**NOTICE OF INTENT**

**Department of Health**

**Board of Pharmacy**

Prescription Monitoring Program (LAC 46:LIII.Chapter 29)

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 Louisiana Board of Pharmacy hereby gives notice of its intent to amend several sections of its chapter of rules for the state prescription monitoring program (PMP). The proposed changes for §2901 remove several terms and their definitions which are duplicated from the PMP law. The proposed amendment of the definition of the term "drugs of concern" adds nine drugs, seven of which are used for the treatment of hepatitis to that list: (1) elbasvir/grazoprevir, (2) glecaprevir / pibrentasvir, (3) ledipasvir/sofosbuvir, (4) ombitasvir / paretaprevir/ritonavir/dasabuvir, (5) sofosbuvir, (6) sofosbuvir/velpatasvir, and (7) sofosbuvir/velpatasvir/ voxilaprevir. The proposal also adds promethazine when present in oral liquid formulation as well as gabapentin. The effect of adding these nine drugs to that list will require pharmacies dispensing these drugs to include those dispensing transactions in their automated reports to the state PMP. The proposed changes for §2903, §2907, and §2909 are to repeal these redundant sections which are duplicated from the PMP law. The proposed change for §2905 is to repeal that section as redundant from the pharmacy law which contains the same authority to hire staff for board operations. The proposed addition of §2914 relative to record retention will implement the provisions of Act 189 of the 2016 Legislature. With respect to the proposed changes in §2917 relative to authorized access privileges to PMP information, Paragraphs 5 and 6 will implement the provisions of Act 241 of the 2017 Legislature; Paragraph 7 will implement the provisions of Act 232 of the 2018 Legislature; and Paragraph 9 will implement the provisions of Act 80 of the 2019 Legislature. With respect to the proposed changes in §2919 relative to PMP access registration procedures, Paragraph 1 will implement the provisions of Act 76 of the 2017 Legislature. Moreover, while the legislation requires automatic registration for prescribers, the board proposes to extend the automatic registration procedures to include dispensers. With respect to the proposed changes in §2921 relative to methods of access to PMP information, the proposed additions to Subsections B, E, F, G, H, K, L, and M were authorized by Act 241 of the 2017 Legislature; the proposed addition to Subsection I was authorized by Act 232 of the 2018 Legislature; the proposed addition to Subsection N was authorized by Act 80 of the 2019 Legislature; and the proposed new Subsection O was authorized by Act 352 of the 2012 Legislature

**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.

*Delegate*—a person authorized by a prescriber or dispenser who is also an authorized user as described in Section 2917 of this Chapter to access and retrieve program data for the purpose of assisting the prescriber or dispenser, and for whose actions the authorizing prescriber or dispenser retains accountability.

*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 when in combination with at least 325 milligrams of acetaminophen per dosage unit;

b. naloxone;

c. promethazine when present in oral liquid formulation;

d. elbasvir / grazoprevir;

e. glecaprevir / pibrentasvir;

f. ledipasvir / sofosbuvir;

g. ombitasvir / paretaprevir / ritonavir / dasabuvir;

h. sofosbuvir;

i. sofosbuvir/velpatasvir;

j. sofosbuvir/velpatasvir/voxilaprevir;

k. 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, amended by LR 39:314 (February 2013), amended LR 40:1096 (June 2014), amended LR 41:684 (April 2015), amended by the Department of Health, Board of Pharmacy, LR 45:42 (January 2019), LR 46:

**§2903. Authority for Program Operation**

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1004.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1345 (July 2007), repealed by the Department of Health, Board of Pharmacy, LR

**§2905. Authority to Engage Staff**

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1179.F(6).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1346 (July 2007), repealed by the Department of Health, Board of Pharmacy, LR 46:

**§2907. Authority to Contract with Vendors**

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1012.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1346 (July 2007), repealed by the Department of Health, Board of Pharmacy, LR 46:

**§2909. Advisory Council**

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1005.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1346 (July 2007), amended LR 39:314 (February 2013), amended LR 40:1096 (June 2014), repealed by the Department of Health, Board of Pharmacy, LR 46:

**§2911. Reporting of Prescription Monitoring Information**

A. Each dispenser shall submit to the board information regarding each prescription dispensed for a controlled substance or drug monitored by the program.

B. - C. …

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1346 (July 2007), amended LR 39:314 (February 2013), amended LR 41:684 (April 2015), amended by the Department of Health, Board of Pharmacy, LR 46:

**§2914. Record Retention of Prescription Transaction Information**

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

B. The board shall archive all prescription transaction information not available for direct or indirect access.

C. The board shall respond to requests for archived prescription transaction information.

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 46:

**§2917. Authorized Direct Access Users of Prescription Monitoring Information**

A. The following persons may access prescription monitoring information in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar protected health information under federal and state law and regulation:

1. - 4. …

5. a medical examiner or coroner, or a delegate thereof, for the purpose of investigating an individual's death.

6. a licensed substance abuse addiction counselor providing services as part of a state-licensed substance abuse or addiction treatment program.

7. an epidemiologist with the Louisiana Department of Health for the purpose of assisting the board in analyzing prescription monitoring information in order to conduct public health evaluations to support public policy and education pursuant to an agreement with the board.

8. prescription monitoring programs, electronic health information systems, and pharmacy information systems located in other states, territories, federal districts, and federal jurisdictions, through a secure interstate data exchange system or health information exchange system approved by the board, but only in compliance with the provisions of R.S. 40:1007(G).

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1347 (July 2007), amended LR 39:315 (February 2013), amended LR 40:1095 (June 2014), amended by the Department of Health, Board of Pharmacy, LR 46:

**§2919. Registration Procedures for Authorized Direct Access Users**

A. Authorized users of prescription monitoring information, and their delegates, shall comply with the following requirements to register with the board, in order to receive the appropriate credentials to access prescription monitoring information.

1.a. A prescriber or dispenser, excluding veterinarians, shall be automatically registered as a participant in the program and shall authenticate their identity through an online process in order to activate their account.

b. An agency applicant shall file an application with the program, using the form supplied by the program for that purpose.

2. The board shall verify the prescriber or dispenser applicant is in possession of a valid license to prescribe or dispense controlled substances, or in the case of an agency application, the board shall verify agency representation.

3. Upon verification of all requirements, the board shall issue the appropriate credential necessary to access prescription monitoring information.

4. Upon receipt of information that an authorized user no longer possesses authority to prescribe or dispense controlled substances, the program shall terminate the user's credentials to access prescription monitoring information. If or when the user's authority to prescribe or dispense controlled substances is reinstated, the program may reinstate the user's credentials to access prescription monitoring information.

5. Prescribers and dispensers approved for access shall be responsible for the enabling and~~/or~~ disabling of access privileges for their delegates, as well as the supervision of their activities.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1347 (July 2007), amended LR 40:1095 (June 2014), amended by the Department of Health, Board of Pharmacy, LR 46:

**§2921. Methods of Access to Prescription Monitoring Information and Audit Trail Information**

A. …

B. Designated representatives from agencies charged with administrative oversight of prescribers and dispensers of controlled substances may solicit prescription monitoring information and audit trail information from the program concerning specific

investigations of prescribers or dispensers. The program may require such users to certify the legitimacy of their inquiry prior to furnishing the requested information.

C. - D. …

E. Upon receipt of one of the following methods of application by local, state, out-of-state, or federal law enforcement or prosecutorial officials, including judicially-supervised specialty courts within the criminal justice system that are authorized by the Louisiana Supreme Court, the program may provide prescription monitoring information and audit trail information:

1. - 3.c. …

F. A medical examiner or coroner, or a delegate thereof, once properly registered, may solicit prescription monitoring information from the program for the purpose of investigating an individual's death. The program may require such users to certify the legitimacy of their inquiry prior to furnishing the requested information.

G. A licensed substance abuse addiction counselor, once properly registered, may solicit prescription monitoring information from the program for the purpose of providing services as part of a state-licensed substance abuse or addiction treatment program. The program may require such users to certify the legitimacy of their inquiry prior to furnishing the requested information.

H. Upon receipt of an administrative request from a probation or parole officer, the program may provide prescription monitoring information. The probation or parole officer must certify the request for prescription monitoring information is for the purpose of monitoring an offender's compliance with participation in a drug diversion program or with other conditions of probation or parole related to monitored drugs.

I. An epidemiologist with the Louisiana Department of Health, once properly registered, may solicit prescription monitoring information from the program for the purpose of assisting the board in analyzing prescription monitoring information in order to conduct public health evaluations to support public policy and education pursuant to an agreement with the board.

J. Individuals may solicit their own prescription monitoring information and audit trail information from the program. To prevent inappropriate access to such information, the requestor shall personally appear at the program office and produce positive photo identification at the time of their request. The program shall furnish a single copy of the report responding to such request at no charge to the individual.

K. A parent, legal guardian, or legal healthcare agent may solicit prescription monitoring information and audit trail information from the program for the purpose of reviewing the history of monitored drugs dispensed to a child or an individual for whom the agent makes healthcare decisions, to the extent consistent with federal and state confidentiality laws and regulations. To prevent inappropriate access to such information, the requestor shall personally appear at the program office and produce positive photo identification at the time of their request. The program shall furnish a single copy of the report responding to such request at no charge to the individual.

L. An executor of a will or a court-appointed succession representative of an estate may solicit prescription monitoring information and audit trail information from the program for the purpose of reviewing the history of monitored drugs dispensed to a deceased individual. To prevent inappropriate access to such information, the requestor shall personally appear at the program office and produce positive photo identification at the time of their request. The program shall furnish a single copy of the report responding to such request at no charge to the individual.

M. Program personnel, once properly registered, may solicit prescription monitoring information from the program's database for the purpose of maintaining the database, analysis and reporting of data, compliance reviews, and responding to legitimate inquiries from authorized users or other individuals.

N. Prescription monitoring programs, electronic health information systems, and pharmacy information systems located in other states, territories, federal districts, and federal jurisdictions may access prescription monitoring information from the program through a secure interstate data exchange system or health information exchange approved by the board, but only in compliance with the provisions of R.S. 40:1007(G).

O. The board may provide prescription monitoring information to authorized users of the prescription monitoring program via a state health information exchange or other third-party conduit that has been approved by the board.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1347 (July 2007), amended LR 39:315 (February 2013), amended LR 40:1095 (June 2014), amended by the Department of Health, Board of Pharmacy, LR 46:

**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 change 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 change 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 change will have no effect on the functioning of the family.

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

5. The Effect on the Behavior and Personal Responsibility of Children. The proposed rule change 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 change 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 change 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 change 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 change will have no effect on employment or workforce development.

4. The Effect on Taxes and Tax Credits. The proposed rule change 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 change 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 change will require a pharmacy dispensing any of the nine listed drugs of concern to include those dispensing transactions in their automated reports of the dispensing of all controlled substances and drugs of concern to the state prescription monitoring program.

The reporting requirements for controlled substances and drugs of concern apply to all pharmacies dispensing outpatient prescriptions.

2. The Establishment of Less Stringent Schedules or Deadlines for Compliance or Reporting Requirements for Small Businesses. The current rule requires all pharmacies to file such automated reports no later than the end of the next business day. The proposed rule change will not affect that reporting schedule.

3. The Consolidation or Simplification of Compliance or Reporting Requirements for Small Businesses. The reporting requirements in the proposed rule change are the same for all pharmacies.

4. The Establishment of Performance Standards for Small Businesses to Replace Design or Operational Standards Required in the Proposed Rule. There no design or operational standards in the proposed rule change.

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.

**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 change will have no effect on the staffing level requirements or the qualifications for that staff 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 change 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 change 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 Malcolm J Broussard, 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.

**Public Hearing**

A public hearing to solicit comments and testimony on the proposed Rule amendment is scheduled for 9 a.m. on Friday, May 29, 2020. During the hearing, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12 p.m. noon that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

Malcolm J Broussard
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 a one-time cost of $2,000 in FY 20 and $2,000 in FY 21. There will be no additional expenditures or cost savings for LBP.

The proposed rule change adds nine drugs, seven of which are used for the treatment of hepatitis to the definition of "Drugs of Concern" presently in the administrative rules: (1) elbasvir / grazoprevir, (2) glecaprevir / pibrentasvir, (3) ledipasvir / sofosbuvir, (4) ombitasvir / paretaprevir / ritonavir / dasabuvir, (5) sofosbuvir, (6) sofosbuvir / velpatasvir, and (7) sofosbuvir / velpatasvir / voxilaprevir. The other drugs to be added are promethazine when present in oral liquid formulation and gabapentin. To the extent other local governmental units report dispensing transactions of controlled substances and drugs of concern to the state prescription monitoring program, there may be a minimal cost for local governmental entities to update their dispensing information systems to include prescriptions for the nine listed drugs in their daily automated reports.

The proposed rule change removes several redundant definitions and other sections and also implements provisions of several legislative acts: Act 352 of 2012, Act 189 of the 2016 Regular Session, Acts 76 and 241 of the 2017 Regular Session, Act 232 of the 2018 Regular Session, and Act 80 of 2019. The revision of the administrative rules associated with the aforementioned acts align the rules with present administrative practice, and will not result in any additional costs or savings for the LBP or other state or local governmental units.

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

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

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

Pharmacies are already required to report their dispensing transactions for controlled substances and drugs of concern to the state prescription monitoring program. Pharmacies which dispense any of the listed drugs in Part I will need to update their dispensing information system to classify the listed drugs as Drugs of Concern so the dispensing transactions for those listed drugs will be included in their daily reports to the state prescription monitoring program. For some providers, there may be no cost to re-classify those drugs in their dispensing information system. Other providers may need to incur an indeterminable cost to perform that process that is anticipated to be nominal.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule change will not affect competition or employment.