

## DECLARATION OF EMERGENCY

### Department of Health Board of Pharmacy

#### Marijuana Recommendations (LAC 46:LIII.2457)

The Louisiana Board of Pharmacy is exercising the emergency provisions of the Administrative Procedure Act, specifically at R.S. 49:953 (B), to amend one section of its rules for marijuana pharmacies relative to recordkeeping requirements as well as professional practice standards relative to recommendations for therapeutic marijuana.

Act 286 of the 2020 Legislature made several changes to the state medical marijuana law (R.S. 40:1046) including changes in the eligibility of physicians authorized to issue recommendations for therapeutic marijuana as well as the removal of the authority for the Louisiana State Board of Medical Examiners to promulgate rules relative to physicians issuing marijuana recommendations. Prior to the August 1, 2020 effective date of the new legislative act, rules had been promulgated by the Louisiana State Board of Medical Examiners and the Louisiana Board of Pharmacy to govern the issuance, receipt, and processing of marijuana recommendations. With the removal of the authority of the Board of Medical Examiners to promulgate rules relative to physicians issuing marijuana recommendations, the Board of Pharmacy has determined it necessary to amend its rules for marijuana recommendations to provide the regulatory structure necessary to properly administer the state medical marijuana law at R.S. 40:1046.

The proposed changes in Subsection D for recordkeeping requirements include a repeal of the existing Paragraph 1 referencing a recommendation as an order, a technical change in the re-numbered Paragraph 1, and a clarification of an inventory recordkeeping requirement in the re-numbered Paragraph 3. The proposed changes in Subsection E for professional practice standards include a new Paragraph 1 with the current paragraphs re-numbered sequentially. Within Paragraph 1, Subparagraph (a) permits a marijuana pharmacy to accept a recommendation from a physician in possession of a current and unrestricted license to practice medicine as well as a current state controlled substance license with privileges for Schedule I. The subparagraph also requires the pharmacy to accept the recommendation directly from the physician either through electronic prescriptions or through facsimile. Subparagraph (b) identifies the information which shall be disclosed within the recommendation. Subparagraph (c) expires a recommendation one year after the date of issue unless a shorter period of time is specified by the physician; and further, permits a pharmacist to dispense products one or more times prior to the expiration date but limits the dispensing to a maximum of a 90-day supply in a single dispensing and a maximum of a one-year supply pursuant to a single recommendation. The proposed change in the re-numbered Paragraph 4 clarifies the requirement for the pharmacist to comply with standards for drug utilization review and patient counseling. The proposed changes in the re-numbered Paragraph 6 remove the prohibition on the return of marijuana product inventory to the marijuana producer as well as the additional requirement to record product disposal in the Louisiana Medical Marijuana Tracking System (LMMTS).

Given the significant and beneficial impact of therapeutic marijuana on the health of patients using such treatment, the Board of Pharmacy has determined this emergency rule is necessary to prevent imminent peril to the public health, safety, and welfare. The emergency rule shall become effective on August 1, 2020 and shall remain in effect for 120 days unless extended or rescinded.

#### Title 46

### PROFESSIONAL AND OCCUPATIONAL STANDARDS

#### Part LIII. Pharmacists

#### Chapter 24. Limited Service Providers

#### Subchapter E. Marijuana Pharmacy

#### §2457. Standards of Practice

A. - C.2.a. ...

#### D. Recordkeeping Requirements

1. When the pharmacy receives a request for marijuana from a recommending physician in written form, the pharmacist shall cause the form to be scanned and filed using an electronic imaging system in compliance with §1123 of this Part.

2. Request forms (and electronic images thereof) shall be retained on the pharmacy's premises for at least two years after the date of dispensing, and further, shall be readily retrievable upon request by the board.

#### 3. Inventory of Marijuana Product

a. The pharmacist-in-charge shall develop and maintain a perpetual inventory of all marijuana products acquired, held, dispensed, and disposed by the pharmacy.

b. The pharmacy shall access the LMMTS and enter all acquisitions and product transfer transactions in that system.

c. In the event the pharmacist-in-charge designates an agent to retrieve new marijuana product inventory from the production facility, the pharmacist shall verify the agent is at least 21 years of age and is eligible to drive on public roadways.

d. The pharmacist-in-charge shall conduct an annual inventory of all marijuana products in the possession of the pharmacy on any date which is within one year of the previous annual inventory, and further, shall conduct additional inventory counts on the following occasions:

i. arrival of a new pharmacist-in-charge;

ii. discovery of any significant loss, disappearance, or theft of marijuana product;

iii. departure of a new pharmacist-in-charge; and

iv. permanent closure of the pharmacy.

e. Inventory records shall be retained on the pharmacy's premises for at least two years after the most recent entry.

4. The pharmacy shall develop and maintain sufficient records to fully reveal the business transactions related to marijuana products, including their procurement and sale, for the current tax year as well as the two immediately preceding tax years, all of which shall be made available to the board upon request.

5. The board may require any pharmacy or its owners to furnish such information as the board considers necessary for the proper administration of R.S. 40:1046, and may require a financial audit of the business of any marijuana pharmacy, and the expense thereof shall be paid by the marijuana pharmacy.

#### E. Professional Practice Standards

1. Recommendation/opinion/referral (hereinafter, "request") for Therapeutic Marijuana

a. The pharmacist may accept any request for a marijuana product which has been:

i. issued by a physician in possession of a current and unrestricted license to practice medicine from the Louisiana State Board of Medical Examiners as well as a current and unrestricted state controlled substance license with therapeutic marijuana privileges from the board; and

ii. received directly from the physician and not from the patient or any third party other than the entity transmitting the request, either by electronic means conforming with the provisions of 21 CFR 1311 or its successor, or in the alternative, by facsimile bearing a handwritten or digital signature of the physician.

b. The request shall disclose the following information, at a minimum:

i. name, address, telephone number, and national provider identifier (NPI) number of the physician issuing the request;

ii. name, address, and date of birth (or age) of the patient for whom the request was issued;

iii. identification of the debilitating medical condition for which the treatment has been requested;

iv. treatment requested;

v. date request was issued;

vi. self-certification the physician holds a current and unrestricted license to practice medicine issued by the Louisiana State Board of Medical Examiners; and

vii. signature of the physician issuing the recommendation, excluding any proxy or agent.

c. Requests for marijuana products shall expire one year after the date of issue, unless a shorter period of time is indicated by the physician. A pharmacist may dispense marijuana product on multiple occasions as indicated by the physician and needed by the patient until the request expires; however, the pharmacist shall not dispense more than a 90-day supply of marijuana product at one time nor more than a one-year supply of marijuana product pursuant to a single request. A pharmacist shall not dispense marijuana product pursuant to an expired request.

2. Prior to dispensing any marijuana product to a patient, the pharmacist shall review the patient's records in the state prescription monitoring program. The pharmacist shall resolve any concerns identified in that review by consultation with the recommending physician.

### 3. Labeling of Marijuana Product Dispensed

a. The pharmacist shall not dispense any marijuana product that does not bear the producer label required by the LDAF, and further, the pharmacy dispensing label shall not overlay or obscure the producer label in any way.

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

i. name and address of the pharmacy dispensing the product;

ii. telephone number or other contact information of the pharmacy dispensing the product;

iii. name of the recommending physician;

iv. name of the patient;

v. date the product was dispensed;

vi. prescription number, which shall be a unique identifier for that specific transaction;

vii. name of the marijuana product, including any concentration, strength, or other identifiers of the marijuana product;

viii. quantity of marijuana dispensed;

ix. directions for use of the product;

x. expiration date of the product, which shall not exceed the expiration date determined by the producer of the product; and

xi. other information selected by the dispensing pharmacist to inform the patient as to the best use of the product for the intended purpose.

4. The pharmacist shall comply with the rules on drug utilization review and patient counseling in Chapter 5 of this Part.

5. Reporting transactions to state prescription monitoring program. The pharmacy shall comply with the reporting requirements as found in Chapter 29 of this Part.

### 6. Disposal of Marijuana Product

a. A pharmacy may refuse to accept the delivery of marijuana product from a producer when it is determined to be misbranded, adulterated, expired, deteriorated, undesired, excess, unauthorized, or unfit for dispensing.

b. When the pharmacist determines a marijuana product is no longer suitable for dispensing, the product shall be removed from active dispensing stock and quarantined in the pharmacy pending its disposal.

c. - e.iv. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1550 (August 2017), amended LR 45:1473 (October 2019), LR 46:

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