



State of Louisiana
Louisiana Department of Health
Office of the Secretary

March 10, 2021

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

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Bureau of Health Services Financing, submits its second report regarding the proposed Registration of Foods, Drugs, Cosmetics, and Prophylactic Devices – LAC 49:501, 503, 509, 513, 517, 519, 521, 527, 529, 531.

A Notice of Intent on the proposed amendments was published in the January 20, 2021 issue of the *Louisiana Register* (LR 47:148). 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 January 20, 2021, Notice of Intent when it is published as a final rule in the April 20, 2021, issue of the *Louisiana Register*.

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

Cc: Kimberly Hood, JD, MPH, Assistant Secretary, OPH
Aliya Rubenstein, Rulemaking Liaison, OPH
Melissa Mendoza, Legislative and Regulatory Affairs Director, OPH
Bethany Blackson, LDH Legislative Liaison
Catherine Brindley, Editor, *Louisiana Register*, Office of the State Register

have no impact on the staffing level requirements or qualifications required to provide the same level of service, but may reduce the total direct and indirect cost to some providers to provide the same level of service, and may enhance those provider's ability to provide the same level of service as described in HCR 170 since this Emergency Rule increases payments to some providers for the same services they already render.

Public Comments

Interested persons may submit written comments to Tara A. LeBlanc, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821 9030. Ms. LeBlanc is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on March 1, 2021.

Public Hearing

Interested persons may submit a written request to conduct a public hearing 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 February 9, 2021. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9:30 a.m. on February 28, 2021 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 February 9, 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 (eater 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.

Dr. Courtney N. Phillips
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

RULE TITLE: Professional Services Program Reimbursement Methodology

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

It is anticipated that implementation of this proposed rule will result in increased state costs of approximately \$42,148 for FY 20 21, \$168,974 for FY 21 22 and \$179,847 for FY 22 23. It is anticipated that \$1,296 (\$648 SGF and \$648 FED) will be expended in FY 20 21 for the state's administrative expense for promulgation of this proposed rule and the final rule.

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

It is anticipated that the implementation of this proposed rule will increase federal revenue collections by approximately \$86,527 for FY 20 21, \$356,935 for FY 21 22, and \$379,900 for FY 22 23. It is anticipated that \$648 will be collected in FY 20 21 for the federal share of the expense for promulgation of this proposed rule and the final rule.

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

This proposed rule amends the provisions governing reimbursement in the Professional Services Program in order to remove information related to programs no longer in operation, remove provisions that are located in other places within the Louisiana Administrative Code, clarify the reimbursement methodology for certain provider types and services, and to provide for a restoration of the reimbursement rates for neonatal critical care services which were previously reduced. Providers of neonatal critical care services will benefit from the increase in reimbursement rates. It is anticipated that implementation of this proposed Rule will increase payments in the Professional Services Program by approximately \$127,379 for FY 20 21, \$525,909 for FY 21 22, and \$559,747 for FY 22 23.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Tara A. LeBlanc
Interim Medicaid Director
2012#050

Alan M. Boxberger
Legislative Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Department of Health Office of Public Health

Registration of Foods, Drugs, Cosmetics and
Prophylactic Devices
(LAC 49: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 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—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 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 topical use.

* * *

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

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1483(J), R.S. 40:5(A)(8)(15)(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:

§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. 3:1483(J), R.S. 40:5(A)(8)(15)(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), 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. 3:1483(J), R.S. 40:5(A)(8)(15)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by the Louisiana State Board of Health, September 1968, amended by the Department of Health and Human Resources, Office of Health Services and Environmental Quality, 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), LR 47:

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

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1483(J), R.S. 40:5(A)(8)(15)(17) and R.S. 40:604.

HISTORICAL NOTE: Adopted by the Louisiana State Board of Health, September 1968, amended by the Department of Health and Human Resources, Office of Health Services and Environmental Quality, 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. 3:1483as promulgated by the 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 remit to (both initially and on or before July 1 of each year) the department the amount of \$50 per each separate and distinct CBD 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 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. 3:1483(J) 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:

§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. 3:1483(J) 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:

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

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 46:359 (March 2020), repealed LR 47:

§527. Industrial Hemp-Derived Cannabidiol Products Requirements: Prohibited Dosage Vehicles/Forms

A. 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. 3:1483(J) and R.S. 40:604.

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

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

A. 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. 3:1483(J) and R.S. 40:604.

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

RULE TITLE: Registration of Foods, Drugs, Cosmetics and Prophyllactic Devices

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

Joseph Kanter, MD, MPH
Interim Assistant Secretary
2012#038

Alan M. Boxberger
Legislative Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Department of Natural Resources Office of Coastal Management

Local Coastal Management Programs (LAC 43:1.725)

~~Under the authority of R.S. 49:214.21 49:214.41 and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:450 et seq., notice is hereby given that the Department of Natural Resources, Office of Coastal Management proposes to amend LAC 43:725 relative to the rules and procedures for local coastal management programs. Amendments include updating procedural information, clarifying funding mechanisms, and updating technical information.~~

Title 43

NATURAL RESOURCES

Part I. Office of the Secretary

Subpart 1. General

Subchapter D. Local Coastal Management Programs

§725. Development, Approval, Modification, and Periodic Review of Local Coastal Management Programs

~~A. Letter of Intent. Parishes intending to prepare a local coastal management program (LCMP) shall notify the secretary of DNR by sending a letter of intent approved by the parish Police Jury or Council.~~

~~B. Program Development~~

~~1. The process for developing a local program will consist of:~~

~~a. a division of the parish's coastal zone into units that have similar environmental and natural resource characteristics (environmental management units) and an identification and mapping of the features, resources, and resource users of those units;~~

~~b. an analysis of the projected social and economic growth for the parish. This analysis should include projected population growth, economic analysis of coastal dependent industries, estimated demand for and use of land, and an assessment of how these projected changes will affect the natural resources of each management unit as well as the parish as a whole;~~

~~c. an identification of existing and potential resource use conflicts including their location and severity. Identified problems should be mapped to the extent possible;~~

~~d. an identification of special management areas, if any, within the parish requiring special management needs~~