



State of Louisiana
Louisiana Department of Health
Office of the Secretary

January 10, 2022

Via Statutorily Prescribed Email

To: The Honorable Fred H. Mills, Jr., Chairman, Senate Health & Welfare Committee
The Honorable Larry Bagley, Chairman, House Health & Welfare Committee

From: Dr. Courtney N. Phillips
Secretary

Re: Second Report Proposed Amendments to LAC 49:501, 517, 519, 521, 523, 525, 527, 529 – Registration of Food, Drugs, Cosmetics and Prophylactic Devices

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Office of Public Health, submits its second report regarding the proposed amendments to LAC 49:501, 517, 519, 521, 523, 525, 527, 529 – Registration of Food, Drugs, Cosmetics and Prophylactic Devices.

A Notice of Intent on the proposed amendments was published in the November 20, 2021 issue of the *Louisiana Register* (LR 47:1769). No written comments were received and there was no request for a public hearing were received during the notice period. Because there were no requests for a public hearing, one was not held for these proposed amendments. Additionally, no substantive changes were made to the proposed amendments since the report provide for in R.S. 49:968B-C was submitted.

Unless otherwise directed, the Department anticipates adopting the November 20, 2021, Notice of Intent when it is published as a final rule in the February 20, 2022, issue of the *Louisiana Register*.

Please contact Brian R. Warren, at brian.warren@la.gov, if you have any questions or require additional information about this matter.

Cc: Kimberly Hood, JD, MPH, Assistant Secretary OPH, LDH
Joseph Kanter, MD, MPH, State Health Officer, LDH
Melissa Mendoza, JD, MPH, OPH Legislative and Regulatory Affairs, LDH
Aliya Rubenstein, JD, MPH, OPH Rulemaking Liaison, LDH
Veronica Dent, Medicaid Program Manager, LDH
Bethany Blackson, Legislative Liaison, LDH
Catherine Brindley, Editor, *Louisiana Register*, Office of the State Register

and floor calculations. It is anticipated that implementation of this proposed rule will not result in costs to nursing facilities for FY 21-22, FY 22-23, and FY 23-24, but will be beneficial by ensuring that the requirements for cost reports are clearly and accurately promulgated in the Louisiana Administrative Code.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

~~This rule has no known effect on competition and employment.~~

Patriek Gillies
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Alan M. Boxberger
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NOTICE OF INTENT

**Department of Health
Office of Public Health**

**Registration of Foods, Drugs, Cosmetics and
Prophylactic Devices (LAC 49:1.Chapter 5)**

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 recodify parts of Chapter 5 of Title 49—Public Health—Food, Drugs, and Cosmetics and to amend those rules to comply with the requirements of Act 336 of the 2021 Regular Legislature.

This rule amends §501 and §§517-525 of Chapter 5 of Title 49—Public Health—Food, Drugs, and Cosmetics. §§527-529 are recodified with new requirement language and the original §§527-529 are relocated to §§531-533. Changes to §501 amend existing definitions and add new definitions. Changes to §§517-533 reflect changes to the name of hemp-derived products regulated by the department as well as changes to the statutory requirements.

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.

Certificate of Consumable Hemp Product Registration (FD-8a)—certificate issued by the department attesting that consumable hemp products produced or distributed by the holder’s company have been registered as required

Consumable Hemp Product—any product derived from industrial hemp that contains any naturally-occurring cannabinoid, including cannabidiol, 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, hemp flower, and pet products. No consumable hemp product may contain a total THC concentration in excess of one percent on a dry-weight basis.

Consumable Hemp Products Database—repository of information on products and firms that are registered with the Food and Drug/Milk and Dairy Unit of LDH/OPH that fall into the category of consumable hemp products.

Industrial Hemp—the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a total delta-9 THC concentration of not more than 0.3 percent on a dry weight basis.

THC—a combination of tetrahydrocannabinol and tetrahydrocannabinolic acid.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J), R.S. 40:4(A)(13), R.S. 40:5(A)(8)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by the Louisiana State Board of Health, September 1968, amended by the Department of Health, Office of Public Health, LR 46:358 (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 47:

§517. Registration of Consumable Hemp Products

A. In accordance with the provisions of R.S. 3:1482 as promulgated by the 2021 Legislature, 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 remit to (both initially and on or before July 1 of each year) the department the amount of \$50 per each separate and distinct product. The initial application packet will consist of the required remittance in a form deemed acceptable by the department, a completed application form, specimen copies of each product label in paper or electronic form, and a list of products the firm intends to register with the department. If the packet meets these regulatory requirements and the other requirements described in these regulations, the department will issue to the applicant an FD-8a Certificate of Consumable Hemp Product Registration and the application information will be entered into the Consumable Hemp Products Database.

D. No person is authorized to distribute any consumable hemp products in the state of Louisiana unless that person has first obtained a Certificate of Consumable Hemp Product Registration from the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1482(J) 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 47:

**§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.10. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1482(J) 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 47:

§523. Consumable Hemp Products Labeling

Requirements: Medical Claims Prohibited

A. No product labeling or advertising material for any consumable hemp product sold or otherwise distributed in the state of Louisiana may bear any implicit or explicit medical claims.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1482(J) 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 48:

§525. Consumable Hemp Products Labeling

Requirements: Dietary Supplements Prohibited

A. No consumable hemp product may be marketed as a dietary supplement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1482(J) 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 48:

§527. Consumable Hemp Products Labeling

Requirements: Marketing for Inhalation Prohibited

A. No hemp flower consumable product may be marketed for inhalation purposes.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13).

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 48:

§529. Consumable Hemp Products Packaging

Requirements: Hemp Flower Packaging

A. Hemp flower consumable products for registration must be packaged in tamper-resistant packaging or with tamper-evident seals and must bear the phrase "not for inhalation" or similar language explicitly contraindicating that usage on the labeling.

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:

§531. Penalties for Violations of Requirements to Register Consumable Hemp Products **[Formerly §529]**

A. Any person who violates the provisions requiring registration of consumable hemp products is subject to the penalties provided for by the State Food, Drug, and Cosmetic Law (R.S. 40:601, et seq.) or other sanctions provided for by R.S. 3:1484.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1482(J) 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), LR 48:

§533. Exemptions

[Formerly §531]

A. Consumable hemp products that have been produced in accordance with R.S. 40: 1046 or that are Food and Drug Administration (FDA)-approved pharmaceuticals are not subject to the requirements of this regulation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(13), R.S. 3:1482(J) 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), LR 48:

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;

or

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; or
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 Small Business Protection 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 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, December 27, 2021 and should be addressed to Michael Vidrine, 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 Friday, December 10, 2021. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9:00AM on Monday, December 27, 2021 in Room 173 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 Friday, December 10, 2021. 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 the Bienville Building's front security desk.

Dr. Courtney N. Phillips
Secretary

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES
RULE TITLE: Registration of Foods, Drugs, Cosmetics
and Prophylactic Devices**

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

The Office of Public Health (OPH) will incur \$6,872 in expenses (\$906 for publication costs, \$350 for supplies, and \$5,616 for equipment) associated with this proposed rule change. The expenses will be paid with Self-generated Revenue.

To the extent that this rule change results in an additional workload to OPH that cannot be absorbed either wholly or partially using existing staff, the agency may need to hire additional staff. It is anticipated that OPH will use the revenue generated from licensing consumable hemp processors and the registration of products to cover these costs. However, if the revenue generated from these fees is not sufficient to cover the cost of additional staff, State General Fund will be used.

The proposed rule implements the regulatory framework for industrial hemp-derived cannabidiol products, as required by Act 336 of the 2021 RLS. This proposed rule amends Chapter 5 of Title 49—Public Health--Food, Drugs, and Cosmetics. The proposed amendments expand the categories of products derived from hemp that will be legal to sell in Louisiana.

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

The rule expands the categories of products derived from hemp that will be legal to sell in Louisiana. These products will require a product label, which must be registered with OPH. OPH charges a product label registration fee of \$50.

To the extent that this rule change results in more consumable hemp processors, these facilities will need to apply for a license from OPH. The license fee on consumable hemp processors for each separate processing facility is based on annual sales and ranges from a minimum of \$175 up to a maximum of \$1,375.

The total revenue generated as a result of this rule change cannot be determined, as it depends on the number of additional products registered and the number of consumable hemp processor licenses that will be granted, which is unknown.

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

It is anticipated that this proposed rule will affect owners of businesses that sell products derived from hemp. The estimated costs or benefits are unknowable at this time; however, manufacturers and retailers of consumable hemp products are expected to experience an increase in income resulting from the increased sale of consumable hemp products.

**IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT
(Summary)**

This proposed rule will broaden the scope of the market of legal consumable hemp products in the state by manufacturers and retailers. Possibly, if there is a large public demand for consumable hemp products, manufacturers and retailers of same may find it necessary to employ additional staff to handle the increased demand. The adoption of this proposed rule should not engender or have any effect on competition among manufacturers and retailers of consumable hemp products.

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Alan M. Boxberger
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Legislative Fiscal Office

NOTICE OF INTENT

**Department of Public Safety and Corrections
Office of Motor Vehicles**

**Designations or Restrictions on Driver's Licenses
and Identification Cards (LAC 55:III.108)**

~~Under the authority of R.S. 37:3270 et seq., and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., the Office of Motor Vehicles, hereby proposes to amend section 108 under Chapter 1 to implement a more comprehensive version of Title 55 as it relates to the rules governing designations or restrictions on driver's licenses and identification cards. In addition to a more comprehensive version of the rules governing driver's licenses and identification cards, the Office of Motor Vehicles implements Act 137 of the 2020 Regular Legislative Session regarding a designation for applicants with autism spectrum disorder.~~

Title 55

PUBLIC SAFETY

Part III. Motor Vehicles

Chapter 1. Driver's License

Subchapter A. General Requirements

**§108 Designations or Restrictions on Driver's
Licenses and Identification Cards**

~~A. A.6.~~