana product in a non-child-resistant, secure and light-resistant container upon a written request from the patient or caregiver so long as all original labeling is maintained with the product.
 - F. Only a pharmacist may dispense marijuana, and only a pharmacist, pharmacy intern, or pharmacy technician may sell marijuana to patients and caregivers. A pharmacy intern or pharmacy technician may assist, under the direct supervision of a pharmacist, in the dispensing of marijuana.
 - G. A marijuana pharmacy shall place all products sold to the patient or caregiver in an opaque package that shall not indicate the contents of the package, the originating facility or in any other way cause another person to believe that the package may contain marijuana.
 - H. A marijuana pharmacy shall not permit any person to enter the prescription department unless that person's responsibilities necessitate access to the department and then for only as long as necessary to perform the person's job duties.
 - I. While inside the pharmacy, all pharmacy employees shall wear name tags or similar forms of identification that clearly identify them to the public, including their position at the pharmacy.
 - J. A marijuana pharmacy shall be open for qualifying patients and primary caregivers to purchase marijuana products for a minimum of 10 hours per week.
 - 1. A marijuana pharmacy that closes during its normal hours of operation shall implement procedures to notify patients and caregivers of when the marijuana pharmacy will resume normal hours of operation. Such procedures may include, but are not limited to, telephone system messages and conspicuously posted signs.
 - 2. In the event the pharmacist on duty leaves the prescription department, the prescription department shall comply with the provisions of §1109 (temporary absence) or §1111 (closure) of the board's rules.
 - K. A marijuana pharmacy shall provide information to patients and caregivers regarding the possession and use of marijuana. Such informational material shall include information related to:
 - 1. Limitations on the right to possess and use marijuana pursuant to R.S. 40:1046;
 - 2. Safe techniques for proper use of marijuana and paraphernalia;
 - 3. Alternative methods and forms of consumption by which one can use marijuana;
 - 4. Signs and symptoms of substance abuse; and
 - 5. Opportunities to participate in substance abuse programs.
 - L. The marijuana pharmacy shall establish, implement and adhere to a written alcohol-free, drug-free and smoke-free work place policy, which shall be available to the board upon request.
 - M. The receipt of all deliveries from producers shall be carried out under the direct supervision of a pharmacist who shall be present to accept the delivery. Upon delivery, the marijuana shall immediately be placed in an approved safe or approved vault within the pharmacy where marijuana is stored.

- 814 N. No marijuana pharmacy shall sell anything other than marijuana products; however, the pharmacy may
815 elect to sell over-the-counter (OTC) medications and/or durable medical equipment (DME) from the
816 same premises but outside the prescription department.
- 817 O. No marijuana shall be administered on the premises of a marijuana pharmacy, except during patient
818 counseling, education or training.
- 819 P. No person associated with a marijuana pharmacy shall enter into any agreement with a physician or
820 health care facility concerning the provision of services or equipment that may adversely affect any
821 person's freedom to choose the marijuana pharmacy at which the patient or caregiver will purchase
822 marijuana.
- 823 Q. No marijuana shall be sold, dispensed or distributed via a delivery service or any other manner outside
824 of a marijuana pharmacy, except that a caregiver may deliver marijuana to the caregiver's patient.
- 825 R. No marijuana shall be sold when the marijuana pharmacy is closed and not open for business.
- 826 S. Board representatives, local law enforcement or other federal, state or local government officials may
827 enter any area of a marijuana pharmacy if necessary to perform their governmental duties.
- 828 T. Right of inspection. The board, or its agent, representative, or designee, is authorized:
- 829 1. To enter a marijuana pharmacy at any time during its hours of operation, or any other place,
830 including a vehicle, wherein marijuana is held, dispensed, sold, or otherwise disposed of;
- 831 2. To inspect within reasonable limits and in a reasonable manner, such place and all pertinent
832 equipment, finished and unfinished material, containers and labeling, and all things therein,
833 including records, files, financial data, sales data, shipping data, pricing data, employee data,
834 research, papers, processes, controls and facilities; and
- 835 3. To inventory any stock of marijuana therein and obtain samples of any marijuana or marijuana
836 product, any labels or containers for marijuana, paraphernalia, and of any finished and unfinished
837 material.
- 838 U. Inspection of records. Every person required to prepare, obtain or keep records, logs, reports or other
839 documents, and every person in charge, or having custody, of such documents shall maintain such
840 documents in an auditable format for no less than two years. Upon request, such person shall make
841 such documents immediately available for inspection and copying by the board or its authorized
842 representative. In complying with this Section, no person shall use a foreign language or codes or
843 symbols to designate marijuana types or persons in the keeping of any required document.
- 844

845 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

846 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR

847

848 **§2453. Security requirements for marijuana pharmacies**

- 849 A. A marijuana pharmacy shall:
- 850 1. Store all marijuana in an approved safe or vault, as defined in this Subchapter, and in such a
851 manner as to prevent diversion, theft, or loss;
- 852 2. Maintain all marijuana in a secure area or location accessible only to specifically authorized
853 employees, which shall include only the minimum number of employees essential for efficient
854 operation;
- 855 3. Not permit any person less than eighteen years of age to enter the prescription department, with
856 the exception of patients being counseled by the pharmacist;
- 857 4. Keep all approved safes and vaults securely locked and protected from entry, except for the actual
858 time required to remove or replace marijuana;
- 859 5. Keep all locks and security equipment in good working order;
- 860 6. Not allow keys to be left in the locks and not store or place keys in a location accessible to persons
861 other than specifically authorized employees;
- 862 7. Not allow other security measures, such as combination numbers, passwords or electronic or
863 biometric security systems, to be accessible to persons other than specifically authorized
864 employees;
- 865 8. Keep the pharmacy securely locked and protected from entry by unauthorized employees;
- 866 9. Keep the outside perimeter of the pharmacy premises well-lit; and
- 867 10. Post a sign at all entry ways into any area of the pharmacy containing marijuana, including a room
868 with an approved safe or vault, which sign shall be a minimum of twelve inches in height and
869 twelve inches in width which shall state: "*Do Not Enter – Limited Access Area – Access Limited
870 to Authorized Employees Only*" in lettering no smaller than one-half inch in height.
- 871 B. All pharmacies shall have an adequate security system to prevent and detect diversion, theft or loss of
872 marijuana utilizing commercial grade equipment, which shall include at a minimum:

- 873
874
875
876
877
878
879
880
881
882
883
884
885
886
887
888
889
890
891
892
893
894
895
896
897
898
899
900
901
902
903
904
905
906
907
908
909
910
911
912
913
914
915
916
917
918
919
920
921
922
923
924
925
926
927
928
929
930
1. A perimeter alarm;
 2. Motion detector;
 3. Video cameras in all areas that may contain marijuana and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance. The pharmacy shall direct cameras at all approved safes and vaults, dispensing areas, marijuana sales areas and any other area where marijuana is being stored or handled. At entry and exit points, the pharmacy shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the pharmacy.
 4. Twenty-four hour recordings from all video cameras, which the pharmacy shall make available for immediate viewing by the board or its authorized representative upon request and shall retain for at least thirty days. If a pharmacy is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, the pharmacy shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the pharmacy that it is not necessary to retain the recording.
 - a. All video recordings shall allow for the exporting of still images in an industry standard image format, including .jpg, .bmp, and .gif. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. A pharmacy shall erase all recordings prior to disposal or sale of the pharmacy.
 5. Duress alarm, which for purposes of this Subsection means a silent security alarm system signal generated by the entry of a designated code in into an arming station in order to signal that the alarm user is being forced to turn off the system.
 6. Panic alarm, which for purposes of this Subsection means an audible security alarm system signal generated by the manual activation of a device intended to signal a life threatening or emergency situation requiring a law enforcement response;
 7. Holdup alarm, which for purposes of this Subsection means a silent alarm signal generated by the manual activation of a device intended to signal a robbery in progress;
 8. Automatic voice dialer, which for purposes of this Subsection means any electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message, when activated, over a telephone line, radio or other communication system, to a law enforcement, public safety or emergency services agency requesting dispatch;
 9. A failure notification system that provides an audible, text or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the pharmacy within five minutes of the failure, either by telephone, email, or text message;
 10. The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded);
 11. A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and
 12. The ability to remain operational during a power outage.
- C. A pharmacy shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations.
 1. A pharmacy shall keep all on-site surveillance rooms locked and shall not use such rooms for any other function.
 2. A pharmacy shall limit access to surveillance areas to persons that are essential to surveillance operations, law enforcement agencies, security system service employees, and the board's authorized representative.
 3. A pharmacy shall make available to the board upon request a current list of authorized employees and service employees that have access to the surveillance room.
 - D. A pharmacy shall keep all security equipment in good working order and shall test such equipment no less than two times per year.
 - E. When a pharmacy presents special security issues, such as an extremely large stock of marijuana, exposed handling or unusual vulnerability to, or actual, diversion, theft or loss, the board may require additional safeguards, including but not limited to, a supervised watchman service.
 - F. Any marijuana not stored in compliance with this Section, or stored at a location other than that for which the pharmacy permit was issued, shall be subject to embargo or seizure by the board.

- 931 G. In the event any marijuana pharmacy permit is revoked, suspended, or not renewed, the pharmacy shall
932 dispose of its entire stock of marijuana in accordance with the disposal provisions in this Subchapter.
933 H. If a pharmacy has provided other safeguards which can be regarded in total as an adequate substitute
934 for some element of protection required of the pharmacy, such added protection may be taken into
935 account by the board in evaluating overall required security measures.
936

937 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

938 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR
939

940 §2455. Reportable security events

- 941 A. Upon becoming aware of discrepancies identified during inventory, diversion, theft, loss, or
942 unauthorized destruction of any marijuana, or of any loss or unauthorized alternation of records related
943 to marijuana or patients, a pharmacy shall immediately notify:
944 1. Appropriate law enforcement authorities; and
945 2. The board.
946 B. A pharmacy shall provide the written notice to the board by way of a signed statement which details
947 the circumstances of the event, including an accurate inventory of the quantity and brand names of the
948 marijuana diverted, stolen, lost, destroyed, or damaged, along with confirmation that the local law
949 enforcement authorities were notified. A pharmacy shall make such notice no later than twenty-four
950 hours after discovery of the event.
951 C. A pharmacy shall notify the board no later than the next business day, followed by written notification
952 no later than ten business days, of any of the following:
953 1. An alarm activation or other event that requires response by public safety personnel;
954 2. A breach of security;
955 3. The failure of the security alarm system due to a loss of electrical support or mechanical
956 malfunction that is expected to last longer than eight hours; and
957 4. Corrective measures taken, if any.
958 D. A pharmacy shall maintain and shall make available all documentation related to an occurrence that is
959 reportable.
960

961 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

962 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR
963

964 §2457. Standards of practice

- 965 A. Environmental Standards
966 1. The prescription department shall be of sufficient size commensurate with the nature and scope of
967 practice. The space occupied by the prescription department shall be restricted to authorized
968 personnel only, as determined by the pharmacist-in-charge, and shall not be accessible to the
969 general public.
970 2. The prescription department shall contain sufficient fixtures, equipment, and supplies
971 commensurate with the nature and scope of practice for that pharmacy.
972 3. The prescription department shall include a sink with a hot and cold water supply, exclusive of
973 restroom facilities, with approved sewage disposal.
974 4. All areas where drugs and devices are stored shall be dry, well-lighted, well-ventilated, and
975 maintained at temperatures which will ensure the integrity of drugs during their storage and prior
976 to their dispensing as stipulated by the United States Pharmacopeia and/or manufacturer's or
977 distributor's product labeling unless otherwise indicated by the board.
978 5. The prescription department shall be secured by one or more physical barriers with suitable locks
979 and a monitored alarm system capable of detecting unauthorized entry, and further, complies with
980 security requirements identified elsewhere in this Subchapter.
981 6. Prescription and other patient healthcare information shall be maintained in a manner that protects
982 the integrity and confidentiality of such information.
983 B. Minimum Staffing Requirements
984 1. There shall be at least one pharmacist on duty at all times the pharmacy is open for business.
985 2. Every pharmacist practicing in the pharmacy shall possess a Louisiana pharmacist license in active
986 status, a Therapeutic Marijuana designation, and access privileges to the state prescription
987 monitoring program.
988 3. A pharmacy intern may assist the pharmacist in the prescription department, but only when in
989 possession of a Louisiana pharmacy intern registration in active status as well as a Therapeutic

- 990 Marijuana designation. The supervising pharmacist may establish a delegate credential for the
991 pharmacy intern in the state prescription monitoring program.
- 992 4. A pharmacy technician may assist the pharmacist in the prescription department, but only when in
993 possession of a Louisiana pharmacy technician certificate in active status as well as a Therapeutic
994 Marijuana designation. The supervising pharmacist may establish a delegate credential for the
995 pharmacy technician in the state prescription monitoring program.
- 996 5. No pharmacy technician candidate may practice in a marijuana pharmacy.
- 997 6. Additional clerical personnel may also be present at the pharmacy.
- 998 C. Operational Standards
- 999 1. The marijuana pharmacy shall comply with the provisions of Chapters 11, 25, 27, 29, and 31 of
1000 the board's rules except when this Subchapter grants exceptions or imposes more stringent
1001 requirements.
- 1002 2. In the event the marijuana pharmacy intends to close permanently, the pharmacist-in-charge (PIC)
1003 shall comply with the pharmacy closure procedures described in Chapter 11 of the board's rules,
1004 and further, the owner of the pharmacy permit shall not prevent or interfere with the PIC's
1005 performance of those tasks.
- 1006 a. In addition to the other closure requirements, the closing pharmacy shall include in its notice
1007 to the board and to the public the identification of the destination pharmacy where the closing
1008 pharmacy's prescription records will be transferred. That destination pharmacy shall be the
1009 marijuana pharmacy nearest the closing pharmacy, unless otherwise approved by the board.
- 1010 D. Recordkeeping Requirements
- 1011 1. Prescription/recommendation/order (hereinafter, "request") for marijuana
- 1012 a. The pharmacy shall not accept a verbal request.
- 1013 b. In the event the pharmacy receives a request in written form by facsimile, the pharmacy may
1014 begin the preparation of the product to be dispensed, but the pharmacist shall not dispense the
1015 product until the original form of the request is delivered to him in the pharmacy and he has
1016 compared it to the product prepared for dispensing.
- 1017 c. The written request shall bear the manual signature of the authorized prescriber. No other
1018 form of signature shall be valid, including (but not limited to) stamps, computer generated
1019 signatures, or signatures of anyone other than the authorized prescriber.
- 1020 d. A request generated, signed, and transmitted in electronic format which is compliant with the
1021 standards for electronic prescribing of controlled substances identified in 21 CFR 1311 (or its
1022 successor) shall be construed as a validly formatted request.
- 1023 2. When the pharmacy receives a request for marijuana from an authorized prescriber in written
1024 form, the pharmacist shall cause the form to be scanned and filed using an electronic imaging
1025 system in compliance with §1123 of the board's rules.
- 1026 3. Request forms (and electronic images thereof) shall be retained on the pharmacy's premises for at
1027 least two years after the date of dispensing, and further, shall be readily retrievable upon request
1028 by the board.
- 1029 4. Inventory of marijuana product
- 1030 a. The pharmacist-in-charge shall develop and maintain a perpetual inventory of all marijuana
1031 products acquired, held, dispensed, and disposed by the pharmacy.
- 1032 b. The pharmacy shall access the LMMTS and enter all inventory-related transactions in that
1033 system.
- 1034 c. In the event the pharmacist-in-charge designates an agent to retrieve new marijuana product
1035 inventory from the production facility, the pharmacist shall verify the agent is at least twenty
1036 one years of age and is eligible to drive on public roadways.
- 1037 d. The pharmacist-in-charge shall conduct an annual inventory of all marijuana products in the
1038 possession of the pharmacy on any date which is within one year of the previous annual
1039 inventory, and further, shall conduct additional inventory counts on the following occasions:
- 1040 i. arrival of a new pharmacist-in-charge;
- 1041 ii. discovery of any significant loss, disappearance, or theft of marijuana product;
- 1042 iii. departure of a pharmacist-in-charge; and
- 1043 iv. permanent closure of the pharmacy.
- 1044 e. Inventory records shall be retained on the pharmacy's premises for at least two years after the
1045 most recent entry.
- 1046 5. The pharmacy shall develop and maintain sufficient records to fully reveal the business
1047 transactions related to marijuana products, including their procurement and sale, for the current tax

- 1048 year as well as the two immediately preceding tax years, all of which shall be made available to
1049 the board upon request.
- 1050 6. The board may require any pharmacy or its owners to furnish such information as the board
1051 considers necessary for the proper administration of R.S. 40:1046, and may require a financial
1052 audit of the business of any marijuana pharmacy, and the expense thereof shall be paid by the
1053 marijuana pharmacy.
- 1054 E. Professional Practice Standards
- 1055 1. Prior to dispensing any marijuana product to a patient, the pharmacist shall review that patient's
1056 records in the state prescription monitoring program. The pharmacist shall resolve any concerns
1057 identified in that review by consultation with the recommending physician.
- 1058 2. Labeling of marijuana product dispensed
- 1059 a. The pharmacist shall not dispense any marijuana product that does not bear the producer label
1060 required by the LDAF, and further, the pharmacy dispensing label shall not overlay or obscure
1061 the producer label in any way.
- 1062 b. The pharmacy's dispensing label shall contain, at a minimum, the following data elements:
- 1063 i. Name and address of the pharmacy dispensing the product;
- 1064 ii. Telephone number or other contact information of the pharmacy dispensing the product;
- 1065 iii. Name of the authorized prescriber;
- 1066 iv. Name of the patient;
- 1067 v. Date the product was dispensed;
- 1068 vi. Prescription number, which shall be a unique identifier for that specific transaction;
- 1069 vii. Name of the marijuana product, including any concentration, strength, or other identifiers
1070 of the marijuana product;
- 1071 viii. Quantity of marijuana dispensed;
- 1072 ix. Directions for use of the product as included in the prescriber's request;
- 1073 x. Expiration date of the product, which shall not exceed the expiration date determined by
1074 the producer of the product; and
- 1075 xi. Other information selected by the dispensing pharmacist to inform the patient as to the
1076 best use of the product for the intended purpose.
- 1077 3. The pharmacist shall perform prospective drug utilization review and shall counsel every patient
1078 receiving marijuana product every time it is dispensed, in compliance with the rules on drug
1079 utilization review and patient counseling in Chapter 5 of the board's rules.
- 1080 4. Reporting transactions to state prescription monitoring program. The pharmacy shall comply with
1081 the reporting requirements as found in Chapter 29 of the board's rules.
- 1082 5. Disposal of marijuana product.
- 1083 a. A pharmacy may refuse to accept the delivery of marijuana product from a producer when it is
1084 determined to be misbranded, adulterated, expired, deteriorated, undesired, excess,
1085 unauthorized, or unfit for dispensing; however, once accepted by the pharmacy, no marijuana
1086 product may be returned to any producer.
- 1087 b. When the pharmacist determines a marijuana product is no longer suitable for dispensing, the
1088 product shall be removed from active dispensing stock and quarantined in the pharmacy
1089 pending its disposal, and further, the removal from active dispensing stock shall be recorded in
1090 the LMMTS.
- 1091 c. The pharmacist-in-charge shall render the waste unusable by grinding and incorporating the
1092 waste with other ground materials so the resulting mixture is at least 50% non-marijuana waste
1093 by volume. Material used to grind with the waste may include:
- 1094 i. Yard waste;
- 1095 ii. Paper waste;
- 1096 iii. Cardboard waste;
- 1097 iv. Plastic waste; or
- 1098 v. Soil or sand
- 1099 d. Waste shall be rendered unusable prior to leaving the pharmacy. Waste rendered unusable
1100 shall be disposed of by delivery to an approved solid waste facility for final disposition.
1101 Examples of acceptable permitted solid waste facilities include:
- 1102 i. Compost; anaerobic digester;
- 1103 ii. Landfill, incinerator; or
- 1104 iii. Waste-to-energy facility.
- 1105 e. The pharmacist-in-charge shall prepare a record of each disposal, and that record shall contain,
1106 at a minimum, the following information:

- 1107
1108
1109
1110
1111
1112
- i. Brand name and other specific identifiers of the marijuana product disposed;
 - ii. Quantity of product disposed;
 - iii. Manner of disposal; and
 - iv. Signatures of the pharmacist-in-charge disposing the product plus at least one witness who is either a credentialed staff member of that pharmacy or an agent of the board.

1113 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

1114 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR

1115

1116 **§2459. Advertising**

- 1117
1118
1119
1120
1121
1122
1123
1124
1125
1126
1127
1128
1129
1130
1131
- A. The marijuana pharmacy shall not advertise through any public medium, including but not limited to newspapers, billboards, television, radio, internet, social media, or any other means designed to market its products to the general public.
 - B. The marijuana pharmacy may market its products through direct mail, brochures, or other means to Louisiana-licensed physicians, but only when such advertising is directed solely to the practitioner and is not available to the general public.
 - C. Any advertisement permitted in Paragraph B of this Section shall not:
 1. Make any deceptive, false, or misleading assertions or statements regarding any product; or
 2. Assert that its products are safe because they are regulated by LDAF or the board. The pharmacy may advertise that its products have been tested by an approve laboratory, but shall not assert that its products are safe because they are tested by an approved laboratory.
 - D. The marijuana pharmacy may attach a maximum of two separate signs to the exterior of the building which identify the business by its business or trade name, provided that neither sign exceeds the size limit of sixteen hundred square inches.

1132 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

1133 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR

1134



Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov



Summary of Testimony & Public Comments
re
Regulatory Project 2016-6 ~ Marijuana Pharmacy
at
March 2, 2017 Public Hearing

1. February 1, 2017 letter from Sen. Fred Mills, Chair of Senate Health & Welfare Committee

Expressed concern for potential interpretation of 'edible dosage forms' found at §2443.C.1.d, that could result in the introduction of marijuana-infused products such as food and candy items. These items were never contemplated by the author of the enabling legislation, and he suggests revising that term to read 'gelatin-based chewable.' That clarification would permit the introduction of a 'gummy' chewable, similar to chewable vitamins.

2. February 15, 2017 letter from Eric Vidrine (PST) on behalf of Professional Arts Pharmacy

Expressed concern for the eligibility criteria for the marijuana pharmacy permit found at §2447.A.4.a. The restriction on campaign contribution penalizes Louisiana residents and gives unfair advantage to non-residents. Since the Board members make the determination to award the marijuana pharmacy permits, restrictions on campaign contributions to legislators and other state officials do not appear to serve any purpose. Recommends removing that restriction.

3. February 23, 2017 email from Dr. William Kirchain, President, La. Pharmacists Association

Suggested several edits of the proposed rule:

- a. §2443.B.5.f, relative to the test for homogeneity of marijuana samples, change the failure point, **from** 10% of the sample containing more than 20% of the total active ingredient **to** 10% of the sample containing more than 10% of the total active ingredient.
- b. §2443.B.5.g, relative to maximum variance from the labeled amount, **from** 15% of the labeled amount **to** 10% of the labeled amount.
- c. §2457.E.1, relative to review of the patient's PMP record prior to dispensing any marijuana product, insert the following language between the first and second sentences in the current proposed rule: *"When a patient is taking opiate or other pain medication the pharmacist make [sic] a specific assessment of cumulative overdose risk. Additionally the pharmacist shall make a reasonable effort to establish that this recommendation is based on a legitimate medical treatment for a qualifying disease. A reasonable effort will include the review of (a) the prescription monitoring program; (b) an assessment of the patient directly or when unable to assess the patient directly; (c) a consultation with the recommending physician."*
- d. §2457.E.2.b.iii, relative to the authorized prescriber being identified on the dispensing label, change "authorized prescriber" to "recommending physician."
- e. §2457.E.2.b.ix, relative to the directions for use being listed on the dispensing label, change "prescriber" to "recommending physician."
- f. §2457.E.3, to clarify the drug utilization review requirement, by adding the following language immediately after the **first** appearance of the words 'drug utilization review': *“, to include a review of herbal and other alternative treatments,”*.

4. Written testimony from Christopher L. Whittington on behalf of Williamson, Fontenot, Campbell & Whittington, LLC, a law firm in Baton Rouge.

- a. §2441.A.4.c, relative to the definition of the term "approved safe", the current clause at the beginning of (c) – 'Depending on the quantities stored' – is undefined. Neither the pharmacy nor the Board's compliance officer has any objective amount above which triggers the alarm requirement. Board should define 'quantity' either in terms of volume, e.g., milliliters, or in dollar amount, e.g., \$25,000.
- b. §2445.B, relative to the status of the pharmacy permit required for active operation of the pharmacy, suggests changing the word '*restricted*' at the end of the sentence to '*unrestricted*.'
- c. §2447.A.4.a, relative to the eligibility criteria for the marijuana pharmacy permit. Suggests the current language penalizes Louisiana residents and favors non-residents. Suggests replacing that entire sentence with the following language: "*Within the two year period preceding the date of the application, has not continuously held an active and unrestricted pharmacist license issued by the board, or*"
- d. §2447.A.20, relative to how long the applicant awarded a marijuana pharmacy permit by the Board has to commence operation, suggests changing the current 180 days to 310 days. The change would provide sufficient time to construct the pharmacy, giving ample time for the normal construction delays associated with any new construction project.
- e. §2451.N, relative to the other types of products the marijuana pharmacy may sell, suggests adding "*vitamins, supplements, minerals*" immediately after the words 'OTC medications'. Enhances the services the facility offers to its customers.
- f. §2451.Q, relative to the restriction on the delivery of marijuana products to pharmacy customers and the current exception for caregivers, suggests adding the following language immediately after the word 'caregiver': "*, including a designated hospice nurse,*".
- g. §2451.R, relative to the restriction on the sale of marijuana products when the pharmacy is closed, suggests an exception for terminally ill patients, by adding the following language immediately after the word 'business': "*, except in emergency situations, as determined by the pharmacist, as it relates to terminally ill patients.*"
- h. §2457.D.1.a, relative to the prohibition on the acceptance of a verbal recommendation, suggests an exception for terminally ill patients, by adding the following language immediately following the word 'request': "*, except in emergency situations, as determined by the pharmacist, as is related to terminally ill patients, as long as the hard copy of the recommendation/prescription/order for marijuana is received prior to the delivery of the marijuana to the patient or the patient's caregiver.*"

5. Testimony from Hunter Chauvin (Liskow & Lewis, a Gulf coast law firm), for himself

Expressed concern for the eligibility criteria for the pharmacy permit found at §2447.A.4.(a) and (b). (a) favors non-residents and unnecessarily penalizes Louisiana residents; should be removed or set a reasonable limit (e.g., contributions above \$___ would disqualify an applicant); and (b) also unnecessarily penalizes Louisiana residents; should be reduced to exclude board members within the two year period preceding the date of the application, and possibly legislators.

6. Testimony from Bretta St. Romain (PST), for herself

Questioned the application fee in a 2015 report as well as the amount of marijuana pharmacy permit revenue identified in the fiscal note. Questioned what standards would be in place for the grower to respond to natural disasters or other interruptions in crop production;

referred that question to the Dept. of Agriculture and Forestry. Also requested information as to when the first crop would be available; referred to same agency, and also offered my understanding that the project timeline estimated either late 2017 or early 2018 for that event.

7. Testimony from Glenn Broom, for himself

Questioned the timeline for the remainder of the overall project, including when the statewide program would be fully operational.

8. Testimony from Bretta St. Romain (PST), for herself

With respect to §2445.E or F, suggested the majority (at least 51%) of ownership of the marijuana pharmacy permit should be held by one or more Louisiana residents. Questioned whether a marijuana pharmacy permit can be operated in conjunction with another pharmacy permit.

9. Testimony from Glenn Broom, for himself

With respect to the previous testimony suggesting Louisiana residency for majority share of the ownership, he suggested the residency must have been for at least two years prior to the date of the application for the marijuana pharmacy permit.

10. Testimony from Eddie Lau, for himself

With respect to §2447.A.4.a, he supports the campaign contribution exclusion as written. Further, with respect to the ownership, he supports a total restriction to Louisiana residents as well as an exclusion for corporate ownership, i.e., owners shall be natural persons and Louisiana residents.

11. Lovie Rodgers (PST), for herself

With respect to §2447.A.4.(a) and (b), suggested extending the two year exclusion to a three year exclusion.

12. Hosea Ned, for himself

With respect to §2447.A.4.a, he suggested the removal of that eligibility criterion, but in the alternative, if it remains, he suggested a specific dollar amount be set (perhaps \$2,500), a contribution in excess of that amount would disqualify the applicant.

13. Andre Stoler, on behalf of La. Independent Pharmacies Association (LIPA)

Informed the group the current law on campaign contributions limits individual contributions to \$2,500.

14. Randy Mire (PST), on behalf of himself

- A. With respect to §2451.N, he suggested the addition of non-controlled prescription drugs to the list of products which may be sold in a marijuana pharmacy.
- B. With respect to §2451.Q, he suggested an allowance for the pharmacy to deliver the marijuana products to their patients.
- C. With respect to §2445.E or F, relative to a requirement for Louisiana residency, he suggested it should apply to at least 51% of the ownership and should have existed for at least two years prior to the date of the application for the permit.
- D. With respect to §2447.A.4.a, he suggested the removal of the campaign contribution exclusion, since the board members make the decision and not the legislator, and further, it favors non-residents to the detriment of residents.

15. Eric Bopp, on behalf of Bopp Law Office

- A. With respect to §2447.A.4.b, he expressed concern for the term "state service" in that the term is not defined, therefore applicants may not have sufficient notice.
- B. With respect to §2451.N, he suggested the allowance for the sale of any other retail products, e.g., water, soft drinks, or even food items such as fruits or vegetables.

16. Peter Prevot, CPA, CIA, for himself

Submitted the following questions:

- 1. §2443.D.1.b (Packaging) states *"Any product containing pharmaceutical grade marijuana or its principal psychoactive constituent tetrahydrocannabinol (THC) shall be packaged so that one dose contains no more than 10 milligrams of THC."*
 - a. What metrics did the board consider when deciding to limit a single dose to 10 milligrams of THC?
 - b. Is there any documentation or support available for review?
 - c. Is there a limit to the amount of THC that can be consumed by patients per day, week or month?
 - d. Do the Board of Pharmacy rules allow physicians to vary the level of THC recommended by patient?
 - e. Do the Board of Pharmacy rules allow physicians to vary the level of THC recommended by disease state?
 - f. Do the Board of Pharmacy rules allow physicians to recommend that a patient consume more than a single dose of a product containing pharmaceutical grade marijuana? For example, can a physician recommend that a particular patient ingest 5 capsules containing 10 mg. of THC each during a single sitting (i.e. 50 milligrams in total)?
 - g. Do the Board of Pharmacy rules allow physicians to recommend that a patient simultaneously consume multiple pharmaceutical grade marijuana products? For example, can a physician recommend that a particular patient consume one capsule containing 10 mg. of THC and also 1 milliliter of tincture that contains a 10 mg. dose of THC in a single sitting?
 - h. Will the Board impose any per dose or per package limits on other cannabinoids, i.e. all cannabinoids other than THC?
 - i. Will the Board impose any per dose or per package limit on cannabidiol (CBD)?
 - j. Will the Board impose any per dose or per package limit with regard to cannabis derived terpene content?
 - k. Has the Board concluded that 10 milligrams of THC is the "lowest acceptable therapeutic level available through scientifically accepted methods" (see La. R.S. 40:1046.I)?
- 2. §2447.A.4 (Application for Initial Issuance of Permit) states *"In the event any person holding any ownership of the entity submitting an application for a marijuana pharmacy permit has engaged in any of the following activities, the entity shall be disqualified and the board shall not issue a marijuana pharmacy permit to that applicant: (a) Within the two year period preceding the date of the application, has made a contribution to a candidate in a Louisiana election for a statewide elected official or state legislative election governed by the provisions of the Campaign Finance Disclosure Act [R.S. 14:1481]; or (b) Within the two year period preceding the date of the application, the person or any member of the person's immediate family held a position in state service in Louisiana, including but not limited to, a legislator, statewide public official, state employee, or member of the*

board.”

- a. What analysis did the Board perform in deciding to include this restriction?
 - b. Is there any support or documentation available for review?
 - c. Does the Board of Pharmacy have any quantitative data to share, i.e. Does the Board know approximately how many Louisiana residents will be impacted by this provision? Does the Board know approximately how many non-Louisiana residents will be impacted by this provision?
 - d. Was it the Board's intention to limit business and investment opportunities for residents of Louisiana?
 - e. Does the Board believe that the inclusion of this provision will create an environment that favors out-of-state businesses and investors?
 - f. Will the Board consider amending this requirement so that it applies as of the date of the application?
 - g. Will the Board consider amending this requirement so that it applies as of the date that final rules are promulgated?
 - h. Can the Board please explain why the two-year cooling off period was selected vs one year (or less)?
 - i. Will the Board consider examining potential violations of the “state service / state employee” rule on a case-by-case basis?
3. §2445 (Marijuana Pharmacy Permit) states:
- A. *The board shall develop and configure a pharmacy permit designated as a marijuana pharmacy permit.*
 - B. *The dispensing of marijuana for therapeutic purposes shall be restricted to those pharmacies holding a marijuana pharmacy permit issued by the board, and only when that permit is in active or restricted status.*
 - C. *When issued to a successful applicant, the permit will authorize the operation of a marijuana pharmacy in compliance with the provisions of this Subchapter.*
 - D. *When the permit is issued, it shall be valid only for the owner and the specific location noted on the application and recorded on the permit.*
 - E. *A marijuana pharmacy permit is non-transferable from one owner to another owner, and moreover, in the event the ownership of the organization that acquired to the permit changes by fifty percent or more, then the ownership will be deemed sufficiently different as to require a new marijuana pharmacy permit. A marijuana pharmacy owner continuing to operate a marijuana pharmacy after its ownership has changed by fifty percent or more without obtaining a new marijuana pharmacy permit shall be deemed guilty of operating a pharmacy without a valid permit, in violation of R.S. 37:1221.*
- La. R.S. 40:1046.E states “*Marijuana, tetrahydrocannabinols, or a chemical derivative of tetrahydrocannabinols recommended pursuant to this Section shall be dispensed in person from a licensed pharmacy in good standing located in Louisiana*”, while §2445.A of the Board's proposed rule states “*The Board shall develop and configure a pharmacy permit designated as a marijuana pharmacy permit.*”
- i. Can the Board please provide some details regarding the relationship between these two related regulatory requirements?
 - ii. Is §2445.A meant to fulfill the pharmacy requirement mandated by La. R.S. 40:1046.E?
 - iii. Is the permit described in §2445.A a stand-alone permit?
 - iv. Must the permit described in §2445.A remain linked or associated with a traditional

- pharmacy permit in order to remain valid?
- v. Must an individual or entity currently operate or own a traditionally licensed pharmacy in Louisiana in order to apply for one of the new "Marijuana Pharmacy Permits" described in §2445.A? Is there a minimum ownership percentage required in a traditional pharmacy in order to apply?
 - vi. Will the Board allow an individual or entity to continue to operate a traditionally licensed pharmacy while also operating a Marijuana Pharmacy at a separate location?
 - vii. Will operation, ownership, or participation in a Marijuana Pharmacy impact or affect the standing of a traditionally licensed pharmacy with the La. Board of Pharmacy?
 - viii. Will operation, ownership, or participation in a Marijuana Pharmacy impact or affect the standing of a licensed pharmacist with the La. Board of Pharmacy?
 - ix. Does the Board anticipate that a traditionally licensed pharmacy's DEA license will be impacted through ownership, operation or participation in a Marijuana Pharmacy licensed by the La. Board of Pharmacy?
4. §2451 (Operation of Marijuana Pharmacy) Paragraph C.2 states "*A marijuana pharmacy shall not obtain, cultivate, deliver, transfer, transport, sell or dispense marijuana except: (2) It may dispense and sell marijuana to a patient with a recommendation/prescription/order for such marijuana or the patient's caregiver.*"
- a. Can you please provide a definition or reference for the term 'caregiver' as used in the above sentence?
5. §2451 (Operation of Marijuana Pharmacy) Paragraph N states "*No marijuana pharmacy shall sell anything other than marijuana products; however, the pharmacy may elect to sell over-the-counter (OTC) medications and/or durable medical equipment (DME) from the same premises but outside the prescription department.*"
- a. Can the Board please describe what analysis was done in deciding to impose this requirement?
 - b. Is there any supporting documentation available for review?
 - c. Is this a common restriction in the medical marijuana industry?
 - d. Why are exceptions allowed for OTC medications and DME but not for other items?
 - e. Has the Board considered the federal tax implications of restricting the types of items that can be sold at Marijuana Pharmacies (see IRS section 280E)?
 - f. Will consumers without a medical marijuana recommendation from a Louisiana physician be allowed to access the premises where OTC and DME items are sold, i.e. the area outside the prescription department.

FRED MILLS, JR.
State Senator
District 22
Parishes of:
Iberia, St. Martin, St. Landry, Lafayette

COMMITTEES
Health and Welfare, Chairman
Judiciary C
Local and Municipal Affairs



SENATE
STATE OF LOUISIANA



1010 Martin Street
Parks, LA 70582
Phone: (337) 845-4240
(800) 259-3142
Fax: (337) 845-4095

800 S. Lewis Street, Suite 203
New Iberia, LA 70560
Phone: (337) 365-8484
(800) 258-3795
Fax: (337) 365-2730

February 1, 2017

Mr. Malcolm Broussard
Louisiana Board of Pharmacy
3388 Brentwood Ave
Baton Rouge, LA 70809



Dear Mr. Broussard,

I am in receipt of the Board of Pharmacy's Notice of Intent dated January 9, 2017, which provides for the dispensing regulations of medical marijuana in accordance with Act 261 of 2015 and Act 96 of 2016. I sincerely appreciate the work that you and the Board have done to implement these laws which are very important to me as the author, and also to the countless individuals with debilitating medical conditions who are counting on this product to relieve some of the horrible ailments they live with every day.

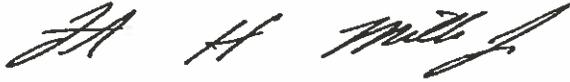
In reviewing the proposed rules, I would like to take this public comment period to recommend one important clarification regarding the dosage forms allowed by law. I respectfully request that the Board revisit §2443(C) which provides for allowable dosage forms. §2443(C)(1)(d) allows for "edible dosage forms". This term is undefined and could be broadly interpreted to include food and candy items that may be recognized as marijuana infused food products, but were never contemplated by my legislation. In speaking about my bill during the legislative process it was always clear that my intent was to make marijuana available to patients in generally recognized medicinal forms, such as those provided for in your rule at §2443(C)(1)(a-c) and (e-g). The undefined term "edible dosage forms" could be interpreted to include things such as brownies, cakes, cookies, gummy bears and hard or soft candies. It was never contemplated that these items would be covered by this law. Therefore, I would recommend the Board consider replacing (d) with something more specific such as, "gelatin-based chewable".

This recommended language would allow for the production of a "gummy" chewable, similar to chewable vitamins. §2443(C)(2)(c)(iv) includes the prohibition that no marijuana product shall be in a form customarily associated with persons under the age of eighteen. I think this is an appropriate prohibition on all allowable dosage forms, particularly on "gelatin-based chewables". This is especially important in light of other states like Colorado banning all gelatin-based or "gummy" chewables that are appealing to children in shapes that resemble humans, animals or fruits. With the years of experience they have ahead of us, this is a problem that we can avert from the outset by your clear language.

Act 261 of 2015 and Act 96 of 2016 granted the Board of Pharmacy the authority to promulgate rules regulating allowable dosage forms. I believe this minimal modification to your Notice of Intent will better reflect the legislative intent of what products would be made available pursuant to this law.

Thank you for your commitment to ensuring the health and safety of the people of Louisiana.

Sincerely,



Fred H. Mills, Jr.
Senate Committee on Health and Welfare, Chairman





Professional Arts Pharmacy
Prescription Compounding Specialist



Louisiana Board of Pharmacy
Attn: Malcolm Broussard
3388 Brentwood Drive
Baton Rouge, La. 70809-1700



RE: Medical Marijuana

Dear Malcolm,

I would like to comment on the proposed regulations on medical marijuana pharmacies related to the exclusion of people that have made political contributions to the campaigns of certain state elected officials.

As a Louisiana Pharmacist and business owner for over 20 years, I find this restriction problematic and feel like it should be removed. It unfairly excludes Louisiana citizens who have made political contributions from participating in this industry and unfairly gives an advantage to out of state applicants since most of them will have never made political contributions to Louisiana politicians.

While I understand the intent of the regulation may have been to make sure there is no corruption or political influence on the licensing process, I also believe it unfairly tilts the scales in favor of out of state applicants. Further, my understanding is that the Board of Pharmacy members will be the only ones involved in awarding the medical marijuana licenses and not any elected officials thus insulating the process from any political influence.

I hope the board considers removing this prohibition and allows Louisiana applicants the same access as out of state applicants.

Sincerely,

Eric Vidrine, PD

128 Curran Lane • Lafayette, LA 70506 • Ph. 337-991-0101 1-888-237-4737 • Fx. 337-991-0151

Eric Vidrine, P.D. F.A.C.A., F.I.A.C.P. David Mayer, P.D. Mandie Romero, P.D. Leah Albarado, Pharm.D.
Kevin LaGrange, P.D. Allison Seilhan, P.D. Shane Landry, Pharm. D. Angela LeBlanc, Pharm. D.
Jimmy Brantley, P.D. Ashley Day, Pharm. D. Krystle LeBlanc, Pharm. D.

Malcolm J. Broussard

From: William Kirchain [wkirchai@xula.edu]
Sent: Thursday, February 23, 2017 11:37 AM
To: Malcolm J. Broussard
Cc: mmckaypd
Subject: Suggested edits to Cannabis Rules
Attachments: Cannabis Changes.docx

Mr. Broussard, Mr. McKay

Please accept the attached suggested changes for consideration by the Rules/Regs Committee at its next meeting in March. I will be unable to attend personally.

Dr. William Kirchain
President, Louisiana Pharmacists Association

E-Mail Privacy/FERPA: This communication may contain confidential information and is intended solely for the use of the addressee. If you received it in error, please contact the sender at once and delete the message. This communication may also contain information subject to restrictions of the Family Educational Rights and Privacy Act (FERPA). Such information may not be disclosed or used in any fashion outside the scope of the service for which you are receiving the information.

- 253 f. With respect to the test for homogeneity, a marijuana sample shall be deemed to have failed if
254 ten percent of the sample contains more than ~~twenty ten~~ percent of the total active ingredient.
255 g. With respect to the analysis of active ingredients, the following substances, when present,
256 shall be identified and measured. The maximum variance permitted is ~~fifteen ten~~ percent from
257 the labeled amount. For example, a product labeled as containing 10 milligrams of
258 tetrahydrocannabinol (THC) shall contain no less than 8.5 milligrams THC and no more than
259 11.5 milligram THC.
- 260 i. THC (tetrahydrocannabinol);
 - 261 ii. THCA (tetrahydrocannabinolic acid);
 - 262 iii. CBD (cannabidiol); and
 - 263 iv. CBDA (cannabidiolic acid).

Currently...

- 1054 E. Professional Practice Standards
- 1055 1. Prior to dispensing any marijuana product to a patient, the pharmacist shall review that patient's
1056 **records in the state prescription monitoring program. The pharmacist shall resolve any concerns**
1057 **identified in that review by consultation with the recommending physician.**
- ...
- 1065 iii. Name of the authorized **prescriber**;
- ...
- 1072 ix. Directions for use of the product as included in the **prescriber's** request;
- 1073 x. Expiration date of the product, which shall not exceed the expiration date determined by
1074 the producer of the product; and
- 1075 xi. Other information selected by the dispensing pharmacist to inform the patient as to the
1076 best use of the product for the intended purpose.
- 1077 **3. The pharmacist shall perform prospective drug utilization review and shall counsel every patient**
1078 **receiving marijuana product every time it is dispensed, in compliance with the rules on drug**
1079 **utilization review and patient counseling in Chapter 5 of the board's rules.**

Recommended Changes

Change line 1056 - 1057: records in the state prescription monitoring program. When a patient is taking opiate or other pain medication the pharmacist make a specific assessment of cumulative overdose risk. Additionally the pharmacist shall make a reasonable effort to establish that this recommendation is based on a legitimate medical treatment for a qualifying disease. A reasonable effort will include the review of (a) the prescription monitoring program; (b) an assessment of the patient directly or when unable to assess the patient directly; (c) a consultation with the recommending physician. The pharmacist shall resolve any concerns identified in that review by consultation with the recommending physician.

Change line 1065: iii. Name of the authorized recommending physician;

Change line 1072: ix. Directions for use of the product as included in the recommending physician request;

Change line 1077-79: **3. The pharmacist shall perform prospective drug utilization review, to include a review of herbal and other alternative treatments, and shall counsel every patient receiving marijuana product every time it is dispensed, in compliance with the rules on drug utilization review and patient counseling in Chapter 5 of the board's rules.**

**Suggested Rule Changes for Louisiana Administrative Code
Title 46 – Professional and Occupational Standards
Part LIII: Pharmacists
Chapter 24. Limited Service Providers
Subchapter E. Marijuana Pharmacy**

§2441(A)(4)(c) Definitions

Depending on the quantities stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or local or state police agency which has a legal duty to respond or a 24-hour control station operated by the licensee, or such other protection as the board or its designee may approve.

Suggested change:

The “amount of quantities stored” should be set out in terms of volume (for example ml) or dollar amount (for example \$25,000) so that the pharmacy will know for certain the exact amount of quantity that is needed in order to have an approved safe in compliance with the rules. Otherwise, the “amount of quantities stored” is too subjective not only for the pharmacy, but also for an inspector looking for compliance.

§2445(B) Marijuana pharmacy permit

The dispensing of marijuana for therapeutic purposes shall be restricted to those pharmacies holding a marijuana pharmacy permit issued by the board, and only when that permit is in active or restricted status.

Suggested change:

Change “restricted” to “unrestricted.” There appears to be a typographical error in the proposed rule.

§2447(A)(4)(a) Licensing procedures

Within the two year period preceding the date of the application, has made a contribution to a candidate in a Louisiana election for a statewide elected official or state legislative election governed by the provisions of the Campaign Finance Disclosure Act [R.S. 14:1481] or . . .

Suggested change:

Delete in its entirety and replace with “Within the two year period preceding the date of the application, has not continuously held an active and unrestricted pharmacist license issued by the board.” This change in the rule will promote the participation of citizens of Louisiana who have a proven record of compliance with the Board of Pharmacy. If left as is, the rule will discriminate against Louisiana citizens who have participated in the election process, which is their constitutional right to do. The rule unchanged arbitrarily restricts participation of Louisiana citizens in favor of out-of-state participants, when there is no rational basis to do so. In other words, since the elected officials in no way decide who will and who will not have a medical marijuana pharmacy permit, there is no rational basis to exclude participants who have made financial contributions to elected officials. Only the Board of Pharmacy has the ability to make these permitting decisions, thereby making the issue of election contributions irrelevant.

§2447(A)(20) Licensing procedures

If an applicant has been awarded a marijuana pharmacy permit and has not commenced operation of such pharmacy within 180 days of being notified of the marijuana pharmacy permit award, the board may, in the board’s discretion, rescind such marijuana pharmacy permit, unless such delay was caused by force majeure.

Suggested change:

Change “180 days” to “310 days.” The purpose of this proposed change is to allow sufficient time in which to construct the pharmacy in a proper manner, giving ample time for the normal construction delays associated with any new construction project.

§2451(N) Operation of marijuana pharmacy

No marijuana pharmacy shall sell anything other than marijuana products; however, the pharmacy may elect to sell over-the-counter (OTC) medications and/or durable medical equipment (DME) from the same premises outside the prescription department.

Suggested change:

“No marijuana pharmacy shall sell anything other than marijuana products; however, the pharmacy may elect to sell over-the-counter (OTC) medications, **vitamins, supplements, minerals** and/or durable medical equipment (DME) from the same premises outside the prescription department.” Allowing vitamins, supplements and minerals to be sold outside of the prescription department will enhance the services that the facility offers to its customers with a goal to meet all of their related

needs.

§2451(Q) Operation of marijuana pharmacy

No marijuana shall be sold, dispensed or distributed via a delivery service or any other manner outside of a marijuana pharmacy, except that a caregiver may deliver marijuana to the caregiver's patient.

Suggested change:

"No marijuana shall be sold, dispensed or distributed via a delivery service or any other manner outside of a marijuana pharmacy, except that a caregiver, **including a designated hospice nurse**, may deliver marijuana to the caregiver's patient." The basis for this change is to make sure that those who work in hospice will be able to fully respond to the needs of their patients.

§2451(R) Operation of marijuana pharmacy

No marijuana shall be sold when the marijuana pharmacy is closed and not open for business.

Suggested change:

"No marijuana shall be sold when the marijuana pharmacy is closed and not open for business, except in emergency situations, as determined by the pharmacist, as it relates to terminally ill patients." The purpose of the proposed change is to make the exception to address the unique needs of terminally ill patients.

§2457(D)(1)(a). Standards of practice

The pharmacy shall not accept a verbal request.

Suggested change:

"The pharmacy shall not accept a verbal request, except in emergency situations, as determined by the pharmacist, as is related to terminally ill patients, as long as a hard copy of the recommendation/prescription/order for marijuana is received prior to delivery of the marijuana to the patient or the patient's caregiver." Once more, this proposed change addresses the unique need of terminally ill patients and is similar to Chapter 21 of the Code of Federal Regulations dealing with Schedule II narcotics.

Submitted by:

Christopher L. Whittington
Williamson, Fontenot, Campbell & Whittington, LLC
P. O. Box 3035
Baton Rouge, LA 70821-3015
Telephone: (225) 383-4010
Facsimile: (225) 383-4114
Email: chris@lawyerbatonrouge.com

PREVOT CPA
ADVISORY | TAX | AUDIT

PETER PREVOT, CPA, CIA
225.571.7617
PREVOTCPA@GMAIL.COM

Date: March 2, 2017

To: Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809
ATTN: Malcom Broussard, Executive Director

From: Peter M. Prevot, CPA, CIA
PO Box 30117
New Orleans, LA 70190
225-571-7617
PREVOTCPA@GMAIL.COM

RE: Regulatory Project 2016-6 ~ Marijuana Pharmacy

Dear Malcom,

I hope this letter finds you doing well!

My written inquires and request for clarification regarding Regulatory Project 2016-6 are contained within.

Please do not hesitate to contact me with any questions or comments.

Thanks for your time and attention!

Respectfully,



Peter Prevot, CPA, CIA

1. Section 2443(D)1.b (Packaging and Labeling)

“Any product containing pharmaceutical grade marijuana or its principal psychoactive constituent tetrahydrocannabinol (THC) shall be packaged so that one dose contains no more than 10 milligrams of THC.”

Questions:

- a. What metrics did board consider when deciding to limit a single dose to 10 milligrams of THC?
- b. Is there any documentation or support available for review?
- c. Is there a limit to the amount of THC that can be consumed by patients per day, week or month?
- d. Do the Board of Pharmacy rules allow physicians to vary the level of THC recommended by patient?
- e. Do the Board of Pharmacy rules allow physicians to vary the level of THC recommended by disease state?
- f. Do the Board of Pharmacy rules allow physicians to recommend that a patient consume more than a single dose of a product containing pharmaceutical grade marijuana? For example, can a physician recommend that a particular patient ingest 5 capsules containing 10 MG of THC each during a single sitting (i.e. – 50 milligrams in total).
- g. Do the Board of Pharmacy rules allow physicians to recommend that a patient simultaneously consume multiple pharmaceutical grade marijuana products? For example, can a physician recommend that a particular patient consume 1 capsule containing 10 MG of THC and also 1 milliliter of tincture that contains a 10 MG dose of THC in a single sitting?
- h. Will the Board impose any per dose or per package limits on other cannabinoids (i.e. – ALL cannabinoids other than THC).
- i. Will the Board impose any per dose or per package limit on cannabidiol (i.e.- CBD)?
- j. Will the Board impose any per dose or per package limit with regard to cannabis derived terpene content?
- k. Has the board concluded that 10 milligrams of THC is the “lowest acceptable therapeutic level available through scientifically accepted methods” (see ACT 96 of the 2016 Regular session page 9 line section I starting on line 15)?

2. Section 2447(A)4.a (Licensing procedures)

“In the event any person holding any ownership interest in the entity submitting an application for a marijuana pharmacy permit has engaged in any of the following activities, the entity shall be disqualified and the board shall not issue a marijuana pharmacy permit to that applicant: within the two-year period preceding the date of the application, has made a contribution to a candidate in a Louisiana election for a statewide elected official or state legislative election governed by the provisions of the Campaign Finance Disclosure Act (R.S. 14:1481)” or within the two-year period preceding the date of the application, the person or any member of the person’s immediate family held a position in state service in Louisiana, including but not limited to, a legislator, statewide public official, state employee, or member of the board.

Questions:

- a. What analysis did the board perform in deciding to include this restriction?
- b. Is there any support or documentation available for review?
- c. Does the Board of Pharmacy have any quantitative data to share?
(i.e. - Does the board know approximately how many Louisiana residents will be impacted by this provision? Does the board know approximately how many non-Louisiana residents will be impacted by this provision?)
- d. Was it the board’s intention to limit business and investment opportunities for residents of Louisiana?
- e. Does the board believe that the inclusion of this provision will create an environment that favors out of state businesses and investors?
- f. Will the board consider amending this requirement so that it applies as of the date of the application?
- g. Will the board consider amending this requirement so that it applies as of the date that final rules are promulgated?
- h. Can the board please explain why the two-year cooling off period was selected vs. 1 year (or less)?
- i. Will the board consider examining potential violations of the “state service/ state employee” rule on a case by case basis?

3. Section 2445 A thru E (Marijuana Pharmacy Permit)

“The board shall develop and configure a pharmacy permit designated as a marijuana pharmacy permit. The dispensing of marijuana for therapeutic purposes shall be restricted to those pharmacies holding a marijuana pharmacy permit issued by the board, and only when that permit is in active or restricted

status. When issued to a successful applicant, the permit will authorize the operation of a marijuana pharmacy in compliance with the provisions of this Subchapter. When the permit is issued, it shall be valid only for the owner and the specific location noted on the application and recorded on the permit. A marijuana pharmacy permit is non-transferable from one owner to another owner, and moreover, in the event the ownership of the organization that acquired the permit changes by 50 percent or more, then the ownership will be deemed sufficiently different as to require a new marijuana pharmacy permit.

A marijuana pharmacy permit owner continuing to operate a marijuana pharmacy after its ownership has changed by 50 percent or more without obtaining a new marijuana pharmacy permit shall be deemed guilty of operating a pharmacy without a valid permit, in violation of R.S. 37:1221.

Questions:

- a. Louisiana R.S.40:1046 states that "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." While Section 2445(A) of the Pharmacy Board draft Regulations states that "the board shall develop and configure a pharmacy permit designated as a marijuana pharmacy permit."
 - i. Can the board please provide some details regarding the relationship between these two related regulatory requirements?
 - ii. Is Item 2445(A) meant to fulfill the pharmacy requirement mandated by Louisiana R.S.40:1046?
 - iii. Is the permit described in 2445(A) a stand-alone permit?
 - iv. Must the permit described in item 2445(A) remain linked or associated with a traditional pharmacy permit in order to remain valid?
 - v. Must an individual or entity currently operate or own a traditionally licensed pharmacy in Louisiana in order to apply for one of the new "Marijuana Pharmacy Permits" described in Section 2445(A)?
 1. Is there a minimum ownership percentage required in a traditional pharmacy in order to apply?

- vi. Will the board allow an individual or entity to continue to operate a traditionally licensed pharmacy while also operating a Marijuana Pharmacy at a separate location?
 - vii. Will operation, ownership, or participation in a Marijuana Pharmacy impact or affect the standing of a traditionally licensed pharmacy with the Louisiana Board of Pharmacy?
 - viii. Will operation, ownership, or participation in a Marijuana Pharmacy impact or affect the standing of a licensed pharmacist with the Louisiana Board of Pharmacy?
 - ix. Does the board anticipate that a traditionally licensed pharmacy's DEA license will be impacted through ownership, operation or participation in a Marijuana Pharmacy licensed by the Louisiana State Board of Pharmacy?
4. Section 2451(C)2
- "It may dispense and sell marijuana to a patient with a recommendation/prescription/order for such marijuana or the patient's caregiver.
- a. Can you please provide a definition or reference for the term "caregiver" as used in the above sentence?
5. Section 2451(N)
- "No marijuana pharmacy shall sell anything other than marijuana products; however, the pharmacy may elect to sell over-the-counter (OTC) medications and/or durable medical equipment (DME) from the same premises but outside the prescription department."
- a. Can the board please describe what analysis was done in deciding to impose this requirement?
 - b. Is there any supporting documentation available for review?
 - c. Is this a common restriction in the medical marijuana industry?
 - d. Why are exceptions allowed for OTC medications and DME but not for other items?
 - e. Has the board considered the federal tax implications of restricting the types of items that can be sold at Marijuana Pharmacies? (see IRS section 280E)
 - f. Will consumers without a medical marijuana recommendation from a Louisiana Physician be allowed to access the premises where OTC and DME items are sold? (i.e – the area outside of the prescription department).



Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov



MEMORANDUM

To: Board Members
From: Malcolm Broussard
Date: March 14, 2017
Re: Regulatory Project 2016-6 ~ Staff Notes re Comments & Testimony

Item 1 – Sen. Mills

§2443.C (Product Dosage Forms)

1. The producer shall limit their production of pharmaceutical grade marijuana products to the following dosage forms:
 - a – c. ...
 - d. ~~Edible dosage forms~~ Gelatin-based chewables;
 - e – g. ...

Staff Note: Since Sen. Mills authored the enabling legislation, and my recollection of all the legislative conversations revolved around the provision of medication – and not food, we suggest the adoption of his requested amendment.

Item 2 – Mr. Vidrine

§2447.A (Licensing Procedures)

4. In the event any person holding any ownership interest in the entity submitting an application for a marijuana pharmacy permit has engaged in any of the following activities, the entity shall be disqualified and the board shall not issue a marijuana pharmacy permit to that applicant:
 - a. ~~Within the two-year period preceding the date of the application, has made a contribution to a candidate in a Louisiana election for a statewide elected official or state legislative election governed by the provisions of the Campaign Finance Disclosure Act [R.S. 14:1481]; or~~
 - b. ...

Staff Note: We have no objection to removing this provision.

Item 3 – Dr. Kirchain

A. §2443.B (Laboratory Testing of Marijuana Products)

5. In the event a sample of marijuana does not pass the microbiological, mycotoxin, heavy metal, pesticide chemical residue, residual solvent, or homogeneity test based on the standards set forth in this Section, the producer shall dispose of the entire batch from which the sample was taken,

in compliance with the marijuana disposal rules promulgated by LDAF.

a – e. ...

- f. With respect to the test for homogeneity, a marijuana sample shall be deemed to have failed if ten percent of the sample contains more than ~~twenty~~ ten percent of the total active ingredient.

Staff Note: We collaborated with the Dept. of Agriculture and Forestry on these testing standards; both sets of proposed rules are identical in this particular standard. Changing one without the other would establish conflicting standards.

Item 3 – Dr. Kirchain (cont.)

B. §2443.B (Laboratory Testing of Marijuana Products)

5. In the event a sample of marijuana does not pass the microbiological, mycotoxin, heavy metal, pesticide chemical residue, residual solvent, or homogeneity test based on the standards set forth in this Section, the producer shall dispose of the entire batch from which the sample was taken, in compliance with the marijuana disposal rules promulgated by LDAF.

a – f. ...

- g. With respect to the analysis of active ingredients, the following substances, when present, shall be identified and measured. The maximum variance permitted is ~~fifteen~~ ten percent from the labeled amount. For example, a product labeled as containing 10 milligrams of tetrahydrocannabinol (THC) shall contain no less than 8.5 milligrams THC and no more than 11.5 milligrams THC.
- i. THC (tetrahydrocannabinol);
 - ii. THCA (tetrahydrocannabinolic acid);
 - iii. CBD (cannabidiol); and
 - iv. CBDA (cannabidiolic acid).

Staff Note: We collaborated with the Dept. of Agriculture and Forestry on these testing standards; both sets of proposed rules are identical in this particular standard. Changing one without the other would establish conflicting standards. USP standards for drugs vary in this parameter: some have a 2% maximum variance, and some have a 20% maximum variance.

C. §2457.E (Professional Practice Standards)

1. Prior to dispensing any marijuana product to a patient, the pharmacist shall review that patient's records in the state prescription monitoring program. When a patient is taking opiate or other pain medication the pharmacist shall make a specific assessment of cumulative overdose risk. Additionally the pharmacist shall make a reasonable effort to establish that this recommendation is based on a legitimate medical treatment for a qualifying disease. A reasonable effort will include the review of (a) the prescription monitoring program and (b) an assessment of the patient directly, or when unable to assess the patient directly, then a consultation with the recommending physician. The pharmacist shall resolve any concerns identified in that review by consultation with the recommending physician.

Staff Note: An alternative approach would be to allow the Board's current rules on drug

utilization review, found in Chapter 5 – Pharmacists (more specifically at §515 – Prospective Utilization Review), abstracted here, be the controlling standard, in lieu of adding the additional more explicit language.

§515. Prospective Drug Utilization Review

A. A pharmacist shall review the patient record and each prescription presented for dispensing for purposes of enhancing pharmacy care and therapeutic outcomes by recognizing the following potential situations:

1. drug over-utilization or under-utilization;
2. therapeutic duplication;
3. drug-disease contraindications;
4. drug-drug interactions;
5. inappropriate drug dosage or treatment duration;
6. drug-allergy interactions; or
7. clinical abuse/misuse.

B. Upon recognizing any of the above situations, the pharmacist, using professional judgment, shall take appropriate actions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2084 (October 2003), effective January 1, 2004.

D. §2457.E (Professional Practice Standards)

E. §2457.E (Professional Practice Standards)

1. ...

2. Labeling of marijuana product dispensed

a. ...

b. The pharmacy's dispensing label shall contain at a minimum the following data elements:

i – ii. ...

(D) ~~iii. Name of the authorized prescriber~~ recommending physician

iv – viii. ...

(E) ix. Directions for use of the product as included in the ~~prescriber's~~ recommending physician's request.

x – xi. ...

Staff Note: We have no objections to these technical corrections.

F. §2457.E (Professional Practice Standards)

3. The pharmacist shall perform prospective drug utilization review, to include a review of herbal and other alternative treatments, and shall counsel every patient receiving marijuana product every time it is dispensed, in compliance with the rules on drug utilization review and patient counseling in Chapter 5 of the board's rules.

Staff Note: see similar alternative approach as above.

Item 4 – Mr. Whittington

A. §2441 (Definitions)

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section:

1 – 3. ...

4. *Approved safe* means a safe which conforms to or exceeds all of the following standards:
 - a – b. ...
 - c. ~~Depending upon the quantities stored, is~~ is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the licensee, or such other protection as the board or its designee may approve.
- 5 – 28. ...

Staff Note: The selection of a specific dollar amount or specific volume is likely an arbitrary decision. Suggest removing that portion of the definition and imposing the alarm requirement on all such safes.

B. §2445.B (Marijuana Pharmacy Permit)

- A. ...
- B. The dispensing of marijuana for therapeutic purposes shall be ~~restricted~~ limited to those pharmacies holding a marijuana pharmacy permit issued by the board, and only when that permit is in active or ~~restricted~~ unrestricted status.

Staff Note: The use of the word ‘restricted’ at the end of the sentence is intentional. ‘Restricted’ status for a pharmacy permit denotes a Board-imposed limitation, most commonly probation, but could include other restrictions. To change that use of the word ‘restricted’ to ‘unrestricted’ would have the effect of prohibiting the Board from placing a permit on probation, because that status would not allow the pharmacy to operate. To improve understanding, we suggest replacing the first occurrence of the word ‘restricted’ with ‘limited’, and then retaining the final occurrence of the word ‘restricted.’

C. §2447.A (Licensing Procedures)

4. In the event any person holding any ownership interest in the entity submitting an application for a marijuana pharmacy permit has engaged in any of the following activities, the entity shall be disqualified and the board shall not issue a marijuana pharmacy permit to that applicant:
 - a. ~~Within the two year period preceding the date of the application, has made a contribution to a candidate in a Louisiana election for a statewide elected official or state legislative election governed by the provisions of the Campaign Finance Disclosure Act [R.S. 14:1481]; or~~
 - a. Within the two year period preceding the date of the application, has not continuously held an active and unrestricted pharmacist license issued by the board; or

Staff Note: The suggested amendment would restrict ownership to Louisiana-licensed pharmacists whose licenses were issued at least two years prior to the date of the application, and which had not been restricted by the board during that time.

D. §2447.A (Licensing Procedures)

A. Application for Initial Issuance of Permit

1 – 19. ...

20. If an applicant has been awarded a marijuana pharmacy permit and has not commenced operation of such pharmacy within ~~480~~ 310 days of being notified of the marijuana pharmacy permit award, the board may, in the board's discretion, rescind such marijuana pharmacy permit, unless such delay was caused by force majeure. A marijuana pharmacy shall be deemed to have commenced operation if the pharmacy is capable of operating in accordance with the applicant's approved application. In the event a marijuana pharmacy permit is rescinded pursuant to this Subsection, the board shall award a marijuana pharmacy permit by selecting among the qualified applicants who applied for the marijuana pharmacy permit that was rescinded. If no other qualified applicant applied for such marijuana pharmacy permit or satisfied the criteria for awarding a permit, the board shall publish, in accordance with this Section, a notice of open applications for marijuana pharmacy permits.

Staff Note: We have no objection to the amendment, or to the selection of another alternative amount of time.

E. §2451 (Operation of Marijuana Pharmacy)

A – M. ...

N. No marijuana pharmacy shall sell anything other than marijuana products; however, the pharmacy may elect to sell over-the-counter (OTC) medications, vitamins, supplements, minerals, and/or durable medical equipment (DME) from the same premises, but outside the prescription department.

O – P. ...

Q. No marijuana shall be sold, dispensed or distributed via a delivery service or any other manner outside of a marijuana pharmacy, except that a caregiver, including a designated hospice nurse, may deliver marijuana to the caregiver's patient.

F.

R. No marijuana shall be sold when the marijuana pharmacy is closed and not open for business, except in emergency situations, as determined by the pharmacist as it relates to terminally ill patients.

G.

S – U. ...

Staff Note: We have no objection to the inclusion of other items for sale in the pharmacy. With respect to the term 'caregiver', we have not specifically defined the term, which means we accept the term as defined in the general dictionary, which means anyone the patient elects to use; therefore, we don't see a need to describe one particular type of caregiver. With respect to dispensing outside of regular business hours, the Board has always allowed pharmacists to open their pharmacies outside of regular business hours to take care of their patients. We don't see a difference for marijuana pharmacies and don't see the need for this; moreover, as it is written, the pharmacist could not include a patient who is not terminally ill in that determination

H. §2457.D (Recordkeeping Requirements)

1. Prescription/recommendation/order (hereinafter, “request”) for marijuana
 - a. The pharmacy shall not accept a verbal request, except in emergency situations, as determined by the pharmacist, as it is related to terminally ill patients, as long as the hard copy of the recommendation/prescription/order for marijuana is received prior to the delivery of the marijuana to the patient or the patient’s caregiver.

Staff Note: As it is written, the suggested amendment would only apply to terminally ill patients and would exclude any other patient using marijuana products from the pharmacy. Since the rest of this section already addresses the requirement for written forms, we could accomplish the same message relative to verbal requests by replacing ‘accept’ with ‘dispense marijuana products pursuant to’.

Item 5 – Mr. Chauvin

§2447.A (Licensing Procedures)

4. In the event any person holding any ownership interest in the entity submitting an application for a marijuana pharmacy permit has engaged in any of the following activities, the entity shall be disqualified and the board shall not issue a marijuana pharmacy permit to that applicant:
 - a. ~~Within the two year period preceding the date of the application, has made a contribution to a candidate in a Louisiana election for a statewide elected official or state legislative election governed by the provisions of the Campaign Finance Disclosure Act [R.S. 14:1481]; or~~
 - b. Within the two year period preceding the date of the application, the person or any member of the person’s immediate family ~~held a position in state service in Louisiana, including but not limited to, a legislator, statewide public official, state employee, or~~ served as a member of the board.

Staff Note: Given the reasons identified in multiple comments, staff believes this is the best revision for this section of the rules.

Item 6 – Ms. St. Romain

No amendments requested.

Item 7 – Mr. Broom

No amendments requested.

Item 8 – Ms. St. Romain

A. §2445.E or F (Marijuana pharmacy permit) for Louisiana residency requirement.

Staff Note: Since permit eligibility criteria are addressed in §2477.A.4, we suggest placement of this requirement in that section.

§2447.A (Application for Initial Issuance of Permit)

- 4.a – 4.b. ...
- 4.c. At the time of the date of the application, a majority of the ownership interest is held by persons other than Louisiana residents.

Staff Note: None of our current rules for pharmacy permits imposes a residency requirement. If there is a desire to start down that path, consult consultation with our legal counsel as to legal pitfalls of the basic requirement as well as the selection of any particular percentage number. We suspect this suggested revision is based on economics as opposed to public health.

Item 9 – Mr. Broom

§2447.A (Application for Initial Issuance of Permit)

4.a – 4.b. ...

4.c. Within the two year period preceding the date of the application, a majority of the ownership interest is held by persons other than Louisiana residents.

Staff Note: See note at Item 8.

Item 10 – Mr. Lau

a. At the time of the date of the application, the entire ownership is held by persons other than natural persons who are Louisiana residents.

Staff Note: See note at Item 8.

Item 11 – Ms. Rodgers

§2447.A (Application for Initial Issuance of Permit)

4. In the event any person holding any ownership interest in the entity submitting an application for a marijuana pharmacy permit has engaged in any of the following activities, the entity shall be disqualified and the board shall not issue a marijuana pharmacy permit to that applicant:
 - a. Within the ~~two~~ three year period preceding the date of the application, has made a contribution to a candidate in a Louisiana election for a statewide elected official or state legislative election governed by the provisions of the Campaign Finance Disclosure Act [R.S. 14:1481]; or
 - b. Within the ~~two~~ three year period preceding the date of the application, the person or any member of the person's immediate family held a position in state service in Louisiana, including but not limited to, a legislator, statewide public official, state employee, or member of the board.

Staff Note: In the drafting of this Section, the committee relied on a similar provision existing in the enabling legislation, found specifically at La. R.S. 40:1046(H)(7), which imposes a prohibition on campaign contributions within the previous five year period for those persons bidding for the single grower's license. The committee believed that a two year restriction would be sufficient for the pharmacy permit selection process. The selection of any number of years is an arbitrary decision, as would be the selection of any amendment of the original number.

Item 12 – Mr. Ned

§2447.A (Application for Initial Issuance of Permit)

4. In the event any person holding any ownership interest in the entity submitting an application for a marijuana pharmacy permit has engaged in any of the following activities, the entity shall be disqualified and the board

shall not issue a marijuana pharmacy permit to that applicant:

- a. ~~Within the two year period preceding the date of the application, has made a contribution to a candidate in a Louisiana election for a statewide elected official or state legislative election governed by the provisions of the Campaign Finance Disclosure Act [R.S. 14:1481]; or~~

Staff Note: We have no objection to this suggested revision.

Item 13 – Mr. Stolier

No amendments requested.

Item 14 – Mr. Mire

A. §2447.A (Application for Initial Issuance of Permit)

- 4. In the event any person holding any ownership interest in the entity submitting an application for a marijuana pharmacy permit has engaged in any of the following activities, the entity shall be disqualified and the board shall not issue a marijuana pharmacy permit to that applicant:

- a. ~~Within the two year period preceding the date of the application, has made a contribution to a candidate in a Louisiana election for a statewide elected official or state legislative election governed by the provisions of the Campaign Finance Disclosure Act [R.S. 14:1481]; or~~
- b. ...
- c. Within the two year period preceding the date of the application, a majority of the ownership interest is held by persons other than Louisiana residents.

B. §2451 (Operation of Marijuana Pharmacy)

A – M. ...

- N. No marijuana pharmacy shall sell anything other than marijuana products; however, the pharmacy may elect to sell over-the-counter (OTC) medications, prescription medications other than controlled substances, and/or durable medical equipment (DME) from the same premises, but outside the prescription department.

O – P. ...

- Q. No marijuana shall be sold, dispensed or distributed via a delivery service or any other manner outside of a marijuana pharmacy, except that a caregiver may deliver marijuana to the caregiver's patient, and further, a pharmacy may deliver dispensed marijuana products to their patients using vehicles under the pharmacist's professional control.

R – U. ...

*Staff Note: We have no objection to the inclusion of other items for sale in the marijuana pharmacy. While we have no objection to a pharmacy delivering marijuana products to its patients, you should take note of the provisions of the enabling legislation, more specifically at La. R.S. 40:1046.E, which states "Marijuana, tetrahydrocannabinols, or a chemical derivative of tetrahydrocannabinols recommended pursuant to this Section shall be dispensed **in person** from a licensed pharmacy in good standing located in Louisiana." **[emphasis added]***

Item 15 – Mr. Bopp

A. §2447.A (Application for Initial Issuance of Permit)

4. In the event any person holding any ownership interest in the entity submitting an application for a marijuana pharmacy permit has engaged in any of the following activities, the entity shall be disqualified and the board shall not issue a marijuana pharmacy permit to that applicant:
 - a. ...
 - b. Within the two year period preceding the date of the application, the person or any member of the person's immediate family held a position in state service in Louisiana, including but not limited to, a legislator, statewide public official, state employee, or member of the board.

Staff Note: State service is not defined. An alternative approach would be to eliminate that provision, reducing the potential for unnecessary administrative action or legal challenge, or adopting the streamlined version noted at Item 5.

B. §2451 (Operation of Marijuana Pharmacy)

A – M. ...

N. No marijuana pharmacy shall sell anything other than marijuana products; however, the pharmacy may elect to sell over-the-counter (OTC) medications and/or, durable medical equipment (DME), and other retail products from the same premises, but outside the prescription department.

O – U. ...

Staff Note: We have no objection to the inclusion of additional items eligible for sale at marijuana pharmacies.

Item 16 – Mr. Prevost

Question 1

- a. As part of the drug product safety considerations, the Board's Regulation Revision Committee discussed establishing a threshold for the amount of THC in a single dose. For any drug product, there is always a concern for accidental ingestion, as well as a desire to limit the adverse consequences of any potential overdose events. The Committee took note of information describing such overdoses in Colorado, and consideration by lawmakers in that state to limit THC to a maximum of 10 mg. per dose. The Committee also took note of dosing guideline information available from the Mayo Clinic, which lists dosing guidelines for marijuana for several medical indications. For at least two of the indications identified in the enabling legislation in Louisiana (spasticity and multiple sclerosis), the maximum recommended dose per day is 10 mg. For the other indications with higher recommended doses, there is nothing to prevent the recommending physician from using multiple dosage forms per dose to achieve the higher total doses. The Committee believes this is a reasonable starting point for the safety threshold. With additional experience in this state, the Board could always revise the rule to establish a different threshold.
- b. (1) Edibles for Experts?, State Legislatures (March 2015), National Council of State Legislatures, available at www.ncsl.org.

- (2) Marijuana Dosing Guidelines, available at www.mayoclinic.org.
- c. Not from the Board's rules.
- d. The Board of Pharmacy does not regulate physicians; therefore, the rules do not address what physicians may or may not do.
- e. The Board of Pharmacy does not regulate physicians; therefore, the rules do not address what physicians may or may not do.
- f. The Board of Pharmacy does not regulate physicians; therefore, the rules do not address what physicians may or may not do.
- g. The Board of Pharmacy does not regulate physicians; therefore, the rules do not address what physicians may or may not do.
- h. There are no such limits anticipated at this time, but the Board reserves the right to promulgate such standards in the future.
- i. There are no such limits anticipated at this time, but the Board reserves the right to promulgate such standards in the future.
- j. There are no such limits anticipated at this time, but the Board reserves the right to promulgate such standards in the future.
- k. No.

Question 2

- a. The Board took note of a similar restriction in the enabling legislation, more specifically at La. R.S. 40:1046(H)(7), but reduced the time frame from five years to two years.
- b. Act 261 of the 2015 Regular Session, available at www.legis.la.gov.
- c. No.
- d. No.
- e. No.
- f. §2447.A (Application for Initial Issuance of Permit)
 - 4. In the event any person holding any ownership interest in the entity submitting an application for a marijuana pharmacy permit has engaged in any of the following activities, the entity shall be disqualified and the board shall not issue a marijuana pharmacy permit to that applicant:
 - a. ~~Within the two year period preceding the date of the application,~~ Prior to the date of the application, has made a contribution to a candidate in a Louisiana election for a statewide elected official or state legislative election governed by the provisions of the Campaign Finance Disclosure Act [R.S. 14:1481]; or
 - b. ~~Within the two year period preceding the date of the application,~~ Prior to the date of the application, the person or any member of the person's immediate family held a position in state service in Louisiana, including but not limited to, a legislator, statewide public official, state employee, or member of the board.
- g. §2447.A (Application for Initial Issuance of Permit)
 - 4. In the event any person holding any ownership interest in the entity submitting an application for a marijuana pharmacy permit has engaged in any of the following activities, the entity shall be disqualified and the board shall not issue a marijuana

pharmacy permit to that applicant:

- c. ~~Within the two year period preceding the date of the application,~~ Prior to the date this rule was promulgated, has made a contribution to a candidate in a Louisiana election for a statewide elected official or state legislative election governed by the provisions of the Campaign Finance Disclosure Act [R.S. 14:1481]; or
 - d. ~~Within the two year period preceding the date of the application,~~ Prior to the date this rule was promulgated, the person or any member of the person's immediate family held a position in state service in Louisiana, including but not limited to, a legislator, statewide public official, state employee, or member of the board.
- h. The anticipated timeline for rule promulgation and implementation of the statewide program.
 - i. Yes.

Question 3

- i. The enabling legislation at La. R.S. 40:1046.E requires the marijuana to be dispensed in pharmacies licensed by the Board. The Louisiana Pharmacy Practice Act, more specifically at La. R.S. 37:1221, authorizes the Board to require permits to operate a pharmacy, and further, La. R.S. 37:1223 authorizes the Board to establish different classifications of pharmacy permits and establish the standards for such permits by rule. The proposed rule at LAC 46:LIII.2440 *et seq.* are the Board's proposed standards for the marijuana pharmacy permit.
- ii. Yes.
- iii. Yes.
- iv. No.
- v. No.
- vi. There is no rule, current or proposed, that would prohibit such activity.
- vii. As long as both pharmacies are operated in compliance with all laws and rules, there is no adverse impact.
- viii. As long as pharmacists perform all of their professional obligations in compliance with all laws and rules, there is no adverse impact.
- ix. See §2440.B and C. Beyond that guidance, questions about a credential issued by another agency are best directed to the issuing agency.

Question 4

- a. The Board did not define the term 'caregiver'; therefore, we would rely on the definition found in a general dictionary. For instance, the Miriam-Webster Dictionary defines that term as "a person who provides direct care (as for children, elderly people, or the chronically ill)."

Question 5

- a. ?
- b. ?
- c. ?
- d. ?

- e. ?
- f. Yes.

Item 17 – Staff Suggestions

We have a number of observations/corrections for your consideration:

- 1. We found an inconsistency in the age below which products should not marketed.

§2443. Marijuana Products

C. Product Dosage Forms

2. No marijuana product shall:

- a – b. ...
- c. Be manufactured or sold in a form or with a design that:
 - i – iii. ...
- v. Is customarily associated with persons under the age of eighteen years; or

D. Packaging and Labeling Requirements

1. Packaging

- a – d. ...
- e. Packaging selected by the producer shall be subject to the following restrictions.
 - i. Shall not specifically target individuals under the age of ~~24~~ eighteen years.

Staff Note: Since both of these passages relate to a minimum age for packaging and labeling of dosage forms, recommend consistency – at eighteen years of age.

- 2. We heard a concern from one of the growers about the amount of information that must be placed on the label of a marijuana product distributed to a marijuana pharmacy. Pharmacists are in the habit of recognizing package inserts as part of the official labeling for a drug product; however, we failed to include that option in the proposed rule. We could potentially interpret the existing rule to include that option, or we could adopt language specifically allowing such option.

§2443. Marijuana Products

D. Packaging and Labeling Requirements

2. Labeling

- a – c. ...
- d. The producer may utilize a package insert which is enclosed or attached to the product container to provide the information required in this Section. If the producer elects to use such supplementary labeling, the label affixed to the outer surface of the product container shall contain the following information, at a minimum:
 - i. The batch or lot number referenced at Subsection D.2.a.i;
 - ii. The potency of the THC and CBD referenced at Subsection D.w.a.iv;
 - iii. The net weight referenced at Subsection D.2.a.v;
 - iv. The expiration date referenced at Subsection D.2.a.vi; and
 - v. The caution statement referenced at Subsection D.2.b.i.

3. We have discovered an inconsistency between our proposed rule and the proposed rule from the Dept. of Agriculture & Forestry (LDAF) concerning procedures to be used by laboratories testing marijuana samples. Since that department regulates the testing facilities and the producers, we suggest an amendment of our proposed rule to harmonize with the proposed rule from LDAF.

§2443. Marijuana products

B. Laboratory Testing

2. A producer shall make available each such batch at the production facility for testing by a laboratory approved by LDAF. The laboratory employee shall select a random sample from each batch. ~~The laboratory shall test each sample for microbiological contaminants, mycotoxins, heavy metals, pesticide chemical residue, residual solvents, homogeneity, and for the purpose of conducting an active ingredient analysis.~~

a. Medical marijuana concentrate shall not be used to produce any form of product until it has passed all analysis limits for:

- i. active ingredient analysis for characterization of potency;
- ii. pesticide active ingredients, including but not limited to, the most recent list of targeted pesticides published by LDAF;
- iii. residual solvents;
- iv. heavy metals; and
- v. mycotoxins.

b. Product shall not be released for delivery to a pharmacy for sale or consumption until it has passed all analysis limits for:

- i. microbiological contaminants;
- ii. active ingredient analysis for accuracy of potency; and
- iii. homogeneity.

c. LDAF personnel may select a random sample at any point in the process for the purpose of analysis for anything the LDAF deems necessary.

d. Samples shall be secured in a manner approved by LDAF at all times when not in immediate use for the analyses being conducted.

3. ...

4. ~~The laboratory shall immediately return or dispose of any marijuana upon the completion of any testing, use, or research. When the laboratory disposes of marijuana, the laboratory shall comply with the marijuana rules promulgated by LDAF.~~

5. ~~In the event a sample of marijuana does not pass the microbiological, mycotoxin, heavy metal, pesticide chemical residue, residual solvent, or homogeneity test based on the standards set forth in this Section, the producer shall dispose of the entire batch from which the sample was taken, in compliance with the marijuana disposal rules promulgated by LDAF.~~ Testing Specifications

a. With respect to the microbiological test, a marijuana sample shall be deemed to have passed if it satisfies the standards set forth in *Chapter 1111—Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use of the United States Pharmacopeia (USP)*,

available at www.usp.org; recommended microbial and fungal limits for cannabis products as follows:

- i. total yeast and mold: < 10,000 colony-forming units per gram (CFU/g); and
- ii. E. coli (pathogenic strains) and Salmonella spp: <1 CFU/g.
- b. With respect to the mycotoxins test, a marijuana sample shall be deemed to have passed if it meets the following standards:
 - i. Aflatoxin B1 < 20 parts per billion (ppb);
 - ii. Aflatoxin B2 < 20 ppb;
 - iii. Aflatoxin G1 < 20 ppb;
 - iv. Aflatoxin G2 < 20 ppb; and
 - v. Ochratoxin **A** < 20 ppb. (note deletion of A)
- c. ...
- d. ...
- e. With respect to the residual solvents test, a marijuana sample shall be deemed to have passed if the following solvents are below the listed limits:
 - i. Butanes < 800 ppm;
 - ii. Heptanes < 500 ppm;
 - iii. Benzene < 1 ppm;
 - iv. Toluene < 1 ppm;
 - v. Hexanes < 10 ppm; and
 - vi. Total Xylenes < 1 ppm; and
 - vii. Ethanol < 5,000 ppm.
- f. ...
- g. ~~With respect to the analysis of active ingredients, the following substances, when present, shall be identified and measured. The maximum variance permitted is fifteen percent from the labeled amount. For example, a product labeled as containing 10 milligrams of tetrahydrocannabinol (THC) shall contain no less than 8.5 milligrams THC and no more than 11.5 milligrams THC.~~
 - i. ~~THC (tetrahydrocannabinol);~~
 - ii. ~~THCA (tetrahydrocannabinolic acid);~~
 - iii. ~~CBD (cannabidiol); and~~
 - iv. ~~CBDA (cannabidiolic acid).~~

Every sample shall undergo an active ingredient analysis or potency analysis.

 - i. For medical marijuana concentrate samples, the potency test is to establish the presence of active ingredients and their concentrations for accurate calculations of amounts needed for the production of products. The analysis must identify the following substances:
 - (a) THC (tetrahydrocannabinol);
 - (b) THCA (tetrahydrocannabinolic acid);
 - (c) CBD (cannabidiol); and
 - (d) CBDA (cannabidiolic acid).
 - ii. For product samples, the potency test is to establish the active ingredient composition for verification of labeling to ensure accurate dosing. The maximum variance permitted is fifteen percent from

the labeled amount. For example, a product labeled as containing 10 milligrams of tetrahydrocannabinol (THC) shall contain no less than 8.5 milligrams THC and no more than 11.5 milligrams THC.

6. ~~If a sample of marijuana passes the microbiological, mycotoxin, heavy metal, pesticide chemical residue, residual solvent, and homogeneity tests, the laboratory shall release the entire batch for immediate manufacturing, packaging, and labeling for sale to a marijuana pharmacy.~~
Procedures for Sample Failures

- a. In the event a medical marijuana concentrate sample fails testing for pesticides, heavy metals or mycotoxin, the entire batch from which the sample was taken shall be disposed of in accordance with the disposal rules promulgated by LDAF.

- b. In the event a medical marijuana concentrate sample fails residual solvent testing, then, with prior approval of LDAF, the product may be subjected to an appropriate remedy, e.g., vacuum drying, reformulated and tested again. The reformulation must pass all required tests for a medical marijuana concentrate in duplicate before it can be released for use in products. If either duplicate fails any test, the entire batch shall be disposed of in accordance with the disposal rules promulgated by LDAF. A batch of medical marijuana concentrate can only be reformulated once and only to remedy excessive residual solvents.

- c. In the event a product fails the microbiological testing, the entire batch from which the sample was taken shall be disposed of in accordance with the disposal rules promulgated by LDAF.

- d. In the event a product fails the potency or homogeneity testing, then, with prior approval of LDAF, the product can be re-sized and tested again. The reformulated product shall be tested again in duplicate and pass all required tests before it can be released for sale or consumption. If either duplicate fails any test, the entire batch shall be disposed in accordance with the disposal rules promulgated by LDAF.

7. In the event of any test failure, the laboratory shall transmit to LDAF an electronic copy of such test result at the same time it transmits those results to the producer. In addition, the laboratory shall maintain the laboratory test results including all relevant chromatograms and quality control documentation for at least five years and make them available to LDAF at its request.

8. ~~The laboratory shall comply with all rules applicable to the testing of marijuana promulgated by LDAF~~ dispose of any remaining medical marijuana concentrate or product samples no sooner than 60 days following the completion of any testing, in compliance with the disposal rules promulgated by LDAF.

9. ...

4. We heard from several interested parties about the potential adverse impact of the amount of funds required for the applicant to demonstrate their financial capacity. In particular, the proposed rule requires a one million dollar initial commitment, which can be reduced by meeting predefined milestones, and then levels off at \$250,000. It has been suggested the one million dollar initial commitment might prevent some small businesses from participating in the application selection process. An alternative

amount is presented for your consideration:

§2447. Licensing procedures

A. Application for Initial Issuance of Permit

1 – 9. ...

10. The applicant shall supplement the application form with sufficient documentation of the applicant's financial capacity to properly operate a marijuana pharmacy, including but not limited to, evidence of his escrow account, letter of credit, or surety bond of at least ~~one million~~ one hundred thousand dollars in a financial institution headquartered in Louisiana.

- a. The pharmacy's ~~one million~~ one hundred thousand dollar escrow account, letter of credit, or surety bond shall be payable to the board in the event the board determines after a due process hearing that the pharmacy has failed to timely and successfully complete the construction of the pharmacy or to operate such pharmacy in compliance with the provisions of this Subchapter.
- b. The board shall permit the pharmacy's escrow account, letter of credit, or surety bond to be reduced by ~~two hundred fifty~~ twenty-five thousand dollars upon the successful achievement of each of the following milestones:
 - i – iii. ...
 - iv. The pharmacy shall maintain the escrow account, letter of credit, or surety bond for a minimum of ~~two hundred fifty~~ twenty-five thousand dollars for the remainder of its operation.

5. We have discovered an inaccurate reference in the section relative to the licensing procedures for the initial issuance of the permit, more specifically in the list of criteria to be considered by the Board's Application Review Committee in their consideration of the application for a marijuana pharmacy permit.

§2447. Licensing procedures

A. Application for Initial Issuance of Permit

1 – 14. ...

15. During the hearing held by the board's Application Review Committee, the members shall consider, but are not limited to, the following criteria when evaluating an application for a marijuana pharmacy permit:

a – e. ...

- f. Any other reason provided by any federal law or rule or state law or rule that is not inconsistent with ~~the Act~~ La. R.S. 40:1046 or 40:1047 or this Subchapter.

6. We have discovered an oversight in the identification of the fees required for the renewal of a marijuana pharmacy permit, and suggest the revision noted here.

§2447. Licensing procedures

B. Application for Renewal of Permit

1. ...

2. The owner's managing officer and pharmacist-in-charge of the marijuana

pharmacy permit shall complete, sign and date a permit renewal application form supplied by the board, and further, shall include all information requested on the form and ~~include~~ attach the pharmacy permit renewal fee and state controlled dangerous substance license renewal fee authorized in R.S. 37:1184 and the prescription monitoring program fee authorized in R.S. 40:1013, and further, shall submit the renewal application package to the board office prior to the expiration date of the pharmacy permit.

Part X-E. Therapeutic Use of Marijuana

[Editor's Note: A prior Part X-A, Therapeutic Use of Marijuana, consisting of R.S. 40:1021 to 40:1026, was repealed by Act 662 of 1989 Legislature, effective July 7, 1989. Act 874 of 1991 Legislature re-established Part X-A, Therapeutic Use of Marijuana. Act 676 of 2006 Legislature re-designated this Part as Part X-E. Subsequent amendments are noted herein. Act 261 of 2015 Legislature designated as "The Alison Neustrom Act."]

§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. (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 recommend, 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.
- (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.
- (b) 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, the medical condition shall no longer be covered by the 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 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.
- (3) For purposes of this Part, "recommend" or "recommended" 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 recommend 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 recommend 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 recommend marijuana for therapeutic use by patients as described in Subsection A of this Section. Any rules published by the Louisiana State Board of Medical Examiners on or before January 1, 2016 that describe the physician's authority to prescribe should be repromulgated to indicate that he is "recommending" use of therapeutic marijuana.

(Added by Act 874 of 1991 Legislature, effective September 6, 1991; amended Act 261 of 2015 Legislature, effective June 29, 2015; amended Act 96 of 2016 Legislature, effective May 19, 2016)

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

therapeutic marijuana.

- (2) The rules shall include but not be limited to:
 - (a) Standards, procedures, and protocols for the effective use of recommended 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 recommended therapeutic marijuana in Louisiana.
 - (c) Procedures and protocols to provide that no recommended 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 recommended 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 recommended 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 recommended therapeutic marijuana samples for levels of tetrahydrocannabinols (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 recommended therapeutic marijuana.
 - (j) Licensure of dispensers of recommended 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.

(Amended by Act 96 of 2016 Legislature, effective May 19, 2016)

- D. Nothing in this Section shall be construed to prohibit the Louisiana State Board of Medical Examiners or the Louisiana Pharmacy Board from adopting emergency rules as otherwise provided for in the Administrative Procedure Act.
- E. Marijuana, tetrahydrocannabinols, or a chemical derivative of tetrahydrocannabinols recommended pursuant to this Section shall be dispensed in person from a licensed pharmacy in good standing located in Louisiana.

(Amended by Act 96 of 2016 Legislature, effective May 19, 2016)

- F. A person who recommends and person who dispenses 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 recommending and dispensing thereof.

(Amended by Act 96 of 2016 Legislature, effective May 19, 2016)

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

(Amended by Act 96 of 2016 Legislature effective May 19, 2016)

- H. (1) (a) The Department of Agriculture and Forestry shall develop the rules and regulations regarding the extraction, processing, and production of recommended 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 recommended 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 license. 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.
 - (c) The Louisiana State University Agricultural Center or the Southern University Agricultural Center may conduct research on marijuana for therapeutic use if the center is licensed as a production facility pursuant to this Section
- (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 and Forestry 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.

(Amended by Act 96 of 2016 Legislature, effective May 19, 2016)

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.

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

(Added by Act 261 of 2015 Legislature, effective June 29, 2015)

§1047. Louisiana Department of Agriculture and Forestry; authorization to obtain criminal history record information

A. As used in this Section, the following terms shall have the following meaning:

- (1) "Applicant" means a natural person, a corporation, limited liability corporation, partnership, joint stock association, sole proprietorship, joint venture, business association, cooperative association, professional corporation, or any other legal entity or organization through which business is conducted.
- (2) "Bureau" means the Louisiana Bureau of Criminal Identification and Information of the office of state police within the Department of Public Safety and Corrections.
- (3) "Criminal history record information" means information collected by state and federal criminal justice agencies on individuals consisting of identifiable descriptions and notations of arrests, detentions, indictments, bills of information, or any formal criminal charges, and any disposition arising therefrom, including sentencing, criminal correctional supervision, and release. It shall not include intelligence information gathered for investigatory purposes or any identification information which does not indicate involvement of the individual in the criminal justice system.
- (4) "Department" means Louisiana Department of Agriculture and Forestry.
- (5) "FBI" means the Federal Bureau of Investigation of the United States Department of Justice.
- (6) "Licensure" means any license or permit that the department is authorized to issue for the production of recommended therapeutic marijuana and the facility producing therapeutic marijuana.

B. In addition to any other requirements established by department rules, the department shall require an applicant, as a condition of eligibility for licensure:

- (1) To submit a full set of fingerprints, in a form and manner prescribed by the department.
- (2) To permit the department to request and obtain state and national criminal history record information on the applicant.
- (3) To pay the reasonable costs to be incurred by the department in requesting and obtaining state and national criminal history record information on the applicant.

C. In accordance with the provisions and procedures prescribed by this Section, the department shall request and obtain state and national criminal history record information from the bureau and the FBI relative to any applicant for licensure whose fingerprints the department has obtained pursuant to this Section for the purpose of determining the applicant's suitability and eligibility for licensure.

D. Upon request by the department and upon submission of an applicant's fingerprints, and such other identifying information as may be required, the bureau shall survey its criminal history records and identification files and make a simultaneous request of the FBI for like information from other jurisdictions. The bureau may charge the department a reasonable processing fee for conducting and reporting on any such search.

E. Any and all state or national criminal history record information obtained by the department from the bureau or FBI which is not already a matter of public record shall be deemed nonpublic and confidential information restricted to the exclusive use of the department in evaluating the applicant's eligibility or disqualification for licensure. No such information or records related thereto shall, except with the written consent of the applicant or by order of a court of competent jurisdiction, be released or otherwise disclosed by the department to any other person or agency.

(Added by Act 96 of 2016 Legislature, effective May 19, 2016)

[Editorial Note: Act 96 of 2016 Legislature contains information not printed here. In particular, Section 2 of the Act contains alternative amendments that will only become effective if, and when, the United States Drug Enforcement Administration reclassifies marijuana from a Schedule I drug to a Schedule II drug. The primary difference is the use of the term “recommend” vs “prescribe”; Section 2 uses the term “prescribe”, which would only be appropriate when the drug is reclassified to Schedule II. If and when that reclassification occurs, we will update the Louisiana Pharmacy Law Book with the language from Section 2 of Act 96 of the 2016 Legislature.]

(end of Part X-E of Chapter 4)



Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov



March 14, 2017

Agenda Item 8: Announcements

- | | |
|------------|---|
| Mar. 24-27 | APhA Annual Meeting – San Francisco, CA |
| Apr. 10 | 2017 Legislature Regular Session convenes |
| Apr. 11-12 | TALKOM Conference – Oklahoma City, OK |
| Apr. 12 | Louisiana Pharmacy Congress |
| | Prescription Monitoring Program Advisory Council |
| Apr. 14 | Good Friday – <i>Board office closed</i> |
| May 9 | Reinstatement, Impairment, & Executive Committees |
| May 10 | Reciprocity Committee |
| | Board Meeting |
| May 11 | Administrative Hearing |
| May 20-23 | NABP Annual Meeting – Orlando, FL |
| May 25-27 | LSHP Annual Meeting – New Orleans, LA |
| May 29 | Memorial Day – <i>Board office closed</i> |