

NOTICE OF INTENT

Department of Health Board of Pharmacy

Prescription Monitoring Program (LAC 46:LIII.2901 and 2914)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Board of Pharmacy hereby gives notice of its intent to amend §2901 and §2914 of its rules relative to the Prescription Monitoring Program (PMP). The proposed rule change in §2901 clarifies intent in regards to butalbital containing products and removes naloxone as a drug of concern. The proposed rule change in §2914 addresses record retention of PMP information.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII.: Pharmacists

Chapter 29. Prescription Monitoring Program §2901. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them unless the context clearly indicates otherwise.

* * *

Drugs of Concern—drugs other than controlled substances as defined by rule whose use requires tracking for public health purposes or which demonstrate a potential for abuse, including any material, compound, mixture, or preparation containing any quantity of the following substances, including its salts, esters, ethers, isomers, and salts of isomers [whenever the existence of such salts, esters, ethers, isomers, and salts of isomers is possible within the specific chemical designation]:

- a. butalbital.
- b. promethazine when present in oral liquid formulation.
- c. gabapentin.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1345 (July 2007), amended LR 36:755 (April 2010), effective September 1, 2010, LR 39:314 (February 2013), LR 40:1095, 1096 (June 2014), LR 41:684 (April 2015), amended by the Department of Health, Board of Pharmacy, LR 45:42 (January 2019), LR 47:84 (January 2021), repromulgated LR 47:248 (February 2021), amended LR 50:

§2914. Record Retention of Prescription Monitoring Information

A. The board shall retain a minimum of five years of prescription monitoring information for review by persons authorized to access such information.

B. The board shall archive all prescription monitoring information not available for direct or indirect access up to 10 years.

C. The board may remove and destroy prescription monitoring information in excess of 10 years.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1006(G).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 47:85 (January 2021), repromulgated LR 47:248 (February 2021), amended LR 50:

Family Impact Statement

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the Rule proposed for adoption, repeal, or amendment. The following statements will be published in the *Louisiana Register* with the proposed agency Rule.

1. The Effect on the Stability of the Family. The proposed rule amendment will have no effect on the stability of the family.

2. The Effect on the Authority and Rights of Parents Regarding the Education and Supervision of their Children. The proposed rule amendment will have no effect on the authority and rights of parents regarding the education and supervision of their children.

3. The Effect on the Functioning of the Family. The proposed rule amendment will have no effect on the functioning of the family.

4. The Effect on Family Earnings and Family Budget. The proposed rule amendment will have no effect on family earnings and family budget.

5. The Effect on the Behavior and Personal Responsibility of Children. The proposed rule amendment will have no effect on 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. The proposed rule amendment will have no effect on the ability of the family or a local government to perform the activity as contained in the proposed Rule.

Poverty Impact Statement

In accordance with Section 973 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a poverty impact statement on the Rule proposed for adoption, repeal, or amendment.

1. The Effect on Household Income, Assets, and Financial Security. The proposed rule amendment will have no effect on household income, assets, or financial security.

2. The Effect on Early Childhood Development and Preschool through Postsecondary Education Development. The proposed rule amendment will have no effect on early childhood development or preschool through postsecondary education development.

3. The Effect on Employment and Workforce Development. The proposed rule amendment will have no effect on employment and workforce development.

4. The Effect on Taxes and Tax Credits. The proposed rule amendment will have no effect on taxes or tax credits.

5. The Effect on Child and Dependent Care, Housing, Health Care, Nutrition, Transportation, and Utilities Assistance. The proposed rule amendment will have no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

Small Business Analysis

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the Rule proposed for

adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed Rule on small businesses:

1. The Establishment of Less Stringent Compliance or Reporting Requirements for Small Businesses. The proposed rule amendment does not establish a less stringent compliance or reporting requirements for small business.

2. The Establishment of Less Stringent Schedules or Deadlines for Compliance or Reporting Requirements for Small Businesses. The proposed rule amendment will have no effect on schedules or deadlines for compliance or reporting requirements for small business.

3. The Consolidation or Simplification of Compliance or Reporting Requirements for Small Businesses. The proposed rule amendment will have no effect on consolidation or simplification of compliance or reporting requirements for small business.

4. The Establishment of Performance Standards for Small Businesses to Replace Design or Operational Standards Required in the Proposed Rule. The proposed rule amendment will have no effect on establishment of performance standards for small businesses to replace design or operational standards for small business.

5. The Exemption of Small Businesses from All or Any Part of the Requirements Contained in the Proposed Rule. There are no exemptions for small businesses in the proposed rule amendment.

Provider Impact Statement

In accordance with House Concurrent Resolution No. 170 of the Regular Session of the 2014 Legislature, there is hereby submitted a provider impact statement on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, the following effects on the providers of services to individuals with developmental disabilities:

1. The effect on the staffing level requirements or qualifications required to provide the same level of service. The proposed rule amendment will have no 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 Provider to Provide the Same Level of Service. The proposed rule amendment will have no effect on the cost to the provider to provide the same level of service.

3. The Overall Effect on the Ability of the Provider to Provide the Same Level of service. The proposed rule amendment will have no effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments, via United States Postal Service or other mail carrier, or in the alternative by personal delivery to M. Joseph Fontenot Jr., Executive Director, at the office of the Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-1700. He is responsible for responding to inquiries regarding the proposed Rule amendment. The deadline for the receipt of all written comments is 12 p.m. on Thursday, December 28, 2023.

Public Hearing

A public hearing to solicit comments and testimony on the proposed Rule changes is scheduled for 9 a.m. on Thursday, December 28, 2023 at the board office. During the hearing, all interested persons will be afforded an opportunity to submit comments and testimony, either verbally or in writing. The deadline for the receipt of all comments and testimony is 12 p.m. that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

M. Joseph Fontenot Jr.
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

RULE TITLE: Prescription Monitoring Program

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

The proposed rule change will require the Louisiana Board of Pharmacy (LBP) to publish the proposed and final rules in the state register, resulting in estimated printing expenses of \$1,000 in FY 24. There will be no additional expenditures or immediate cost savings for LBP or other state or local governmental units. Future contracts with the Prescription Monitoring Program (PMP) vendor may result in long-term cost savings to LBP, but the amount is indeterminable at this time since the current contract is in place until 2029.

The proposed rule change in §2901 amends the definition of Drugs of Concern to include all butalbital containing products instead of only butalbital when in combination with at least 325 milligrams of acetaminophen per dosage unit and to remove naloxone.

The proposed rule change in §2914 replaces the term "prescription transaction information" with "prescription monitoring information," limit the time the Board shall archive such information to up to 10 years, and allow the board to remove and destroy such information in excess of 10 years.

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

The proposed rule change will not affect revenue collections of state or local governmental units.

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

The proposed rule change will benefit pharmacies and prescribers by requiring all butalbital products to be reported to the Prescription Monitoring Program, which will result in a more complete review of the patient's medication history.

Pharmacies will be required to report additional butalbital prescription transactions than is currently required, but the process will be less complicated. Since pharmacies report the transactions electronically through automated means, the impact will be minimal.

By removing naloxone as a drug of concern, pharmacies will no longer be required to report those transactions electronically but the impact will be minimal.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule change will have no effect on competition or employment.

M. Joseph Fontenot, Jr.
Executive Director
2311#020

Patrice Thomas
Deputy Fiscal Officer
Legislative Fiscal Office