John Bel Edwards
GOVERNOR

Dr. Courtney N. Phillips
SECRETARY

State of Louisiana

Louisiana Department of Health
Office of the Secretary

January 8, 2021

Via Statutorily Required Email

To: The Honorable Patrick Cortez, President, Louisiana Senate
The Honorable Clay Schexnayder, Speaker, Louisiana House of Representatives
The Honorable Chairman Fred H. Mills, Jr., Senate Health & Welfare Committee
The Honorable Chairman Larry Bagley, House Health & Welfare Committee

From: Dr. Courtney N. Phillips
Secretary

Re: First Report: Proposed Amendments to LAC 49:501, 503, 509, 513, 517, 519, 521, 527, 529, 531 – Registration of Foods, Drugs, Cosmetics, and Prophylactic Devices

Under the authority of the laws of the State of Louisiana and in accordance with the provisions of Chapter 6 of Title 36 of the Louisiana Revised Statutes of 1950, and with the Administrative Procedure Act, La. R.S. 49:950 *et seq.*, the secretary hereby gives notice that rulemaking procedures have been initiated to promulgate amendments to the rules governing the administration of Registration of Foods, Drugs, Cosmetics, and Prophylactic Devices.

I. Copy of the rule as it is proposed after amendment, with new proposed language indicated by the underscored text and deleted language indicated by the strike-through type.

See attachment.

II. A statement of the proposed action.

This rule will provide the regulatory framework for the registration of industrial-hemp-derived cannabidiol products and the inspection of facilities manufacturing industrial-hemp-derived cannabidiol products by the department, as mandated by Act 344 of the 2020 Legislature.

III. Specific citation of law authorizing promulgation of the rule.

Act 344 of the 2020 Louisiana Legislature; R.S. 3: 1483

IV. Circumstances which require the amendment of the rule.

Act 344 requires the department to promulgate rules outlining policies needed to enforce the stipulations of the legislation.

V. Statement of Fiscal and Economic Impact.

See attachment.

Please contact Aliya Rubenstein, at aliya.rubenstein@la.gov, if you have any questions or require additional information about this matter.

Attachments (2)

Cc: Joseph Kanter, MD, MPH, Interim Assistant Secretary, OPH
Aliya Rubenstein, Rulemaking Liaison, OPH
Melissa Mendoza, Legislative and Regulatory Affairs Director, OPH
Anita Dupuy, Legislative Liaison, LDH
Catherine Brindley, Editor, *Louisiana Register*, Office of the State Register

NOTICE OF INTENT

Department of Health
Office of Public Health

Registration of Foods, Drugs, Cosmetics and Prophylactic Devices
LAC 49:501, 503, 509, 513, 517, 519, 521, 527, 529, 531

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 adopt one new Section and amend certain existing 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. This proposed rule will update LDH-OPH's currently existing rule pertaining to industrial hemp-derived cannabidiol products (IHDCP). This rulemaking is proposed pursuant to Section 1483 of Title 3 of the Revised Statutes of 1950, enacted as part of Act 344 of the 2020 Regular Session of the Louisiana Legislature.

For the reason set forth above, the following proposed additions and amendments to LAC 49 are hereby proposed to be adopted.

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 Registration (FD-8)—certificate issued by the department attesting that products produced or distributed by the holder's company have been registered as required.

Certificate of IHDCP Registration (FD-8a)—certificate issued by the department attesting that IHDCP produced or distributed by the holder's company have been registered as required.

* * *

Dietary Supplement—~~means~~ a product other than tobacco intended to supplement the diet that is not represented for use as a conventional food, that is not a drug, and that is labeled as a dietary supplement and bears or contains one or more of the following dietary ingredients or a concentrate, metabolite, constituent, extract, or combination thereof: a vitamin, a mineral, a botanical, an amino acid, or a dietary substance for use by man to supplement the diet by increasing the total dietary intake.

* * *

Federally defined THC level for hemp—the greater of the following:

a. A delta-9 THC concentration of not more than 0.3 percent on a dry weight basis.

b. The THC concentration for hemp defined in 7 U.S.C. 1639o.

* * *

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 delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis~~ no more than the federally defined THC level for hemp.

Industrial Hemp-Derived Cannabidiol Products (IHDCP)—any industrial-hemp derived product that contains CBD intended for consumption or ~~human~~ topical use ~~and containing cannabidiol that was made from industrial hemp~~.

* * *

THC—delta-9 tetrahydrocannabinol, tetrahydrocannabinolic acid, or a combination of both.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:14832(J), R.S. 40:5(A)(8)(15)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by the ~~Department of Health and Human Resourdes, Office of Preventive and Public Health Services~~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:

§503. Registration Provisions
[Formerly 49:2.2110]

A. In accordance with the provisions of R.S. 40:627, each manufacturer, packer or proprietor of processed foods, drugs, proprietary or patent medicines, prophylactic devices and cosmetics in packaged form shall register each separate and distinct product annually with the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:14832(J), R.S. 40:5(A)(8)(15)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by the ~~Department of Health and Human Resourdes, Office of Preventive and Public Health Services, ~~,~~~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:

§509. Product Registration Procedure
[Formerly 49:2.2140]

A. In accordance with the provisions of R.S. 40:627 and 628 and in order to establish revised procedures for the annual registration of products, manufacturers, packers, processors and distributors of all processed foods, drugs, proprietary or patent medicines, prophylactic devices and cosmetics in packaged form, whose names appear on the labels, must submit an application for registration of such products on or before July 1 of each year. Certificates of registration will be issued to each firm for a period of one year expiring on June 30 of each year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:14832(J), R.S. 40:5(A)(8)(15)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by the ~~Department of Health and Human Resources, Office of Preventive and Public Health Services,~~ Louisiana State Board of Health, September 1968, amended by the Department of Health and Human Resources, Office of Health Services and Environmental Quality, ~~LR 10:9 (January 1984),~~ LR 9:562 (August 1983), LR 10:9 (January 1984), amended by the Department of Health and Human Resources, Office of Preventive and Public Health Services LR 11:1161 (December 1985), 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:

§513. Late Registration Penalty—New Firms [Formerly 49:2.2160]

~~A. The late penalty fees will be assessed to new firms found doing business in Louisiana which, after being duly notified and allowing 45 days to respond to first notifications, do not remit the appropriate application and fees within 45 days after having been sent a final notification.~~ Repealed.

AUTHORITY NOTE: Promulgated in accordance with ~~Louisiana Revised Statutes of 1950, Title 40, as amended~~R.S. 3:1483(J), R.S. 40:5(A)(8)(15)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by the ~~Department of Health and Human Resources, Office of Preventive and Public Health Services~~Louisiana State Board of Health, September 1968, amended by the Department of Health and Human Resources, Office of Health Services and Environmental Quality, ~~LR 10:9 (January 1984),~~ LR 9:562 (August 1983), LR 10:9 (January 1984),amended by the Department of Health and Human Resources, Office of Preventive and Public Health Services LR 11:1161 (December 1985)~~.~~, repealed by the Department of Health, Office of Public Health, LR 47:

§517. Registration of Industrial Hemp-Derived Cannabidiol Products

A. In accordance with the provisions of R.S. 3:~~14821483~~ as promulgated by the ~~2019 Legislature~~2020 Legislature, manufacturers or distributors of industrial hemp-derived cannabidiol 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 an industrial hemp-derived cannabidiol product registration must ~~provide~~ remit to (both initially and on or before July 1 of each year) the department ~~with an application form, a cashier's check or money order made payable to the department in~~ the amount of $50 per each separate and distinct CBD product~~, specimen copies of labeling in paper or electronic format, and a list of all products the applicant wishes to register with the department~~. 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

IHDCP (Industrial Hemp-Derived Cannabidiol Products) Registration and the application information will be entered into the Industrial Hemp-Derived Cannabidiol Products Database.

D. No person is authorized to distribute any industrial hemp-derived cannabidiol products regulated by the department in the state of Louisiana unless that person has first obtained a Certificate of IHDCP Registration from the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:14832~~2~~(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:

§519. Industrial Hemp-Derived Cannabidiol Products Labeling Requirements: Certificate of Analysis

A. …

B. The certificate of analysis must be from a laboratory that is accredited by the Louisiana Department of Health, Office of Public Health (LDH/OPH). Accreditation will be demonstrated by the availability of a current audit from a third-party entity indicating that the laboratory meets the criteria specified in Standard 17025 of the accrediting body.

C. — C.10. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:14832~~2~~(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:

§521. Industrial Hemp-Derived Cannabidiol Products Labeling Requirements: Disclaimer

~~A. Each primary container of industrial hemp-derived cannabidiol product must bear the following statement: "This product has not been evaluated by the Food and Drug Administration and is not intended to diagnose, treat, cure, or prevent any disease."~~Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:14832~~2~~(J) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:359 (March 2020)~~.~~, repealed by the Department of Health, Office of Public Health, LR 47:

§527. ~~Penalties for Violations of Requirements to Register~~ Industrial Hemp-Derived Cannabidiol Products Requirements: Prohibited Dosage Vehicles/Forms

A. ~~Any person who violates the provisions requiring registration of industrial hemp-derived cannabidiol products is subject to the penalties provided for by R.S. 3:1484 and other sanctions as provided for by the State Food, Drug, and Cosmetic Law.~~No industrial hemp derived cannabidiol product will be registered when one or more of the following criteria regarding the product is applicable:

1. it is a food or beverage or it is explicitly intended to be added to a food or beverage;
2. it is explicitly intended for inhalation;
3. it is explicitly intended for subcutaneous or transdermal use;
4. it is explicitly intended for intravenous or intramuscular infusion or injection;

5. it is explicitly intended for rectal insertion;

6. it contains one or more active pharmaceutical ingredients, other than CBD, in approved over-the-counter pharmaceuticals; or

7. it is a product that would not otherwise be registered by the department if it did not contain industrial hemp-derived cannabidiol, including raw plant materials, aromatherapy products not intended for topical use, candles, or products intended for animal use.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:14832(J) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:360 (March 2020), amended by the Department of Health, Office of Public Health, LR 47:

§529. ~~Exemptions~~Penalties for Violations of Requirements to Register Industrial Hemp-Derived Cannabidiol Products

A. ~~Industrial hemp-derived cannabidiol 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~~.Any person who violates the provisions requiring registration of industrial hemp-derived cannabidiol products is subject to the penalties provided for by the State Food, Drug, and Cosmetic Law (R.S. 40:601, et seq.).

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:14832(J) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:360 (March 2020), amended by the Department of Health, Office of Public Health, LR 47:

§531. Exemptions

A. Industrial hemp-derived cannabidiol 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. 3:1483(J) and R.S. 40:604.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 47:

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 Thursday, February 25, 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 Wednesday, February 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 Thursday, February 25, 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 Wednesday, February 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

Person Preparing Statement: Brian R. Warren
Phone: 225-342-7514
Return Address: 628 N. 4th Street, Baton Rouge, LA 70802

Dept.: Louisiana Department of Health
Office: Office of Public Health

Rule Title: Registration of Foods, Drugs, Cosmetics, and Prophylactic Devices

Date Rule Takes Effect: Upon promulgation

SUMMARY

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 change is anticipated to increase expenditures for the Office of Public Health (OPH) by approximately $1,025 in FY 21 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 updates the regulatory framework for industrial hemp-derived cannabidiol products, as required by Act 344 of the 2020 Regular Session of the Louisiana Legislature. Specifically, this rule updates definitions for industrial hemp, industrial hemp-derived cannabidiol products (IHDCP), and THC to align with federal law, repeals late fees for new industrial hemp business that do not remit appropriate application and late fees, provides clarification on the required components of initial IHDCP registration application packets, clarifies labeling requirements for IHDCP, and clarifies that persons violating IHDCP registration requirements may be subject to penalties as provided for by the State Food, Drug, and Cosmetic Law.

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

The proposed rule change is not estimated to impact revenue collections for state or local governmental units. The rule repeals late fees for new industrial hemp business that do not remit appropriate application and late fees. However, this has no impact on revenue collections because OPH never charged late fees to new businesses. The rule also clarifies that persons violating IHDCP registration requirements may be subject to penalties as provided for by the State Food, Drug, and Cosmetic Law. However, it does not change the amount penalty.

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

Implementation of this proposed rule change is not anticipated to have a cost or direct economic benefit to small businesses or non-governmental groups.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

There is no anticipated effect on competition and employment.

Signature of Agency Head or Designee

Joseph Kanter, MD, MPH
Interim Assistant Secretary, Office of Public Health
Typed Name & Title of Agency Head or Designee

1/6/21
Date of Signature

Legislative Fiscal Officer or Designee

1/7/21
Date of Signature