

NOTICE OF INTENT

**Department of Health
Office of Public Health**
Registration of Foods, Drugs, Cosmetics and
Prophylactic Devices
(LAC 49:501, 517, 519, 527, 529, 531, 533, and 535)

Under the authority of R.S. 40:4 and 40:5, and in accordance with R.S. 49:950 et seq., the Administrative Procedure Act, notice is hereby given that the state health officer, acting through the Louisiana Department of Health, Office of Public Health (LDH-OPH), intends to reenact and amend certain sections of Chapter 5 (Registration of Foods, Drugs, Cosmetics and Prophylactic Devices) of Title 49 (Public Health—Food, Drugs, and Cosmetics) of the Louisiana Administrative Code. The LDH/OPH finds it necessary to make changes to the Louisiana Administrative Code as a consequence of changes made to hemp regulations under Act No. 752 of the 2024 Louisiana Legislature. The following changes will modify the requirements to properly register these items, inspect firms that manufacture such items for human consumption, and conduct oversight of labeling, which could affect the health of Louisiana’s citizens and visitors.

This rule amends §501 and §§517–535 of Chapter 5 of Title 49—Public Health—Food, Drugs, and Cosmetics. §§517, 519, 533, and 535 are recodified with new requirement language and §§527-531 are deleted in accordance with the new statutory prohibition on the sale of hemp flower. New language is implemented in the current §§517- 535 to enact new requirements from the 2024 legislation. Changes to §501 amend existing definitions and add new definitions.

Title 49
PUBLIC HEALTH—FOOD, DRUGS, AND COSMETICS
Part I. Regulations

**Chapter 5. Registration of Foods, Drugs, Cosmetics and
Prophylactic Devices**

§501. Definitions
[Formerly 49:2.2100]

A. Unless otherwise specifically provided herein, the following words and terms used in this Chapter of Title 49, and all other Chapters of Title 49 which are adopted or may be adopted, are defined for the purposes thereof as follows.

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Adult- Use Consumable Hemp Product—Repealed.

* * *

Consumable Hemp Product—any product derived from industrial hemp that contains any cannabinoid, including cannabidiol or THC, and is intended for consumption or topical use. This special class of products includes, but is not limited to, the following: food, animal foods or feed, and pet products.

Consumable Hemp Products Database—repository of information on products and firms that are registered with the Cannabis Program of LDH/OPH that fall into the category of consumable hemp products.

* * *

Department—for the purposes of this Chapter, the Office of Public Health, Louisiana Department of Health.

* * *

Distillate—the product of condensation of an evaporated substance to produce a highly-concentrated solution

* * *

Industrial Hemp-Derived Cannabidiol Products (IHDCP)—Repealed.

Industrial Hemp-Derived Cannabidiol Products Database—Repealed.

* * *

Liquid Concentrate—concentrated water-soluble liquid containing THC components derived from consumable hemp that can be consumed directly or added to a food or beverage.

* * *

Package—container or wrapping in which any consumer commodity is enclosed for the purposes of display or delivery to retail purchasers; in the context of consumable hemp products, this term refers to a group of individual servings offered together as a single unit.

* * *

Serving—total quantity of discrete units or of liquid in a package a processor recommends for consumption at one time; in the context of consumable hemp products, this term refers to discrete (i.e., separate and completely unattached to other servings) pieces of a solid substance, containers of a beverage, or one milliliter of a tincture, extract or distillate designed for oral or sublingual use.

* * *

THC—any combination of tetrahydrocannabinol, THC components, and tetrahydrocannabinolic acid.

THC components—any isomer, analog or derivative of the tetrahydrocannabinol molecule.

Tincture—an extract of plant material produced using an organic solvent, frequently mixed with a carrier oil and optional flavorants to generate a finished product; this category does not include liquid concentrates, which are prohibited.

* * *

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1483(L), R.S. 40:4(A)(13), R.S. 40:5(A)(8)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968, amended by the

Department of Health, Office of Public Health, LR 46:358 (March 2020), LR 47:479 (April 2021), LR 48:1290 (May 2022), repromulgated LR 48:1583 (June 2022), amended LR 48:2982 (December 2022), amended by the Department of Health, Office of Public Health, LR 49:1940 (November 2023); amended LR 51:

§517. Registration of Consumable Hemp Products

A. The manufacturers or distributors of consumable hemp products must register each separate and distinct product with the department—annually and initially within 90 days of the effective date of these regulations or prior to marketing the products in the state of Louisiana, whichever comes first.

B. ...

C. In lieu of the annual examination and administration charge normally collected under R.S. 40:628(B), the applicant for a consumable hemp product registration must provide (both initially and on or before January 1 of each subsequent year) the department with a packet that includes:

1.-7. ...

8. for each separate and distinct product, a detailed written description of how individual servings will be packaged and marketed for sale. A product whose label fails to comply with §533 of this Chapter will not be registered. A product packaged, labeled, or marketed in a manner that physically or functionally combines individual servings, resulting in a functional or suggested product serving size that exceeds 5 milligrams of total THC per serving, shall not be registered and shall be subject to revocation of registration pursuant to §518 of this Chapter.

D. ...

E. No person is authorized to distribute any consumable hemp product in the state of Louisiana unless such product is currently registered and entered into the consumable hemp products database by the department, except that if a firm submits product labeling and supporting documentation for review to the department and does not receive a written response within 60 business days of that initial submission, the product may be sold after the sixtieth business day by any permitted wholesaler or retailer until the submitting party receives notice in writing from the department that the product in question is accepted or rejected for registration. Upon the expiration of the 60 business days, the department will send written notice, via electronic mail only, confirming the “pending” status of any application and, if known, a date by which a final determination will be made

F. Any firm may apply with the department for the designation of its products as “Louisiana Hemp Products,” provided that those products are produced from hemp grown in Louisiana and are processed at a Louisiana-based manufacturer. These items will be designated with a special mark on the department’s list of registered products once they have been registered with the department.

G. No consumable hemp product shall be registered if one or more of the following conditions concerning dosage vehicles apply:

1. it is explicitly or clearly intended or characterized as being for inhalation, or to facilitate same;

2. it is explicitly or clearly intended or characterized as being for subcutaneous or transdermal use, or to facilitate same;

3. it is explicitly or clearly intended or characterized as being for intravenous or intramuscular infusion or injection, or to facilitate same;

4. it is explicitly or clearly intended or characterized as being for rectal or vaginal insertion, including, but not limited to, vaginal or anal suppositories; this prohibition shall not apply to products that are topical personal lubricants; or

5. it includes floral hemp material, or constitutes a vape cartridge, vape pen, e-cigarette or a substantially similar item designed to facilitate inhalation;

6. it is a liquid concentrate; or

7. it is an alcoholic beverage as defined in R.S. 26:2.

H. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1483(L) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:359 (March 2020), amended by the Department of Health, Office of Public Health, LR 47:479 (April 2021), amended by the Department of Health, Office of Public Health, LR 48:1290 (May 2022), amended by the Department of Health, Office of Public Health, LR 48:2982 (December 2022), amended by the Department of Health, Office of Public Health, LR 49:1940 (November 2023), amended LR 51:

§519. Consumable Hemp Products Labeling Requirements: Certificate of Analysis

A. Consumable hemp products must bear labeling that includes a scannable bar code, QR code, or a web address linked to a document or website containing the certificate of analysis for that product.

B. – C.4. ...

5. a cannabinoid profile for the finished product listing all major cannabinoid constituents by percentage of dry weight;

6-10.d. ...

11. a cannabinoid profile for the “active ingredient” (cannabinoid-containing distillate or isolate used in formulating the finished product) listing all major cannabinoid constituents by percentage of dry weight.

D. Repealed.

E. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1483(L) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:359 (March 2020), amended LR 47:480 (April 2021), LR 48:1291 (May 2022), amended LR 48:2982 (December 2022), amended LR 50:395 (March 2024); amended LR 51:

§527. Consumable Hemp Products Labeling Requirements: Marketing for Inhalation Prohibited

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 47:480 (April 2021), amended LR 48:1291 (May 2022); repealed LR 51:

§529. Consumable Hemp Products Packaging Requirements: Hemp Flower Packaging

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1483(J) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:1291 (May 2022); repealed LR 51:

§531. Consumable Hemp Products Labeling Requirements: Adult Use Products

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1483 and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2983 (December 2022); repealed LR 51:

§533. Consumable Hemp Products Labeling and Packaging Requirements: Serving Sizes, Packaging Limits, and THC Content

- A. Labeling must clearly indicate the amount of THC per serving in a product, the serving size, and the number of servings per package.
- B. Consumable hemp beverages must meet the following requirements:
 - 1. A serving must be 12 fluid ounces or greater.
 - 2. A serving must not include more than 5 mg THC.
 - 3. A container may not contain more than one serving.
 - 4. A container must be tamper-evident.
 - 5. A package may not include more than four containers.
- C. Consumable hemp tinctures must meet the following requirements:
 - 1. A serving must be one milliliter and may not contain more than one milligram of THC.
 - 2. A container may not exceed 30 milliliter.
 - 3. Containers must include a dropper that readily dispenses precisely one serving.
 - 4. Must be oil-based and may not include any concentrated water-soluble liquid that can be consumed directly or added to any food or beverage.
 - 5. Packaging must be child-resistant by design.
- D. Products other than beverages and tinctures must meet the following requirements:
 - 1. An individual serving must not include more than 5 mg THC.
 - 2. A package must not contain more than 40 mg THC.
 - 3. Packaging must be child-resistant by design.
- E. Packaging of consumable hemp products may not be designed explicitly to appeal to children by means of the employment of naming, branding, or use of a logo bearing a substantial similarity to that of conventional food or beverage products already on the market.
- F. Labeling on THC-containing products must bear a disclaimer that consumption of such products may cause the user to fail a pre-employment or routine drug screen.
- G. Nonedible topical consumable hemp products shall not be subject to the requirements of this Section.
- H. Products registered prior to the effective date of this rule that do not meet the requirements of this Section may be sold until January 1, 2025.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1483 and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:2982 (December 2022), amended by the Department of Health, Office of Public Health, LR 49:1940 (November 2023), amended LR 51:

§535. Penalties for Violations of Requirements to Register Consumable Hemp Products [Formerly §531]

A. Any person who violates the provisions requiring registration of consumable hemp products is subject to the penalties provided for by R.S. 3:1482 and other sanctions as provided for by the State Food, Drug, and Cosmetic Law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1483 and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:359 (March 2020), amended by the Department of Health, Office of Public Health, LR 47:480 (April 2021), amended by the Department of Health, Office of Public Health, LR 48:1290 (May 2022), amended by the Department of Health, Office of Public Health, LR 48:2982 (December 2022), amended by the Department of Health, Office of Public Health, LR 49:1940 (November 2023), amended LR 51:

Family Impact Statement

The proposed Rule should not have any known or foreseeable impact on family formation, stability, and autonomy. In particular, the proposed Rule has no known or foreseeable impact on:

1. the stability of the family;
2. the authority and rights of persons regarding the education and supervision of their children;
3. the functioning of the family;
4. family earnings and family budget;
5. 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.

Poverty Impact Statement

The proposed Rule should not have any known or foreseeable impact on any child, individual or family as defined by R.S. 49:973(B). In particular, there should be no known or foreseeable effect on:

1. the effect on household income, assets, and financial security;
2. the effect on early childhood development and preschool through postsecondary education development;
3. the effect on employment and workforce development;
4. the effect on taxes and tax credits;
5. the effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

Small Business Analysis

The proposed Rule should have no adverse impact on small businesses as defined in the Regulatory Flexibility Act.

Provider Impact Statement

The proposed Rule should not have any known or foreseeable impact on providers as defined by HCR 170 of the 2014 Regular Legislative Session. In particular, there should be no known or foreseeable effect on:

1. the effect on the staffing level requirements or qualifications required to provide the same level of service;
2. the total direct and indirect effect on the cost to the providers to provide the same level of service; or
3. the overall effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments on the proposed rule. Such comments must be received no later than Monday, November 11, 2024 at COB, 4:30 pm, and should be addressed to Tiffany Meche, Director, Sanitarian Services, P.O. Box 4489, Baton Rouge, LA 70821.

Public Hearing

Interested persons may submit a written request to conduct a public hearing either by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on Monday, November 11, 2024. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 10 am on Monday, December 2, 2024, in Room 118 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Allen Enger at (225) 342-1342 after Monday, November 11, 2024. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing attendees when the parking ticket is presented to LDH staff at the hearing.

Michael Harrington, MA, MBA
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

Person
Preparing
Statement: Brian R. Warren Dept.: Louisiana Department of Health

Phone: 225-342-7545 Office: Office of Public Health

Return
Address: 628 N. 4th Street,
Baton Rouge, LA 70802 Rule Title: Registration of Foods, Drugs,
Cosmetics, and Prophylactic Devices

Date Rule Takes Effect: January 20, 2025

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)

Besides the cost of publishing, the proposed rule change is anticipated to result in implementation costs or savings. The cost of rulemaking is anticipated to increase expenditures for the Office of Public Health (OPH) by approximately \$905 in FY 24-25 for the publication of the proposed rule. It is not anticipated that any other state or local governmental units will incur costs or savings as a result of this rule change.

The proposed rule amends the requirements for regulating consumable hemp product manufacturing and distribution as required by Act 752 of the 2024 Louisiana Legislature.

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

There will be no effect on revenue collections of state or local governmental units as a result of this proposed rule.

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

It is anticipated that this proposed rule will significantly constrict the market in terms of what products may be available to consumers and this will have a detrimental impact on industry stakeholders.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The adoption of this proposed rule will have an effect on competition because it limits the number of retailers which would effect competition.

Signature of Agency Head or Designee

Tonya Joiner
Assistant Secretary, Office of Public Health
Typed Name & Title of Agency Head or Designee

Legislative Fiscal Officer or Designee

Date of Signature

Date of Signature