



**State of Louisiana**  
Department of Health and Hospitals

September 5, 2014

TO: The Honorable Bobby Jindal, Governor  
The Honorable James D. "Buddy" Caldwell, Attorney General  
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. Kleibert, Secretary

RE: **Title 51 Part VI Revision**

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), is promulgating a proposed rule to reenact and amend parts of Sections 101 and 105 of Part VI (Manufacturing, Processing, Packing, and Holding of Food, Drugs, and Cosmetics) of the Louisiana *Public Health Sanitary Code* (LAC 51).

The Department of Health and Hospitals published a Notice of Intent in the Louisiana Register Vol. 40, No. 07 July 20, 2014, issue of the Louisiana Register. A public hearing was held August 29, 2014. No members from the public were present to provide oral or written testimony; nor were any official comments received on the published deadline by 4:30 p.m. on August 29, 2014.

The Department anticipates adopting the Notice of Intent as a final rule in the October 20, 2014, issue of the *Louisiana Register*.

Enclosed are copies of the following documents:

1. Notice of Intent as published in the *Louisiana Register* on July 20, 2014,
2. Public Hearing Certification, and
3. Public Hearing attendance roster.

If you have any questions, please contact Chief Sanitarian Tenney Sibley, DHH OPH Sanitarian Services Division at (225) 342-7550.

KHK:JTL:JG:TS:amr-g

Attachments

C: Jimmy Guidry, State Health Officer | J.T. Lane, Assistant Secretary, OPH | Avis Richard-Griffin, DHH/OPH Rulemaking Liaison Officer | Tenney Sibley, Chief Sanitarian, Sanitarian Services Division, OPH | Tessa Dixon, Food and Drug Program, Manager, Sanitarian Services Division, OPH

Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

**Family Impact Statement**

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule may have a positive impact on family functioning, stability or autonomy as described in R.S. 49:972 by increasing access to long-acting reversible contraceptives.

**Poverty Impact Statement**

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule may have a positive impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973 by reducing the financial burden to families for costs associated with the acquisition of long-acting reversible contraceptives.

**Provider Impact Statement**

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service, may reduce the total direct and indirect cost to the provider to provide the same level of service, and may enhance the provider's ability to provide the same level of service as described in HCR 170 since this proposed Rule increases payments to providers for services they already render.

**Public Comments**

Interested persons may submit written comments to J. Ruth Kennedy, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030 or by email to MedicaidPolicy@la.gov. Ms. Kennedy is responsible for responding to inquiries regarding this proposed Rule. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

**Public Hearing**

A public hearing on this proposed Rule is scheduled for Wednesday, August 27, 2014 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing.

Kathy H. Kliebert  
Secretary

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

**RULE TITLE: Professional Services Program  
Family Planning Services—Long-Acting Reversible  
Contraceptives Reimbursements**

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

It is anticipated that the implementation of this proposed rule will result in estimated state general fund programmatic costs of \$478,892 for FY 14-15, \$699,958 for FY 15-16 and

\$719,236 for FY 16-17, which includes the cost for the unit differential and increased utilization by physicians. However, the costs associated with long-acting reversible contraceptives may be offset by an indeterminable savings realized from a reduction in expenditures associated with avoided pregnancy and infant medical costs. The savings is currently unknown for exceeding the cost in any out years. It is anticipated that \$328 (\$164 SGF and \$164 FED) will be expended in FY 14-15 for the state's administrative expense for promulgation of this proposed rule and the final rule. The numbers reflected above are based on a blended Federal Medical Assistance Percentage (FMAP) rate of 62.06 percent in FY 14-15 and 62.30 in FY 15-16. The enhanced rate of 62.11 percent for the first three months of FY 15 is the federal rate for disaster-recovery FMAP adjustment states.

**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 \$783,239 for FY 14-15, \$1,156,695 for FY 15-16 and \$1,193,117 for FY 16-17. It is anticipated that \$164 will be expended in FY 14-15 for the federal administrative expenses for promulgation of this proposed rule and the final rule. The numbers reflected above are based on a blended Federal Medical Assistance Percentage (FMAP) rate of 62.06 percent in FY 14-15 and 62.30 in FY 15-16.

The enhanced rate of 62.11 percent for the first three months of FY 15 is the federal rate for disaster-recovery FMAP adjustment states.

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

This proposed Rule amends the provisions governing the reimbursement methodology for family planning services covered under the Professional Services Program in order to establish provider reimbursements at the cost of acquisition for long-acting reversible contraceptives. It is anticipated that implementation of this proposed rule will increase programmatic expenditures in the Medicaid Program by approximately \$1,261,803 for FY 14-15, \$1,856,653 for FY 15-16 and \$1,912,353 for FY 16-17.

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

It is anticipated that the implementation of this proposed rule will not have an effect on competition, but may have a positive effect on employment if the financial standing of providers is improved by the increased payment amounts.

J. Ruth Kennedy  
Medicaid Director  
1407#072

John D. Carpenter  
Legislative Fiscal Officer  
Legislative Fiscal Office

**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 Sections 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 Unit of the OPH/DHH

B. - D. ...

E. Food and Drug Unit Office, R.S. 40: 627(1D)

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;



**Public Hearing Number: 2014-08-29-B**

**Topic:** Public Hearing – Food and Drug Program

Proposed revisions relative to Registration of Foods, Drugs, Cosmetics, and Prophylactic Devices (LAC 51:VI.105) as published in the Louisiana Register Vol. 40, No. 07 July 20, 2014, Hearing Location: Bienville Building, Room 173, 628 N. 4th Street, Baton Rouge, LA 70802.

**Attachments:**

- Sign-in sheet dated: August 29, 2014
- Public Hearing Posted Announcement
- Notice of Intent as published in the July 20, 2014, issue of the Louisiana Register

Avis Richard-Griffin, MPA

DHH OPH Rulemaking Hearing Officer

Sworn before me on this 29<sup>th</sup> day of \_\_\_\_\_ August, 2014

NOTARY PUBLIC

DAVID L. McCAY  
LA BAR ROLL #23527  
NOTARY PUBLIC, STATE OF LOUISIANA  
MY COMMISSION IS FOR LIFE

Printed Name of Notary Public

Bar Roll Number

SIGN-IN SHEET

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 Sections 101 and 105 of Part VI (Manufacturing, Processing, Packing, and Holding of Food, Drugs, and Cosmetics) of the Louisiana state Sanitary Code (LAC 51). Hearing date, time and location: August 29, 2014, at 9:00 a.m., DHH Bienville Building, 628 N. 4th Street, Baton Rouge, LA 70802, Room 173.

| FNAME | LNAME           | EMAIL                   | TELEPHONE#   | AFFILIATION OR ORGANIZATION | SIGNATURE            |
|-------|-----------------|-------------------------|--------------|-----------------------------|----------------------|
| Brian | Warren          | brian.warren@hhs.la.gov | 225.382.7074 | DHH/OPH                     | Brian Warren         |
| Avis  | Richard-Griffin |                         | 225.342.9355 | DHH OPH                     | Avis Richard-Griffin |
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Administrative Hearing Officer: Avis Richard-Griffin  
 Avis Richard-Griffin

# PUBLIC HEARINGS: AUGUST 29, 2014



## AGENDA

**DHH Bienville Building  
628 N. 4th Street, Room 173  
Baton Rouge, LA 70802  
Beginning at 9:00 a.m.**

## NOTICE OF INTENT

Department of Health and Hospitals  
Office of Public Health

### Health Examination for Employees, Volunteers and Patients at Certain Medical Facilities (LAC 51:II.503)

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 update and revise the *Louisiana Administrative Code* (Louisiana Sanitary Code), Title 51, "The Control of Diseases," Chapter 5, "Health Examination for Employees, Volunteers and Patients at Certain Medical Facilities." This action will provide a third alternative to the annual screening testing of employees and volunteers at Louisiana hospitals and nursing homes now required on an annual basis. This third alternative is a simple screening questionnaire, which may be used instead of the other alternatives, the tuberculin skin test, also known as the Mantoux test, or the blood test, also known as the blood assay test. The initial screening test of an employee or volunteer upon initial employment or acceptance as a volunteer will remain either the skin test or the blood assay test. The requirement for screening testing of patients remains unchanged.

## 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 Sections 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.