



Louisiana Board of Pharmacy

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February 8, 2022

Senator P. Page Cortez
President, Louisiana Senate
Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2022-1 ~ Marijuana Products

Dear Senator Cortez:

The Board seeks to amend its rules for marijuana pharmacies for two purposes – to implement the provisions of Act 424 of the 2021 Legislature authorizing the use of raw or crude marijuana for therapeutic purposes, and to remove an unnecessary restriction on the storage of marijuana products in marijuana pharmacies. The proposed rule changes add raw products to the list of allowable dosage forms, establish testing standards for raw products, and specifies the dispensing limitations for raw products identified in the legislation. Further, the proposed rule changes allow marijuana pharmacies to temporarily store marijuana products outside safes and vaults but still within the prescription department during their operating hours to facilitate efficient dispensing procedures.

The Occupational Licensing Review Commission approved the initiation of this project during their January 11, 2022 meeting. In connection with this regulatory project, the following items are appended:

- Notice of Intent Page 2
- Fiscal & Economic Impact Statement Page 8

As indicated in the solicitation, we will convene a public hearing on March 25, 2022 to receive public comments and testimony on this proposed rule. We will summarize those comments and our responses thereto in our next report to you. In the event you have any questions or need additional information about this project, please contact me directly at mbroussard@pharmacy.la.gov or 225.925.6481.

For the Board:

Malcolm J. Broussard
Executive Director

cc: Chair, Senate Health & Welfare Committee
Via Email: APA.S-H&W@legis.la.gov
Speaker, House of Representatives
Via Email: APA.HouseSpeaker@legis.la.gov
Chair, House Health & Welfare Committee
Via Email: APA.H-HW@legis.la.gov
Director, Community Competitiveness & Small Business Services, La. Economic Development
Via Email: Witty@la.gov
Editor, *Louisiana Register*
Via Email: Reg.Submission@la.gov
Reference File

NOTICE OF INTENT

Department of Health Board of Pharmacy

Raw Marijuana Products (LAC 46:LIII.2440, 2443, 2453, and 2457)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy hereby gives notice of its intent to amend Sections 2440, 2443, 2453, and 2457 of its rules relative to marijuana pharmacies to implement the provisions of Act 424 of the 2021 Legislature. The proposed changes in Section 2440 make a technical change in the reference to the initial enabling legislation for the medical marijuana program and identifies the mandates within 2021 legislation. The proposed changes in Section 2443 add raw marijuana products to those items which producers are authorized to distribute to marijuana pharmacies, identify laboratory testing standards for such raw products, add additional dosage forms including pectin-based chewables as well as combustible and edible dosage forms and removes the prohibition on inclusion of marijuana in beverages. The proposed changes in Section 2453 authorize marijuana pharmacies to temporarily maintain a supply of marijuana products outside safes and vaults during their hours of operation. The proposed changes in Section 2457 remove the reference to referral as a description of a recommendation form, adds a requirement for recommendations for raw products when intended for persons under the age of 21 years, and identifies the dispensing limitations of raw marijuana products included in the 2021 legislation.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII. Pharmacists

Chapter 24. Limited Service Providers

Subchapter E. Marijuana Pharmacy

§2440. Preamble; Warning; Consultation Suggested

A. Pursuant to Act 261 of the Regular Session of the 2015 Legislature as well as ~~the subsequent amendments found in Act 96 of the Regular Session of the 2016 Legislature~~, the Board of Pharmacy was directed to:

1. ...
2. Adopt rules relating to the dispensing of recommended marijuana for therapeutic use, with such rules to include, at a minimum, the following:
 - a. – d. ...
 - e. Standards, procedures, and protocols to ensure all recommended therapeutic marijuana dispensed, with the exception of raw or crude marijuana product, is consistently pharmaceutical grade.
 - f. – k. ...
 - l. limitations on dispensing of raw or crude marijuana.

B. – C. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1538 (August 2017), amended LR

* * *

§2443. Marijuana Products

A. Exclusive Source

1. The exclusive source of marijuana products shall be the producers licensed for that activity by the Department of Agriculture and Forestry (LDAF).
2. ~~That~~ Licensed producers shall prepare pharmaceutical grade marijuana products as well as raw marijuana products for

distribution to marijuana pharmacies licensed by the board.

3. ...

B. Laboratory Testing

1. ...

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 such batch.

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

i. – v. ...

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

i. – iii. ...

c. Final products not produced from concentrate, e.g., dried and cured flower, shall not be released for delivery to a marijuana pharmacy for sale or consumption 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. heavy metals;

iv. mycotoxins;

v. microbiological contaminants; and

vi. homogeneity.

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

e. 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. Testing Specifications

a. – c.iv. ...

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~~ does not contain any residues appearing on LDAF's approved list and any approved residues present are less than the limits allowed by LDAF.

e. ...

f. With respect to the test for homogeneity, a marijuana sample shall be deemed passed if each aliquot tested is within plus or minus 15 percent of the total aliquots average finding for potency for each labeled active ingredient. Any solid product will be considered not homogenous to have failed if 10 percent of the sample product contains more than 20 percent of the total active ingredient.

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

i. – i.(d) ...

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 15 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. For final products containing THCA, the total THC determined shall also be within the variance allowed for the THC as labeled.

B.5. – B.8. ...

C. Product Dosage Forms

1. The producer shall limit their production of pharmaceutical grade products to the following dosage forms:

a. – c. ...

d. Gelatin-based or pectin-based chewables;

e. – h. ...

i. Bulk raw product.

2. The producer may produce other products from raw or crude marijuana, including dried flower, buds, and other plant material, intended for the following methods of administration:

a. Combustible forms for inhalation, including but not limited to pre-rolls; and

b. Edible forms for ingestion.

~~2~~ 3. 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 0.5 percent of alcohol by volume, or ethanol-based tinctures.

~~b. be manufactured or sold as a beverage.~~

~~e~~ b. be manufactured or sold in a form or with a design that:

i. – iv. ...

~~d~~ c. have had pesticide chemicals or organic solvents used during the production or manufacturing process other than those which may be approved by the commissioner of LDAF.

~~3~~ 4. Any marijuana product not in compliance with the provisions of this ~~Paragraph~~ Section shall be deemed adulterated.

D. – E.4.f. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1540 (August 2017), amended LR 45:1473 (October 2019), LR 46:568 (April 2020), LR 46:1227 (September 2020), LR 47:590 (May 2021), LR

* * *

§2453. Security Requirements for Marijuana Pharmacies

A. A marijuana pharmacy shall:

1. – 3. ...

4. keep all approved safes and vaults securely locked and protected from entry, except for the actual time required to remove or replace marijuana, provided that during hours of operation the pharmacist-in-charge may authorize the placement of a limited quantity of dispensing stock outside such safes or vaults but within the secure prescription department.

A.5. – H. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1548 (August 2017), amended LR

* * *

§2457. Standards of Practice

A. – D.5. ...

E. Professional Practice Standards

1. Recommendation / opinion ~~/ referral~~ (hereinafter, “request”) for Therapeutic Marijuana

1.a. – 1.a.ii. ...

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

i. – iii. ...

iv. ~~treatment~~ type of marijuana product requested;

v. – vii. ...

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 as 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 of supply of marijuana product pursuant to a single request.~~ A pharmacist shall not dispense marijuana product pursuant to an expired request.

d. Requests for raw or crude marijuana products intended for persons under 21 years of age shall specifically indicate a recommendation for raw or crude forms of marijuana for such persons.

~~d e.~~ A marijuana pharmacy shall transfer an unexpired request for marijuana product to another marijuana pharmacy when requested by the patient or his caregiver.

2. Dispensing Marijuana Products

a. 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.

b. Dispensing Limitations

i. A pharmacist shall not dispense more than two and one-half ounces, or 71 grams, of raw or crude marijuana every 14 days to any person.

ii. Subject to the above limitation on dispensing raw or crude marijuana products, a pharmacist may dispense marijuana products 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 pursuant to a single request.

E.3. – E.6.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 47:246 (February 2021), LR 47:1111 (August 2021), LR

Family Impact Statement

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the Rule proposed for adoption, repeal, or amendment. The following statements will be published in the *Louisiana Register* with the proposed agency Rule.

1. The Effect on the Stability of the Family. The proposed rule changes will have no effect on the stability of the family.
2. The Effect on the Authority and Rights of Parents Regarding the Education and Supervision of their Children. The proposed rule changes will have no effect on the authority and rights of parents regarding the education and supervision of their children.
3. The Effect on the Functioning of the Family. The proposed rule changes will have no effect on the functioning of the family.
4. The Effect on Family Earnings and Family Budget. The proposed rule changes will have no effect on family earnings or family budget.
5. The Effect on the Behavior and Personal Responsibility of Children. The proposed rule changes will have no effect on the behavior and personal responsibility of children.
6. The Ability of the Family or a Local Government to Perform the Function as Contained in the Proposed Rule. The proposed rule changes will have no effect on the ability of the family or a local government to perform the activity as contained in the proposed rule changes.

Poverty Impact Statement

In accordance with Section 973 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a poverty impact statement on the Rule proposed for adoption, repeal, or amendment.

1. The Effect on Household Income, Assets, and Financial Security. The proposed rule changes will have no effect on household income, assets, or financial security.
2. The Effect on Early Childhood Development and Preschool through Postsecondary Education Development. The proposed rule changes will have no effect on early childhood development or preschool through postsecondary education development.
3. The Effect on Employment and Workforce Development. The proposed rule changes will have no effect on employment or workforce development.
4. The Effect on Taxes and Tax Credits. The proposed rule changes will have no effect on taxes or tax credits.
5. The Effect on Child and Dependent Care, Housing, Health Care, Nutrition, Transportation, and Utilities Assistance. The proposed rule changes will authorize the use of raw or crude marijuana for therapeutic purposes, which could provide more appropriate dosage forms for children, which could affect healthcare of children or other dependents.

Small Business Analysis

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed Rule on small businesses:

1. The Establishment of Less Stringent Compliance or Reporting Requirements for Small Businesses. The proposed rule changes will have no effect on compliance or reporting requirements for small businesses.
2. The Establishment of Less Stringent Schedules or Deadlines for Compliance or Reporting Requirements for Small Businesses. The proposed rule changes will have no effect on schedules or deadlines for compliance or reporting requirements for small businesses.
3. The Consolidation or Simplification of Compliance or Reporting Requirements for Small Businesses. The proposed rule changes will have no effect on compliance or reporting requirements for small businesses.
4. The Establishment of Performance Standards for Small Businesses to Replace Design or Operational Standards Required in the Proposed Rule. The proposed rule changes do not include design standards but do include a provision for temporary relaxation of security standards for marijuana products to facilitate efficient dispensing operations in marijuana pharmacies.
5. The Exemption of Small Businesses from All or Any Part of the Requirements Contained in the Proposed Rule. There are no exemptions for small businesses in the proposed rule changes.

Provider Impact Statement

In accordance with House Concurrent Resolution No. 170 of the Regular Session of the 2014 Legislature, there is hereby submitted a provider impact statement on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, the following effects on the providers of services to individuals with developmental disabilities:

1. The effect on the staffing level requirements or qualifications required to provide the same level of service. The proposed rule changes will have no effect on the staffing level requirements or the qualifications for that staff to provide the same level of service.
2. The Total Direct and Indirect Effect on the Cost to the Provider to Provide the Same Level of Service. The proposed rule changes will have no effect on the cost to the provider to provide the same level of service.
3. The Overall Effect on the Ability of the Provider to Provide the Same Level of service. The proposed rule changes will have no effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments, via United States Postal Service or other mail carrier, or in the alternative by personal delivery to Malcolm J Broussard, Executive Director, at the office of the Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-1700. He is responsible for responding to inquiries regarding the proposed Rule amendment.

Public Hearing

A public hearing to solicit comments and testimony on the proposed rule changes is scheduled for 9:00 am on Friday, March 25, 2022 at the board office which is located at 3388 Brentwood Drive, Baton Rouge, Louisiana 70809. During the hearing, all interested persons will be afforded an opportunity to submit comments or testimony, either verbally or in writing. The deadline for the receipt of all comments and testimony is 12 p.m. noon that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

Malcolm J Broussard
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

RULE TITLE: Raw Marijuana Products

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

The proposed rule changes will require the Louisiana Board of Pharmacy (LBP) to publish the proposed and final rules in the state register, resulting in printing expenses of \$1,000 in FY 22. There will be no additional expenditures or cost savings for LBP or other state or local governmental units.

The proposed rule changes authorize the use of raw marijuana products, establish laboratory and testing standards and permissible dosage forms for such products, as well as dispensing limitations for such products at marijuana pharmacies. Other proposed rule changes include an allowance for the temporary placement of marijuana products outside safes and vaults but within the prescription department to facilitate efficient dispensing operations in marijuana pharmacies.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed rule change will not affect revenue collections of state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

The proposed rule changes will authorize producers of marijuana products to include raw marijuana products among the items they may distribute to marijuana pharmacies. The marijuana pharmacies may sell raw marijuana products pursuant to recommendations, subject to certain dispensing limitations. The addition of new products and dosage forms may increase sales transactions in pharmacies, however, additional product selection may lead to substitutional rather than additive sales. This rule does not directly influence existing recommendation volume by prescribers.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

To the extent the addition of new products and dosage forms increases the number of sales transactions in marijuana pharmacies, it is possible the pharmacies may need to hire more employees, which would improve employment opportunities in those geographical areas. The proposed rule changes may also stimulate price competition among the marijuana pharmacies.

**FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET**

Person Preparing Statement:	Malcolm J. Broussard Executive Director	Dept.: Dept. of Health
Telephone:	225.925.6481	Office: Board of Pharmacy
Return Address:	3388 Brentwood Drive Baton Rouge, LA 70809	Title: Raw Marijuana Products
		Effective Date of Rule: Upon promulgation May 2022 (est.)

SUMMARY
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed rule changes will require the Louisiana Board of Pharmacy (LBP) to publish the proposed and final rules in the state register, resulting in printing expenses of \$1,000 in FY 22. There will be no additional expenditures or cost savings for LBP or other state or local governmental units.

The proposed rule changes authorize the use of raw marijuana products, establish laboratory and testing standards and permissible dosage forms for such products, as well as dispensing limitations for such products at marijuana pharmacies. Other proposed rule changes include an allowance for the temporary placement of marijuana products outside safes and vaults but within the prescription department to facilitate efficient dispensing operations in marijuana pharmacies.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed rule change will not affect revenue collections of state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NON-GOVERNMENTAL GROUPS (Summary)

The proposed rule changes will authorize producers of marijuana products to include raw marijuana products among the items they may distribute to marijuana pharmacies. The marijuana pharmacies may sell raw marijuana products pursuant to recommendations, subject to certain dispensing limitations. The addition of new products and dosage forms may increase sales transactions in pharmacies, however, additional product selection may lead to substitutional rather than additive sales. This rule does not directly influence existing recommendation volume by prescribers.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

To the extent the addition of new products and dosage forms increases the number of sales transactions in marijuana pharmacies, it is possible the pharmacies may need to hire more employees, which would improve employment opportunities in those geographical areas. The proposed rule changes may also stimulate price competition among the marijuana pharmacies.

Malcolm Broussard
Executive Director, Louisiana
Board of Pharmacy
2022.01.31 14:10:17 -06'00'

Signature of Agency Head or Designee

Malcolm J. Broussard, Executive Director
Typed Name and Title of Agency Head

January 31, 2022
Date of Signature


Legislative Fiscal Officer or Designee

2/1/22
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

The proposed rule changes authorize the use of raw marijuana products, establish laboratory and testing standards and permissible dosage forms for such products, as well as dispensing limitations for such products at marijuana pharmacies. Other proposed rule changes include an allowance for the temporary placement of marijuana products within the prescription department to facilitate efficient dispensing operations in marijuana pharmacies.

- B. Summarize the circumstances, which require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

Act 424 of the 2021 Legislature amended the state medical marijuana program law to authorize the use of raw or crude marijuana for therapeutic use and establish laboratory testing standards for such products. The act also established dispensing limitations for such products. The Board proposes to amend the medical marijuana rules to incorporate the provisions of the legislation, and to make other changes requested by various program stakeholders. A copy of the legislation is attached.

- C. Compliance with Act 11 of the 1986 First Extraordinary Session

- (1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

LBP has allocated \$1,000 for printing the Notice of Intent and the Rule. LBP operates on self-generated funds.

- (2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

- (a) _____ Yes. If yes, attach documentation.
- (b) No NO. If no, provide justification as to why this rule change should be published at this time

LBP operates on self-generated funds, and they have determined the proposed rule changes will implement the legislative mandates in Act 424 of the 2021 Legislature.

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

COSTS	FY 22	FY 23	FY 24
Personal Services			
Operating Expenses	\$ 1,000	None	None
Professional Services			
Other Charges			
Equipment			
Major Repairs & Constr.			
TOTAL	\$ 1,000	None	None
POSITIONS (#)			

2. Provide a narrative explanation of the costs or savings shown in "A. 1.", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

The proposed change will require LBP to print the Notice of Intent and Rule in the State Register at a cost of \$1,000 in FY 22.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

3. Sources of funding for implementing the proposed rule or rule change.

SOURCE	FY 22	FY 23	FY 24
State General Fund			
Agency Self-Generated	\$ 1,000	None	None
Dedicated			
Federal Funds			
Other (Specify)			
TOTAL	\$ 1,000	None	None

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

LBP has sufficient self-generated funds available to implement the proposed rule change.

B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.
2. Indicate the sources of funding of the local governmental unit, which will be affected by these costs or savings.

SOURCE	FY 22	FY 23	FY 24
State General Fund			
Agency Self-Generated			
Dedicated			
Federal Funds			
Other (Specify)			
TOTAL	None	None	None

The proposed rule change does not impact local governmental units.

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

REVENUE INCREASE/DECREASE	FY 22	FY 23	FY 24
State General Fund			
Agency Self-Generated			
Dedicated Funds*			
Federal Funds			
Local Funds			
TOTAL	None	None	None

*Specify the particular fund being impacted.

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A." Describe all data, assumptions, and methods used in calculating these increases or decreases.

The proposed rule changes will not affect revenue collections of state or local governmental units.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS

A. What persons, small businesses, or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

FISCAL AND ECONOMIC IMPACT STATEMENT WORKSHEET

The proposed rule changes will authorize producers of marijuana products to include raw marijuana products among the items they may distribute to marijuana pharmacies. The marijuana pharmacies may sell raw marijuana products pursuant to recommendations, subject to certain dispensing limitations. The addition of new products and dosage forms may increase the number of sales transactions in pharmacies which may improve their sales revenue. However, such sales are still contingent upon the availability and distribution of recommendations, which are not directly influenced by these rules. For this reason, the amount of such increase will vary by pharmacy and is indeterminable.

- B. Also provide an estimate and a narrative description of any impact on receipts and/or income resulting from this rule or rule change to these groups.

The addition of raw or crude marijuana products to the list of permissible dosage forms of marijuana products would increase the number and variety of marijuana products available for sale in marijuana pharmacies. The addition of new products and dosage forms desired by patients could increase sales in marijuana pharmacies and improve their sales revenue. The amount of such increases would vary from one pharmacy to another and are indeterminable until further information on prescriber behaviors are known.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

To the extent the addition of new products and dosage forms increases the number of sales transactions in marijuana pharmacies, it is possible the pharmacies may need to hire more employees, which would improve employment opportunities in those geographical areas. The proposed rule changes may also stimulate price competition among the marijuana pharmacies. A more complete picture of competition and employment impacts are contingent on marginal changes to recommendation volume by prescribers.