

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

It is anticipated that the implementation of this proposed rule will not affect federal revenue collections as this measure has no impact on licensing or Healthcare Facility Sanctions (HFS) fees.

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

This proposed rule amends provisions governing HFS in order to define the terms sanction and repeat violation. It is anticipated that implementation of this proposed rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service, no direct or indirect cost to providers to provide the same level of service, and will have no impact on the providers' ability to provide the same level of service.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

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

Tasheka Dukes, RN
Deputy Assistant Secretary
2410#073

Patrice Thomas
Deputy Fiscal Officer
Legislative Fiscal Office

PROPOSED RULE
Department of Health
Office of Public Health

Commercial Body Art (LAC 51:XXVIII.107)

Under the authority of R.S. 40:4 and 40:5 and 40:2831 et seq., 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~~^{ed} ~~has~~ amend Part XXVIII (Commercial Body Art) of Title 51. These amendments are being ~~proposed~~ to comply with the provisions of Act 365 of the 2024 Regular Legislature.

Title 51

PUBLIC HEALTH—SANITARY CODE

Part XXVIII. Commercial Body Art

Chapter 1. Commercial Body Art Regulation

§107. Practice Standards; Restrictions

[Formerly Paragraph 28:004]

A. [Formerly Paragraph 28:004-1] Prior to any body art procedure, a consent form shall be completed and signed by each client. This consent form shall include a prominent statement regarding the regulatory status of any inks being used for the procedure (i.e., whether those inks are regulated or approved by the state of Louisiana or the federal Food and Drug Administration). Aftercare instructions shall be given to the client both verbally and in writing after every service. The written care instructions shall advise the client to consult the body art operator or a qualified health care professional at the first sign of abnormal inflammation/swelling or possible infection.

B. - M. ...

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4, R.S. 40:5, and 40:2833.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1458 (June 2002), 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. 49:950. 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 providers 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 p.m., and should be addressed to: Meche, Director of Sanitarian Services, P.O. Box 4489, Baton Rouge, LA 70821-4489.

Public Hearing

Interested persons may submit a written request to conduct a public hearing either by letter 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 a.m. 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 comments, views, comments, or suggestions, 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.

Dr. Ralph Abraham
Surgeon General
and
Michael Harrington, M.A., MA
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: **Commercial Body Art**

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 cost savings. The cost of rulemaking is anticipated to increase expenditures for the Office of Public Health (OPH) by approximately \$266 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 a commercial body art consent form as required by Act 365 of the 2024 Regular Legislative Session of the 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 government units as a result of this proposed rule.

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

It is anticipated that the proposed rule will add a nominal cost to the business owners of commercial body art establishments.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The adoption of this proposed rule should not engender or have any effect on competition among commercial body art facility owners.

Tonya Joiner
Assistant Secretary
2410#051

Allen Enger
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:I.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 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.

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.
