

## NOTICE OF INTENT

### Department of Health and Hospitals Board of Medical Examiners

#### Mandatory Access and Review of the Prescription Monitoring Program Data (LAC 46:XLV.6931-6937)

Notice is hereby given that in accordance with the Louisiana Administrative Procedure Act, R.S. 49:950 *et seq.*, and pursuant to the authority of the Louisiana Medical Practice Act, R.S. 37:1270, the Louisiana Podiatry Practice Act, La. Rev. Stat. §§37:611-37:628, the Louisiana Physician Assistant Practice Act, La. Rev. Stat. §37:1360.23, and the Uniform Controlled Dangerous Substances Law, R.S. 40:978, as amended by Act 76 of the 2017 Regular Session of the Louisiana Legislature, the Louisiana State Board of Medical Examiners (Board) intends to adopt rules requiring mandatory access and review of prescription monitoring program data prior to initially prescribing any opioid to a patient and at intervals of at least every 90 days if opioids are prescribed for more than 90 days. The proposed rules are applicable to individuals licensed by the Board whose scope of practice includes the authority to prescribe opioids *e.g.*, physicians, podiatrists and physician assistants. The proposed rules also provide applicable definitions, specify certain exceptions provided by law and provide for non-compliance.

#### Title 46

## PROFESSIONAL AND OCCUPATIONAL STANDARDS

### Part XLV. Medical Professions

#### Subpart 3. Practice

#### Chapter 69. Prescription, Dispensation, and Administration of Medications

#### Subchapter C. Mandatory Access and Review of Prescription Monitoring Program Data

#### §6931. Scope of Subchapter

A. The rules of this Subchapter provide for prescriber mandatory access and review of the Louisiana Prescription Monitoring Program, R.S. 40:1001 *et seq.*, as from time to time may be amended (PMP), and for exceptions and non-compliance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270, 37:611-37:628, 37:1360.23, and 40:978.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR

#### §6933. Definitions

A. As used in this Subchapter, the following terms and phrases shall have the meanings specified.

*Administer*—with respect to a medication provided or dispensed by a prescriber for use by a patient, the term *administer* means directly or through an agent to give, provide, or supply for immediate oral ingestion, insertion, or topical application by the patient, or to insert, apply topically, or inject intravenously, intramuscularly, subcutaneously, intrathecally, or extrathecally.

*Board*—the Louisiana State Board of Medical Examiners, as constituted under R.S. 37:1263.

*Controlled Dangerous Substance*—any substance defined, enumerated or included in federal or state statute or regulations 21 C.F.R. §§1308.11-15 or R.S. 40:964, or any substance which may hereafter be designated as a controlled substance by amendment or supplementation of such regulations and statute.

*Delegate*—an individual authorized by a prescriber or dispenser who is also authorized to access and retrieve prescription monitoring program data for the purpose of assisting the prescriber or dispenser, and for whose actions the authorizing prescriber or dispenser retains accountability.

*Prescribe*—to issue a request or order for a drug or medical device by an individual licensed under this Part for a legitimate medical purpose. The act of prescribing must be in good faith and in the usual course of the licensee's professional practice.

*Prescriber*—a physician, podiatrist, physician assistant, and any other category of health care provider as may hereafter be licensed by the Board under this Part, whose scope of practice includes authority to prescribe opioids.

*Prescription*—an order from a practitioner authorized by law to prescribe for a drug or device that is patient specific and is communicated by any means to a pharmacist in a permitted pharmacy.

*Prescription Monitoring Program or PMP*—The electronic system for the monitoring of controlled substances and other drugs of concern established by the Prescription Monitoring Program Act, R.S. 40:1001 *et seq.*, as may from time to time be amended.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270, 37:611-37:628, 37:1360.23, and 40:978.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR

#### §6935. Mandatory Access and Review of Prescription Monitoring Program Data; Exceptions

A. Prior to initially prescribing any opioid to a patient, a prescriber or his/her delegate shall access and review the patient's record in the PMP; and

B. If opioids are prescribed to the patient for more than 90 days, the prescriber or his/her delegate shall access and review the record in the PMP at least every 90 days.

C. This Section shall not apply if:

1. the drug is prescribed or administered to a hospice patient or any other patient who has been diagnosed as terminally ill;

2. the drug is prescribed or administered for the treatment of cancer-related chronic or intractable pain;

3. the drug is ordered or administered to a patient being treated in a hospital;

4. the PMP is not accessible or not functioning properly due to an electronic issue. However, the prescriber shall check the PMP after electronic accessibility has been restored and note the cause for the delay in the patient's chart; or

5. no more than a single 7-day supply of the drug is prescribed or administered to a patient.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270, 37:611-37:628, 37:1360.23, and 40:978.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR

### **§6937. Effect of Non-Compliance**

A. For non-compliance with any of the provisions of this Subchapter the board may suspend, revoke, refuse to issue or impose probationary or other terms, conditions and restrictions on any license to practice in the state of Louisiana, or any registration issued under this Part, held or applied for by: a physician culpable of such violation under R.S. 37:1285A; a podiatrist culpable of such violation under R.S. 37:624A; and a physician assistant culpable of such violation under R.S. 37:1360.33.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270, 37:611-37:628, 37:1360.23, and 40:978.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR

### **Family Impact Statement**

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of the proposed rules on the family has been considered. It is not anticipated that the proposed rules will have any impact on family, formation, stability or autonomy, as described in R.S. 49:972.

### **Poverty Statement**

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the impact of the proposed rules on those that may be living at or below one hundred percent of the federal poverty line has been considered. It is not anticipated that the proposed rules will have any impact on child, individual or family poverty in relation to individual or community asset development, as described in R.S. 49:973.

### **Provider Statement**

In compliance with HCR 170 of the 2014 Regular Session of the Louisiana Legislature, the impact of the proposed rules on organizations that provide services for individuals with developmental disabilities has been considered. It is not anticipated that the proposed rules will have any impact on the staffing, costs or overall ability of such organizations to provide the same level of services, as described in HCR 170.

### **Public Comments**

Interested persons may submit written data, views, arguments, information or comments on the proposed rules to Rita Arceneaux, Confidential Executive Assistant, Louisiana State Board of Medical Examiners, 630 Camp Street, New Orleans, Louisiana, 70130, (504) 568-6820, Ex. 242. She is responsible for responding to inquiries. Written comments will be accepted until 4:00 p.m., November 20, 2017.

### **Public Hearing**

A request pursuant to R.S. 49:953(A)(2) for a public hearing must be made in writing and received by the Board within 20 days of the date of this notice. If a public hearing is requested to provide data, views, arguments, information or comments orally in accordance with the Louisiana Administrative Procedure Act, the hearing will be held on Monday, November 27, 2017 at 10:00 a.m. at the office of the Louisiana State Board of Medical Examiners, 630 Camp

Street, New Orleans, Louisiana 70130. Any person wishing to attend should call to confirm that a hearing is being held.

Vincent A. Culotta, Jr., M.D.  
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT  
SUMMARY

Person Preparing Statement: VINCENT A CULOTTA, JR., M.D. Dept.: HEALTH AND HOSPITALS  
Executive Director

Phone: (504) 568-6820 Office: LOUISIANA STATE BOARD OF MEDICAL EXAMINERS

Return Address: Post Office Box 30250 Rule Title: PHYSICIAN, PODIATRIST AND PHYSICIAN ASSISTANT PRACTICE: MANDATORY ACCESS AND REVIEW OF PRESCRIPTION MONITORING PROGRAM DATA  
New Orleans, LA 70190-0250  
630 Camp Street  
New Orleans, LA 70130

Date Rule Takes Effect: On Final Promulgation—  
JAN. 20, 2018 (est.)

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, based on the attached worksheets, 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 proposed rules will not result in additional expenditures for state or local governmental units. The LA State Board of Medical Examiners anticipates devoting existing resources and personnel to processing information or reports concerning non-compliance with the proposed rules

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

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

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

The proposed rules will likely result in an indeterminable, but marginal workload increase for physicians and other health care professionals licensed by the Board whose scope of practice includes the authority to prescribe opioids e.g., podiatrists and physician assistants. The proposed rules are being promulgated in accordance with Act 76 of the 2017 Regular Session, which requires physicians and other authorized providers to access and review a patient's record in the Louisiana Prescription Monitoring Program (PMP), either individually or through a delegate, prior to initially prescribing any opioid to a patient. If opioids are prescribed for more than 90 days, the proposed rules further provide that the prescriber or his delegate shall access and review the patient's PMP record at least every 90 days. Exceptions to the need to access the PMP, which are authorized by Act 76, are incorporated into the proposed rules, which also provide that non-compliance may serve as a basis for enforcement action by the Board. The impact of the proposed rules is indeterminable because there is no information or data available concerning the number of physicians, podiatrists or physician assistants who prescribe opioids or the number that do so in a manner outside of the proposed exceptions. Furthermore, there is no data or information regarding the amount of time or associated costs related to accessing, reviewing, and reacting to PMP data. However, the proposed rules may benefit the public generally to the extent that enhanced access and review of PMP data may reduce diversion and inappropriate prescribing which, in turn, may decrease patient mortality associated with the misuse of opioids and healthcare costs related to the treatment and care of overuse and addiction.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rules will not affect competition or employment.

  
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Signature of Agency Head or Designee  
VINCENT A. CULOTTA, JR., M.D.  
Executive Director  
Name and Title of Agency Head or Designee  
10/9/17  
\_\_\_\_\_  
Date of Signature

  
\_\_\_\_\_  
Legislative Fiscal Officer or Designee  
9/10/2017  
\_\_\_\_\_  
Date of Signature