



State of Louisiana
Department of Health and Hospitals
Office of Public Health

July 7, 2014

TO: The Honorable John A. Alario, President, Louisiana Senate
The Honorable David Heitmeier, Chair, Senate Committee on Health and Welfare
The Honorable, Jack Donahue, Chair, Senate Finance Committee
The Honorable Chuck Kleckley, Speaker of the House of Representatives
The Honorable Scott Simon, Chair, House Committee on Health and Welfare
The Honorable James R. "Jim" Fannin, Chair, House Appropriations Committee
Catherine Brindley, Louisiana Register

FR: Kathy H. Kliebert, Secretary *Approved for*

RE: Notice of Intent on Proposed Rulemaking

In accordance with the provisions of the Administrative Procedure Act, (R.S. 49:950 et seq.) as amended, the Department of Health and Hospitals/Office of Public Health is promulgating a proposed rule to amend Part VI of the Louisiana State Sanitary Code. This action is required to raise registration fees to the maximum permitted under statutory revisions of R.S. 40: 628 (B) made during the 1st Extraordinary Session of the 2000 Louisiana Legislature.

The proposed rule codifies the product registration fee schedule within §105 of Part VI of Title 51 of the Louisiana Administrative Code and raises the per-product fee from \$20 to \$27, as provided for by Act 125 of the 1st Extraordinary Session of the 2000 Louisiana Legislature.

This proposed rule is being submitted as a Notice of Intent in accordance with L.R.S. 49:950-970. Attached please find a:

1. Copy of the proposed Rule
2. Fiscal and Economic Impact Statement as approved by the Legislative Fiscal Office, and the
3. Family Impact Statement

Should you have any questions, please contact Brian R. Warren, Food and Drug Unit, Office of Public Health, at (225) 342-7514.

BG:JTL:BRW

cc: J.T. Lane, Assistant Secretary
Jimmy Guidry, State Health Officer
Lance Broussard, Chief Sanitarian
Tessa R. Dixon, Program Administrator, Food and Drug/Milk and Dairy Unit
Avis Richard-Griffin, DHH/OPH Rulemaking Liaison Officer

NOTICE OF INTENT

Department of Health and Hospitals
Office of Public Health

Registration of Foods, Drugs, Cosmetics, and Prophylactic Devices (LAC 51: VI.105)

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 Department of Health and Hospitals, Office of Public Health (DHH-OPH), intends to reenact and amend parts of Section 101 and 105 of Part VI (Manufacturing, Processing, Packing, and Holding of Food, Drugs, and Cosmetics) of the Louisiana State Sanitary Code (LAC 51). This Rule is being proposed to increase the fees assessed for product registration from their current levels to the maximum allowed by statute (R.S. 40:628). The Legislature last granted a fee increase during the 1st Extraordinary Session but fees were not subsequently raised by Rule.

Title 51

PUBLIC HEALTH—SANITARY CODE

Part VI. Manufacturing, Processing, Packing, and Holding of Food, Drugs, and Cosmetics

Chapter 1. General Regulations, Definitions, Permits, Registration, Machinery, Equipment and Utensils, Premises and Buildings, Temperature Control

§101. Definitions [formerly paragraph 6:001]

A. Unless otherwise specifically provided herein, the following words and terms used in this Chapter of the sanitary code, and all other Chapters which are adopted or may be adopted, are defined for the purposes thereof as follows.

* * *

Dba—the actual or juridical person whose name and address appear on the label of a product as the responsible party for said product.

* * *

Out-of-state Soft Drink—those items meeting the definition of *Soft drink* in §1101.A of this Part and bearing a *dba* statement whose address is outside of the state of Louisiana

* * *

Product category—classification of products subject to registration into one of five groups: milk and dairy products (M), seafood products (S), other foods and beverages (F), drugs (D), cosmetics (C), or prophylactics (P). These categories are exclusive of items defined as *Out-of-state Soft Drinks*.

* * *

AUTHORITY NOTE: The first source of authority for promulgation of the sanitary code is in R.S. 36:258(B), with more particular provisions found in Chapters 1 and 4 of Title 40 of the Louisiana Revised Statutes. This Part is promulgated in accordance with R.S. 40:4(A)(1)(a) and R.S. 40:5(2)(3)(5)(8)(15)(17)(19)(21). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1230 (June 2002), amended LR 40:

§105. Registration of Foods, Drugs, Cosmetics, and Prophylactic Devices [formerly paragraph 6:008-1]

- A. . . . Louisiana Food and Drug ~~Control~~ Unit of the OPSEQ/DHHR-OPH/DHH. . .
- B. . . .
- C. . . .
- D. . . .
- E. . . . Food and Drug ~~Control~~ Unit Office . . . R.S. 40: 627(~~4~~D).

F. Product registration fees shall be assessed according to the following schedule:

- 1. For out-of-state soft drinks, according to the provisions of R.S. 40:716;
- 2. For all other products subject to registration requirements, a per product per dba per product category fee, up to the maximum allowed for under R.S. 40: 628(B) per dba per product category.

G. The provisions of Section F will be effective starting July 1, 2014.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(1)(a), R.S. 40:5(2)(3)(5)(8)(15)(17)(19)(21), R.S. 40:628 and R.S. 40:716.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28: 1232 (June 2002), amended LR 40:

NOTICE OF INTENT

Department of Health and Hospitals
Office of Public Health

Registration of Foods, Drugs, Cosmetics, and Prophylactic Devices (LAC 51: VI.105)

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Part VI. Manufacturing, Processing, Packing, and Holding of Food, Drugs, and Cosmetics

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HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1230 (June 2002), amended LR 40:

§105. Registration of Foods, Drugs, Cosmetics, and Prophylactic Devices [formerly paragraph 6:008-1]

A. . . . Louisiana Food and Drug Unit of the OPH/DHH. . .

B. . . .

C. . . .

D. . . .

E. . . . Food and Drug Unit Office . . . R.S. 40: 627(4D).

F. Product registration fees shall be assessed according to the following schedule:

1. For out-of-state soft drinks, according to the provisions of R.S. 40:716;

2. For all other products subject to registration requirements, a per product per *dba* per product category fee, up to the maximum allowed for under R.S. 40: 628(B) per *dba* per product category.

G. For registration renewals, the provisions of Subsection F will be effective beginning with registrations having an expiration date of June 30, 2016.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(1)(a), R.S. 40:5(2)(3)(5)(8)(15)(17)(19)(21), R.S. 40:628 and R.S. 40:716.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28: 1232 (June 2002), amended LR 40:

Family Impact Statement

1. The effect on the stability of the family.

The goal of this Rule is to prevent disease and illnesses; therefore, a lower disease and illness rate of family members because of this Rule should help the family to remain stable.

2. The effect on the authority and rights of parents regarding the education and supervision of their children.

No effect on the authority and rights of parents regarding the education and supervision of their children is anticipated as a result of this proposed rulemaking.

3. The effect on the functioning of the family.

The goal of this Rule is to prevent disease and illnesses; therefore, a lower disease and illness rate of family members because of this Rule should help the family to function better than it may should a family member become ill if such Rule did not exist.

4. The effect on the family earnings and family budget.

It is expected that family members would remain more healthy with the adoption of this rule than if such Rule did not exist; therefore, the family earnings and budget may be protected from additional costs should a family member become ill if such Rule did not exist.

5. The effect on the behavior and personal responsibility of children.

No effect on the behavior and personal responsibility of children is anticipated as a result of this proposed rulemaking.

6. The ability of the family or local government to perform the function as contained in the proposed Rule.

The family or local governments have no function to perform under this Rule; therefore, the family or local government's ability to perform the function under this Rule is a non-issue.

Poverty Impact Statement

1. The effect on household income, assets, and financial security.

There will be no effect on household income, assets and financial security.

2. The effect on early childhood development and preschool through postsecondary education development.

There will be no effect on childhood development and preschool through postsecondary education development.

3. The effect on employment and workforce development.

There will be no effect on employment and workforce development.

4. The effect on taxes and tax credits.

There will be no effect on taxes and tax credits

5. The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

There will be no effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

Provider Impact Statement

The proposed Rule should not have any known or foreseeable impact on providers as defined by HCR 170 of 2014 Regular Legislative Session. Per HCR 170, "provider" means an organization that provides services for individuals with developmental disabilities. In particular, there should be no known or foreseeable effect on the:

1. Effect on the staffing level requirements or qualifications required to provide the same level of service;
2. Total direct and indirect effect on the cost to the providers to provide the same level of service; or
3. Overall effect on the ability of the provider to provide the same level of service.

Public Hearing

DHH-OPH will conduct a public hearing at 9:00 am on August 29, 2014 in Room 173 of the Bienville Building, Baton Rouge, LA. Persons attending the hearing may have their parking ticket validated when one parks in the 7-story Galvez Parking Garage which is located between N. 6th and N. 5th/North and Main Sts. (catercorner and across the street from the Bienville Building). All interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing.

Public Comments

In addition, all interested persons are invited to submit written comments on the proposed Rule. Such comments must be received no later than Friday, August 29, 2014 by close of business or by 4:30 pm, and should be addressed to Brian R. Warren, Food and Drug Unit, Center for Environmental Health Services, Office of Public Health, CEHS Mail Bin # 10, P.O. Box 4489, Baton Rouge, LA 70821-4489, or faxed to (225) 342-7672. If comments are to be shipped or hand-delivered, please deliver to the Bienville Building, 628 N. 4th Street - Room 166, Baton Rouge, LA 70802.

Kathy H. Kliebert

Secretary

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES**

Person(s) Preparing Statement: Brian R. Warren **Department:** Department of Health and Hospitals/
Office of Public Health

Telephone: 225-342-7514

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

Return Address: 628 N 4th Street, Baton Rouge,
LA 70821

Effective Date: October 20, 2014

SUMMARY (Use complete sentences)

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 Department of Health and Hospitals, Office of Public Health, intends to reenact and amend Title 51 Part VI Sections 101 and 105 (Manufacturing, Processing, Packing, and Holding of Food, Drugs, and Cosmetics) of the Public Health Sanitary Code. This Rule is being proposed to add definitions, correct obsolete and typographical references, and to indicate that the Office of Public Health shall charge a fee for product registrations in accordance with R.S. 40:628 and R.S. 40:716.

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 Department of Health and Hospitals (DHH), Office of Public Health (OPH) proposes to amend Title 51, Part VI, Chapter 1, Sections 101 and 105 of the Public Health Sanitary Code related to Manufacturing, Processing, Packing, and Holding of Food, Drugs, and Cosmetics.

In Section 101, the proposed rule adds three new definitions relative to product registration. In Section 105, the proposed rule corrects some obsolete program and department references as well as corrects a typographical reference to a nonexistent "Section 1" of R.S. 40:628. Also, the proposed rule codifies the revised fee schedule that indicates OPH shall charge an additional \$7 fee for product registrations in accordance with R.S. 40:628 and R.S. 40:716. The increase changed the current fee from \$20 to \$27 which is the maximum authorized fee.

It is not anticipated that the proposed action will result in any significant implementation costs to local governmental units. The proposed rule changes will result in an estimated cost of \$1,148 to publish the notice of intent and final rule in the *Louisiana Register*. OPH has sufficient funds in its annual operating budget to implement the proposed rule.

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

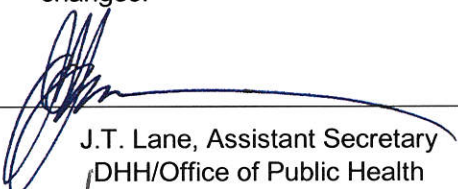
There are no anticipated effects on revenue collections of local governmental units anticipated as a result of promulgating the proposed rule change. However, the proposed rule gives OPH the authority to increase registration fees for most products from the current level of \$20 capped at \$200 to a higher level of \$27 capped at \$270, thereby increasing OPH's projected self-generated revenues by approximately \$165,200 per year ($4720 \text{ companies} \times 5 \text{ products each avg} = 23,600 \text{ products} \times \text{increase of } \$7 = \$165,200$). Under Act 125 of the 2000 1st Extraordinary Session, the Louisiana Legislature established a maximum fee of \$27. With implementation of this proposed rule, OPH is proposing to increase the fee to the maximum amount of \$27 previously approved by the legislature.

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

The proposed rule change will result in an economic cost to those entities in the United States that currently hold or in the future will hold Certificates of Registration issued by the Louisiana DHH OPH. There are 4,720 manufacturing, processing, packing, and holding of food, drugs, and cosmetics establishments that are Louisiana Food and Drug registrants throughout the United States. OPH estimates that each registrant will pay an additional \$7 per registration.

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

There are no effects on competition and employment anticipated as a result of these proposed rule changes.


J.T. Lane, Assistant Secretary
DHH/Office of Public Health


Legislative Fiscal Officer or Designee

7/9/2014

Date of Signature

8/9/14

Date of Signature

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES**

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberations on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).**

The first proposed rule change in Section 101 adds definitions relative to product registration. The second proposed rule change corrects some obsolete program and department references 105.A. The third proposed rule change corrects an additional obsolete reference in 105.E and corrects a typographical reference to a nonexistent section "1" of R.S. 40:628. The fourth proposed rule change adds 105.F. to indicate that OPH shall charge a fee for product registrations in accordance with R.S. 40:628 and R.S. 40:716.

- B. Summarize the circumstances which require this action. If the action is required by federal regulations, attach a copy of the applicable regulations.**

The first proposed rule change in Section 101 adds definitions relative to product registration. The second proposed rule change corrects some obsolete program and department references 105.A. The third proposed rule change corrects an additional obsolete reference in 105.E and corrects a typographical reference to a nonexistent section "1" of R.S. 40:628.

The fourth proposed rule just explicitly states that OPH shall charge a fee for product registrations. Act 125 of the 2000 1st Extraordinary Session gives OPH the authority to charge up to \$27 in fee charges to manufacturing, processing, packing, and holding of food, drugs, and cosmetics establishments.

There are 4,720 manufacturing, processing, packing, and holding of food, drugs, and cosmetics establishments that are Louisiana Food and Drug registrants throughout the United States.

- C. Compliance with Act 11 of the 1986 First Extraordinary Session:**

- (1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.**

Yes, OPH is expected to expend \$1,148 in operating expenses to pay the Office of the State Register to publish the Notice of Intent and Final Rule in the *Louisiana Register*.

- (2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?**

(a) _____ Yes. If yes, attach documentation.

(b) X _____ No. If no, provide justification as to why this rule change should be published at this time:

OPH currently has sufficient funds to implement the proposed action.

**FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET**

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

Costs	FY 2014-2015	FY 2015-2016	FY 2016-2017
Personal Services	\$0	\$0	\$0
Operating Expenses	\$1,148	\$0	\$0
Professional Services	\$0	\$0	\$0
Other Charges	\$0	\$0	\$0
Equipment	\$0	\$0	\$0
TOTAL	\$1,148	\$0	\$0
Major Repair/Construction	\$0	\$0	\$0
POSITIONS	\$0	\$0	\$0

2. Provide a narrative explanation of the costs or savings shown in "A.1", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.
The proposed rule changes will result in an estimated cost of \$1,148 to publish the Notice of Intent and Final Rule in the *Louisiana Register*.

3. Sources of funding for implementing the proposed rule or rule change.

Source	FY 2014-2015	FY 2015-2016	FY 2016-2017
Agency Gen. Fund	\$1,148	\$0	\$0
Agency Self Gen.	\$0	\$0	\$0
Dedicated	\$0	\$0	\$0
Federal	\$0	\$0	\$0
Other (Specify)	\$0	\$0	\$0
Total	\$1,148	\$0	\$0

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?
Yes, OPH currently has sufficient funds to implement the proposed action.

B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.
No impact is anticipated by these proposed actions local governmental units.

2. Indicate the sources of funding of the local governmental unit which will be affected by these costs or savings.
N/A

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS.

A. What increase (decrease) in revenues can be anticipated from the proposed action?

REVENUE INCREASE/ DECREASE	FY 2014-2015	FY 2015-2016	FY 2016-2017
State General Fund	\$0	\$0	\$0
Agency Self-Gen.	\$165,200	\$165,200	\$165,200
Restricted*	\$0	\$0	\$0
Federal Funds	\$0	\$0	\$0
Local Funds	\$0	\$0	\$0
TOTAL	\$0	\$0	\$0

*Specify particular fund being impacted.

Note: OPH estimates that each registrant will pay an additional \$7 per registration with an estimated net increase in agency self-generated revenues at approximately \$165,200.

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A". Describe all data, assumptions, and methods used in calculating these increases or decreases.

The self-generated revenue enhancements are not possible to estimate with any degree of accuracy because the database used to track product registrations does not provide for the generation of metrics that would allow for such estimates to be made. Based on current registrations and past trends, OPH estimates that each registrant will pay an additional \$7 per registration with an estimated net increase in state revenues at approximately \$165,200.

A crude cost estimate is based on the number of registrants currently in the database and derived as follows:

Approximately 4,720 companies pay for products to be registered. Depending on the number of products each register, each product would cost an extra \$7. Food and Drug staff do not know how many products are actually registered therefore using an average estimate of each company registering five products, then the increase in revenue would be approximately \$165,200.

4720 companies X 5 products each = 23,600 products X increase of \$7 = \$165,200

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS.

A. What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

The rule change will result in an economic cost to those entities in the United States that that currently hold or will in the future hold Certificates of Registration issued by OPH. OPH estimates that each registrant will pay an additional \$7 per registration.

B. Also provide an estimate and a narrative description of any impact on receipts and/or income resulting from this rule or rule change to their groups.

See III A.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

There are no effects on competition and employment anticipated as a result of these rule changes.