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 OR NONGOVERNMENTAL GROUPS (Summary)

This proposed Rule amends the provisions governing cost reports for nursing facilities in order to establish guidelines for submitting amended cost reports and to ensure that the appropriate cross-walk is used to calculate the provider’s rate 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.

Patrick Gillies
Medicaid Executive Director
2111#036
Alan M. Boxberger
Deputy Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT
Department of Health
Office of Public Health

Registration of Foods, Drugs, Cosmetics and Prophylactic Devices (LAC 49:1.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 in 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.

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.


§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.

§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. A. Consumable hemp products for inhalation purposes.

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

B. 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.

A. No hemp flower consumable product for inhalation purposes.

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.

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

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.

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.

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.

A. Consumable hemp products for inhalation purposes.

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

Kim Hood, JD, MPH
Assistant Secretary
2110#043

Alan M. Boxberger
Deputy Fiscal Officer
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. …