John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Office of the Secretary

December 9, 2019

Via Statutorily Required Email

To: The Honorable John Alario, President, Louisiana Senate
The Honorable Taylor Barras, Speaker, Louisiana House of Representatives
The Honorable Fred H. Mills, Jr. Chairman, Senate Health & Welfare Committee
The Honorable Frank A. Hoffmann, Chairman, House Health & Welfare Committee

From: Rebekah E. Gee, MD, MPH
Secretary

By Cindy Rives for

Re: First Report. Proposed Amendments to LAC 49:501, 503, 509, 511, 515, 517, 519, 521, 523, 525, 527, 529 and LAC 51.VI.301

Under the authority of the laws of the State of Louisiana and in accordance with the provisions of Chapter 6 of Title 36 of the Louisiana Revised Statutes of 1950, and with the Administrative Procedure Act, La. R.S. 49:950 *et seq.,* the secretary hereby gives notice that rulemaking procedures have been initiated to promulgate amendments to the rules governing the Registration of Foods, Drugs, Cosmetics, and Prophylactic Devices – LAC 49 Chapter 5; and Manufacturing, Processing, Packing, and Holding of Food, Drugs, and Cosmetics.

I. Copy of the rule as it is proposed after amendment, with new proposed language indicated by the underscored text.

See attachment.

II. A Statement of the proposed action.

The department proposed to the regulatory framework for the registration of industrial-hemp-derived cannabidiol products and the inspection of facilities manufacturing industrial-hemp-derived cannabidiol products by the department, as mandated by Act 164 of the 2019 Legislature.

III. Specific citation of law authorizing promulgation of the rule.

Act 164 of the 2019 Regular Legislative Session.

Circumstances which require the amendment of the rule.

The proposed rule is being issued in order to implement the requirements per ACT 164 of 2019 Regular Legislative Session.

IV. Statement of Fiscal and Economic Impact.

See attachment.

Please contact Michael Vidrine at Michael.Vidrine@la.gov or (225) 342-7542, if you have any questions or require additional information about this matter.

Attachments (2)

cc: Jimmy Guidry, MD, State Health Officer
Alexander Billioux, MD, DPhil, Assistant Secretary, Office of Public Health
Michael Vidrine, Chief Sanitarian, Bureau of Sanitarian Services, Office of Public Health
Anita Dupuy, Legislative Liaison, Louisiana Department of Health
Rhea Davis, Rulemaking Liaison, Office of Public Health
Allen Enger, Rulemaking Coordinator, Louisiana Department of Health
Catherine Brindley, Editor, *Louisiana Register*, Office of State Register

NOTICE OF INTENT

Louisiana Department of Health
Office of Public Health
Registration of Foods, Drugs, Cosmetics and
Prophylactic Devices
LAC 49:501, 503, 509, 511, 515, 517, 519, 521, 523, 525, 527, 529 and LAC 51.VI.301

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) and Section 301 of Part VI (Manufacturing, Processing, Packing and Holding of Food, Drugs, and Cosmetics) of Title 51 (Public Health-Sanitary Code) of the Louisiana Administrative Code. This rule is being proposed to implement a regulatory framework for industrial hemp-derived cannabidiol products (IHDCP) in accordance with directives of Subsection J of Section 1382 of Title 3 of the Revised Statutes of 1950, enacted as part of Act 164 of the 2019 Louisiana Legislature.

For the reason set forth above, the following proposed additions and amendments to LAC 49 and 51 are hereby proposed to be adopted.

Title 49
PUBLIC HEALTH—FOOD, DRUGS, AND COSMETICS
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.

Accrediting Body—for the purposes of this Chapter, the International Organization for Standardization (ISO).

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Cannabidiol—a nonpsychotropic cannabinoid found in *Cannabis sativa* L. and other conspecifics that can have a variety of physiological effects on the human body.

CBD—cannabidiol.

Certificate of Analysis—a document produced by an approved laboratory attesting to the composition of a product.

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

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Department—for the purposes of this Chapter, the Food and Drug/Milk and Dairy Unit of the Office of Public Health, Louisiana Department of Health.

***

Dietary Supplement—means 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.

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Examination and Investigation Fee—as required by R.S. 40:628, shall be referred to as registration fee.

F~~W~~ood—includes all substances and preparations used for or entering into the composition of food, drink, confectionery, chewing gum or condiment for man or beast.

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 delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis.

Industrial Hemp-Derived Cannabidiol Products (IHDCP)—any product intended for human use and containing cannabidiol that was made from industrial hemp.

Industrial Hemp-Derived Cannabidiol Products Database—repository of information on products and firms that are registered with the department that fall into the category of industrial hemp-derived cannabidiol products.

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Medical Opinion—the opinion, within their respective fields, of the ~~practioners~~ practitioners of any branch of the medical profession, the practice of which is licensed by law in this State.

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QR Code—Quick Response Code, a type of machine-readable, two-dimensional barcode that stores information about a product.

Registration Fee—Examination and Investigation Fee.

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THC—delta-9 tetrahydrocannabinol.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J), R.S. 40:4(A)(13), 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.

§503. Registration Provisions
[Formerly 49:2.2110]

A. In accordance with the provisions of LSA R.S. 40:627, each manufacturer, packer or proprietor of processed foods, proprietary or patent medicines, prophylactic devices and cosmetics in packaged form shall register each separate and distinct product annually with the department ~~Louisiana Food and Drug Unit/OPH/DHH~~.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J), R.S. 40:5(A)(8)(15)(17) and R.S. 40:604.
HISTORICAL NOTE: Adopted by Louisiana State Board of Health, September 1968, amended by the Department of Health, Office of Public Health, LR 46.

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§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, 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 ~~August~~ 1 of each year. Certificates of registration will be issued to each firm for a period of one year expiring on June 30 ~~July 31~~ of each year. ~~The staggering of expiration dates of certificates will be discontinued and consolidated into one expiration date (July 31). The four registration categories, as established by previous rule of January 20, 1984, will be eliminated thus placing all firms into the same registration period of August 1 thru July 31 of the following year. The current expiration dates for the four registration categories are as follows.~~

~~Category 1~~	~~January 31~~
~~Category 2~~	~~April 30~~
~~Category 3~~	~~July 31~~
~~Category 4~~	~~October 31~~

~~B. In order to implement a smooth transition from staggered expiration dates to one annual expiration date, the Food and Drug Control Unit shall extend the expiration dates of the current registration certificates from each registration category, excluding category 3, to the July 31, 1986 expiration date. Thus, certificates of registration for categories 1, 2, and 4 expiring on January 31 and April 30, 1986, and October 30, 1985, respectively, will automatically be extended until July 31, 1986. For the purposes of avoiding confusion on the part of industry with respect to the filing of correct registration fees, the Food and Drug Control Unit shall waive the~~

~~submission of applications for registration and registration fees for those firms in categories I, 2, and 4 which would otherwise be prorated over periods of three, six and nine months.~~

~~C. This rule will allow a smooth transition into the revised registration fee schedule as provided by Act 344 of the 1985 Legislative Session which amended R.S. 40:627(D) of the Food and Drug Law. The new fee schedule is effective as of February I, 1986; however, the new fees will not be collected until August I, 1986. Registration fees as provided by the amended law are as follows.~~

~~1. Each manufacturer, packer, or proprietor shall be assessed an annual expiration and investigation charge of not more than $10 for any one separate and distinct product registered, up to a maximum of $100.~~

~~2. Registration fees for products will be assessed as outlined in the following schedule.~~

~~Number of Products~~	~~Penalty Fee~~
~~1~~	~~$10~~
~~2~~	~~$20~~
~~3~~	~~$30~~
~~4~~	~~$40~~
~~5~~	~~$50~~
~~6~~	~~$60~~
~~7~~	~~$70~~
~~8~~	~~$80~~
~~9~~	~~$90~~
~~10~~	~~$100~~
~~More than 10~~	~~$100~~

~~D. Notification of renewal of certificates and revised examination and Investigation Fee schedules will be made known to certificate holders in categories 1, 2, and 4 by way of a letter to each firm announcing the proposed changes in fees and extension of certificates. Certificates of category 3 firms will not be affected in that certificates in that category currently expire on July 31 of each year.~~

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(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 10:9 (January 1984), LR 9:562 (August 1983), 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.

§511. Late Registration Penalty Fees - Repealed
[Formerly 49:2.2150]

~~A. The late registration penalty fees as required by R.S. 40:627(D) will be revised effective February 1, 1986, in accordance with Act 344 of the 1985 Legislature. Late registration penalty fees currently assessed are $100 per product with a maximum penalty fee of $500 for any one firm during the calendar year.~~

~~B. Thus, late penalty fees are currently as follows.~~

~~Number of Products~~	~~Penalty Fee~~
~~1~~	~~$100~~
~~2~~	~~$200~~
~~3~~	~~$300~~
~~4~~	~~$400~~
~~5~~	~~$500~~
~~More than 5~~	~~$500~~

~~C. The revised penalty fees for late registration will be subject to implementation effective February 1, 1986, but assessment of the fees will not be initiated in that the current certificates will automatically be extended by this proposed rule.~~

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:604 and R.S. 40:627(D).
HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Office of Preventive and Public Health Services, September 1968, amended by the Department of Health and Human Resources, Office of Health Services and Environmental Quality, LR 10:9 (January 1984), LR 9:562 (August 1983), 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 46.

§515. Penalty Fee Assessment
[Formerly 49:2.2170]

A. The late registration penalty fees as established by Act 344 of the 1985 Louisiana Legislature will assess~~, effective February 1, 1986,~~ each manufacturer, packer, or proprietor a penalty of $10 for failure to register each separate and distinct product annually. The penalty assessed shall be in addition to the examination and investigation charge (registration fee). No manufacturer, packer, or proprietor shall be assessed a late registration penalty fee of more than $100 in any calendar year.

B. ...

C. ~~Late registration penalty fees, effective February 1, 1986, will be imposed on those firms which fail to submit an application for registration and registration fees on or before August 1 of each year. However, a grace period of 45 days will be given to all firms extending the deadline for receipt of applications and fees to September 15 of each year. A final notice reminder letter will be sent to all firms on or about September 1 of each year thus serving notice to firms 15 days prior to implementing penalty fees denoted above.~~ Late registration penalty fees will be imposed on those firms which fail to submit an application for registration and registration fees on or before July 1 of each year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:604 and R.S. 40:627(D).
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 10:9 (January 1984), LR 9:562 (August 1983), 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.

§517. Registration of Industrial Hemp-Derived Cannabidiol Products

A. In accordance with the provisions of R.S. 3:1482 as promulgated by the 2019 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. The manufacturer of any product that is not registered within the specified timeframe will be deemed to be in violation of these rules with respect to such product(s).

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 provide (both initially and on or before July 1 of each year) the department with an application form, a cashier's check or money order made payable to the department in the amount of $50 per each separate and distinct CBD product, specimen copies of labeling in paper or electronic format, and a list of all products the applicant wishes to register with the department. If the packet meets these regulatory requirements, 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 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. 3:1482(J) and R.S. 40:604.
HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46.

§519. Industrial Hemp-Derived Cannabidiol Products Labeling Requirements: Certificate of Analysis

A. In addition to the requirements enumerated in R.S. 40:608, industrial hemp-derived cannabidiol 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. The certificate of analysis must be from a laboratory that is accredited by LDH/OPH.

C. The certificate of analysis must include, at a minimum, the following information:

1. the batch number of the product;
2. the date the batch was received by the laboratory;
3. the date the testing was completed;
4. the laboratory methodology used for each analysis referenced in the report;
5. the amount of THC by dry weight in milligrams;
6. the amount of CBD by dry weight in milligrams;
7. the amount of any detected residual solvent in the product in parts per million;
8. the amount of any detected pesticide residues in the product in parts per million;
9. the amount of any microbiological contaminants in the product in appropriate units; and
10. the amount of any detected heavy metal traces in the product in parts per million.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J) and R.S. 40:604.
HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46.

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

A. Each primary container of industrial hemp-derived cannabidiol product must bear the following statement: "This product has not been evaluated by the Food and Drug Administration and is not intended to diagnose, treat, cure, or prevent any disease."

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J) and R.S. 40:604.
HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46.

§523. Industrial Hemp-Derived Cannabidiol Products Labeling Requirements: Medical Claims Prohibited

A. No product labeling or advertising material for any industrial hemp-derived cannabidiol product sold or otherwise distributed in the state of Louisiana may bear any implicit or explicit medical claims.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J) and R.S. 40:604.
HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46.

§525. Industrial Hemp-Derived Cannabidiol Products Labeling Requirements: Dietary Supplements Prohibited

A. No industrial hemp-derived cannabidiol product may be marketed as a dietary supplement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J) and R.S. 4O:604.
HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46.

§527. 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 R.S. 3:1484 and other sanctions as provided for by the State Food, Drug, and Cosmetic Law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:1482(J) and R.S. 40:604.
HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46.

§529. 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. 3:1482(J) and R.S. 40:604.
HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46.

Title 51
PUBLIC HEALTH—SANITARY CODE
Part VI. Manufacturing, Processing, Packing and Holding of Food, Drugs and Cosmetics

Chapter 3. Current Good Manufacturing Practices in Manufacturing, Processing, Packing or Holding Human Food

§301. General Provisions; Code of Federal Regulations [formerly paragraph 6:039]

A. The Criteria in 21 CFR 117 Subpart A, Subpart B and Subpart F ~~110.10, 110.19, 110.20, 110.35, 110.37, 110.40, 110.80, and 110.93~~ (Code of Federal Regulations) shall apply in determining whether the facilities, methods, practices, and controls used in the manufacturing, processing, packing or holding of food are in conformance with or are operated or administered in

conformity with good manufacturing practices to assure that food for human consumption is safe and has been prepared, packed and held under sanitary conditions.

B. In accordance with R.S. 3:1468, facilities producing industrial hemp-derived cannabidiol products intended for human consumption will be inspected under the provisions of this Chapter.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq., and R.S. 3:1482(J).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1234 (June 2002), amended by the Department of Health, Office of Public Health, LR 46.

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. 49:973(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;
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 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 Tuesday, January 28, 2020 at COB, 4:30 pm, 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 4:30 p.m. on January 10, 2020. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9 am on Tuesday, January 28, 2020, 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 January 10, 2020. 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 LDH staff at the hearing.

Jimmy Guidry, MD
State Health Officer
and
Rebekah E. Gee, MD, MPH
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: Brian R. Warren

Dept.: Louisiana Department of Health

Phone: 225-342-7514

Office: Office of Public Health

Return Address: 628 N. 4th Street,
Baton Rouge, LA 70802

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

Date Rule Takes Effect: March 20, 2020

SUMMARY
(Use complete sentences)

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)

As required by Act 164 of the 2019 Louisiana Legislative Session, the proposed rule implements the regulatory framework for the hemp industry and authorizes the Office of Public Health (OPH) to inspect and permit any facility producing hemp and cannabidiol (CBD) products for consumption.

The proposed rule change is anticipated to increase expenditures for OPH by approximately $96,790 in FY 20 for salaries and benefits associated with hiring four sanitarians to perform the duties of permitting and inspecting hemp production firms. This amount will be annualized in future fiscal years and is estimated to be $387,162 in FY 21 and 22.

Other costs OPH estimates include $41,880 for recurring operating services expenditures (travel, supplies, vehicle rental, telephone) and a one time expenditure in FY 20 of $5,544 for the acquisition of office equipment.

The agency was not appropriated funding in FY 20 to implement this rule. It is anticipated that the revenue collections detailed in Section II below will be sufficient to pay for the estimated expenses.

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

The proposed rule is anticipated to generate $270,875 in revenue in FY 20 for OPH associated with permitting fees ($875) and label registration fees ($270,000).

The rule authorizes OPH to charge a fee to issue a permit to any facility producing hemp and CBD products for consumption. The amount of the permit fee is based on sales revenue and will range from $175 to $1,375. OPH anticipates that the producers will likely start out at the bottom of the revenue scale. Therefore, the permit fee charged to these producers is estimated to be $175. OPH anticipates that 5 permits will be issued in FY 20. (5 producers x $175 permit fee = $875 in permit fees collected in FY 20)

The rule also authorizes OPH to charge a label registration fee of $27 per label. OPH estimates that 10,000 labels will be registered in FY 20. (10,000 labels x $27 fee = $270,000 in label registration fees collected in FY 20)

The number of producers is projected to grow by 2-3 per year and the number of label registrations is projected to grow by 20% per year. Therefore, revenue collections in FY 21 and FY 22 are estimated to be as follows:

$ 1,225 permit fees (7 producers x $175 permit fee)
$324,000 label fees (12,000 labels x $27 fee)
$325,225 Total collection in FY 21

$ 1,750 permit fees (10 producers x $175 permit fee)
$388,800 label fees (14,400 labels x $27 fee)
$390,550 Total collection in FY 22

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

Facilities producing hemp and CBD products for consumption will incur the cost of permits and label registration fees, as detailed in section II above. Additionally, manufacturers and retailers of CBD products are expected to experience an increase in income resulting from the sale of CBD products, which this proposed rule assists in authorizing.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This proposed rule will assist in authorizing the sale of CBD products by manufacturers and retailers. If there is a large public demand for CBD products, manufacturers and retailers may find it necessary to employ additional staff to handle the increased demand.

Signature of Agency Head or Designee

Alexander Billioux, MD, DPhil
Assistant Secretary, Office of Public Health
Typed Name & Title of Agency Head or Designee

12/6/19
Date of Signature

Evan Brasseaux, Staff Director
Legislative Fiscal Officer or Designee

12/10/19
Date of Signature