

LOUISIANA STATE BOARD OF MEDICAL EXAMINERS

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January 4, 2018

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Re: Final Report: Proposed Rules; Mandatory
Access and Review of Prescription Monitoring
Program Data — (LAC 46:XLV.6931-6937)

Dear Sirs:

Pursuant to La. Rev. Stat. §49:968(D), the Louisiana State Board of Medical Examiners respectfully submits the enclosed report on the final adoption of the captioned rules. Notice was previously published in the October 2017 edition of the *Louisiana Register*, Vol. 43, No. 10, pp. 2022-2024. The Board plans to adopt the rules by and upon publication in the February 20, 2018, edition of the *Register*.

Very truly yours,

**LOUISIANA STATE BOARD OF
MEDICAL EXAMINERS**

By: _____

A handwritten signature in blue ink, appearing to read "Vincent A. Culotta, Jr.", written over a horizontal line.

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

Enclosure

**FINAL REPORT RELATIVE TO PROPOSED
ADOPTION OF ADMINISTRATIVE RULES GOVERNING
MANDATORY ACCESS AND REVIEW OF PRESCRIPTION
MONITORING PROGRAM DATA**
(La. Rev. Stat. §49:968(D))

By The

LOUISIANA STATE
BOARD OF MEDICAL EXAMINERS

Submitted To The

COMMITTEE ON HEALTH AND WELFARE,
LOUISIANA SENATE,

COMMITTEE ON HEALTH AND WELFARE,
LOUISIANA HOUSE OF REPRESENTATIVES,

PRESIDENT OF THE SENATE

And

SPEAKER OF THE HOUSE OF REPRESENTATIVES

January 4, 2018

**FINAL REPORT RELATIVE TO PROPOSED
ADOPTION OF ADMINISTRATIVE RULES GOVERNING
MANDATORY ACCESS AND REVIEW OF PRESCRIPTION
MONITORING PROGRAM DATA**

Jan. 4, 2018

(La. Rev. Stat. §49:968(D))

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This Report is respectfully submitted by the Louisiana State Board of Medical Examiners (the “Board”), within the Department of Health and Hospitals, pursuant to La. Rev. Stat. §49:968(D).

By Notice of Intent published in the October 20, 2017, edition of the *Louisiana Register*, Vol. 43, No. 10, pp. 2022-2024, the Board proposed to adopt rules requiring mandatory access and review of Prescription Monitoring Program data by individuals licensed by the Board whose scope of practice includes the authority to prescribe opioids *e.g.*, physicians, podiatrists and physician assistants, LAC 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), Sections 6931-6937. Concurrently with submission of the Notice of Intent to the *Register*, in accordance with La. Rev. Stat. §40:968, the Board submitted a Report on the proposed rules to the Senate and House Committees on Health and Welfare, the President of the Senate and the Speaker of the House of Representatives.¹ Following publication of Notice of Intent, the Board did not receive a request for public hearing; however, during the comment period it did receive written comments from one (1) individual on the proposed rules.

This Report, submitted by the Board pursuant to and as prescribed by La. Rev. Stat. §49:968(D), sets forth a summary of the comments received by the Board on the subject rules, and a statement of the Board's response to such comment, including a concise statement of the principal reasons for and against adoption of any modifications or changes.² A copy of the Notice of Intent containing the full text of the proposed rules that were previously published and appeared in the October 2017 edition of the *Louisiana Register* accompanies this Report as

¹*Electronic Mail*, Vincent A. Culotta, Jr., M.D., Exec. Dir., La. State Bd. Med. Exam., RE: Report Relative to Proposed Rules Governing Mandatory Access and Review of Prescription Monitoring Program Data (Oct. 9, 2017).

²*See*: La. Rev. Stat. §49:968(D)(1)(b).

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(La. Rev. Stat. §49:968(D))

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Appendix A, in the form of the final rules adopted by the Board and which are to be promulgated by and upon publication in the February 2018, edition of the *Louisiana Register*.

The subject rules are proposed for adoption and promulgation pursuant to the Board's administrative rule making authority under the Louisiana Medical Practice Act, La. Rev. Stat. §37:1270, the 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.

I. Background—Act 76 of the 2017 Regular Session of the Louisiana Legislature requires that licensing boards regulating practitioners with applicable prescribing authority, adopt rules requiring the prescriber or his delegate to access and review a patient's Prescription Monitoring Program (PMP) data prior to initially prescribing any opioid to the patient. The Act further provides that the prescriber or his delegate shall access and review the patient's PMP data at least every ninety days if the patient's course of treatment continues for more than ninety days. The Act also provides for specific exceptions and enforcement, La. Rev. Stat. §40:978.

II. Summary of Proposed Rules—In conformity with Act 76, the proposed rules require physicians and other health care professionals licensed by the Board, whose scope of practice includes prescribing opioids *e.g.*, physicians, podiatrists and physician assistants (*See Definitions, 6933*), or their delegates, to access and review the patient's record in the PMP prior to initially prescribing any opioid to the patient (*6935A*). If opioids are prescribed to the patient for more than 90 days, the proposed rules provide that the prescriber or his delegate shall access and review the patient's PMP record at least every 90 days (*6935B*). The specific exceptions to accessing the PMP that were included in Act 76 are incorporated into the proposed rules (*6935C*), which also provide that non-compliance could serve as a basis for enforcement action by the Board (*6937*).

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(La. Rev. Stat. §49:968(D))

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III. Summary of the Comments and Board Response—As noted above, the Board received written comments from one (1) a commenter to the Notice of Intent that appeared in the October 2017 edition of the *Register*. A summary of the comment, as well as the Board’s response, is set forth below.

Comment (6935C.2). The commenter question whether proposed Section 6935C.2 applies to “intractable pain from any cause, or just intractable pain that is cancer-related?”

Response. Section 6935C.2 of the proposed rules provides: “This Section shall not apply if: (2) the drug is prescribed or administered for the treatment of cancer-related chronic or intractable pain.” As constructed “cancer-related” modifies both “chronic [pain]” or “intractable [pain]”. Therefore, the exception applies only to pain related to cancer, whether it is cancer-related chronic pain or cancer-related intractable pain. Stated differently, the exception does not apply to pain that is unrelated to cancer.

* * *

course of opioid treatment lasts for 90 days or more, unless certain circumstances apply. In the event a dentist fails to monitor as outlined in the proposed rule changes, they are subject to punishment, penalty, sanction, or remediation as provided for in the Dental Practice Act.

Dentists and dental hygienists may realize reduced expenses as a result of reduced continuing education requirements. The proposed rule changes alter annual continuing education (CE) requirements for dentists and dental hygienists. CE for dentists is reduced by 10 hours, from 40 hours annually to 30 hours annually, and must consist entirely of clinical service courses. Under the current rules, dentists may take 20 hours of clinical service CE and 20 hours of more general CE. Furthermore, the proposed rule changes add a requirement that dentists take a 3-hour course on opioid management at least once during their career. Lastly, the proposed rule changes state that dentists holding permits for adult and/or pediatric sedation must complete a 12-hour CE course in order to renew their permits, e.g. if a dentist holds both permits, they must take 24 hours of CE regarding clinical and pediatric sedation to qualify for permit renewal. These CE hours will count toward the 30-hour requirement.

The proposed rule changes reduce CE requirements for dental hygienists by 4 hours, from 24 hours to 20 hours. However, all hours must consist entirely of clinical service courses.

The proposed rule changes allow dentists and dental hygienists who have failed a licensure examination three or more times the ability to become licensed in Louisiana through alternative means. Dentists and hygienists must have initially passed a licensure examination, been actively practicing using an unrestricted dental license for 5 or more years in another state, not faced discipline from dental boards in any state, and receives approval from a majority of the LA Board of Dentistry after meeting with the full board in person. In lieu of the aforementioned requirements for dentists, dentists completing an accredited dental post-doctoral program lasting at least one year or more may gain licensure after meeting with the full LA Board of Dentistry and receiving approval from a majority of the members.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes will impact competition and employment to the extent the new alternative means of licensure allow for more dentists and dental hygienists to practice in Louisiana. The amount of new dentists and hygienists that may receive licensure is unknown, therefore the effect on competition and employment is indeterminable.

Arthur Hickham, Jr.
Executive Director
1710#030

Evan Brasseaux
Staff Director
Legislative Fiscal Office

NOTICE OF INTENT

Department of Health Board of Medical Examiners

Mandatory Access and Review of Prescription Monitoring Program Data (LAC 46:XLV.Chapter 69)

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, R.S. 37:611-37:628, the Louisiana Physician Assistant Practice Act, R.S. 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 Rule is 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 Rule will 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, Board of Medical Examiners, LR 44:

§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 CFR §§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, Board of Medical Examiners, LR 44:

§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 seven-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, Board of Medical Examiners, LR 44:

§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:

1. a physician culpable of such violation under R.S. 37:1285(A);

2. a podiatrist culpable of such violation under R.S. 37:624(A); and

3. 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, Board of Medical Examiners, LR 44:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of the proposed Rule on the family has been considered. It is not anticipated

that the proposed Rule will have any impact on family, formation, stability or autonomy, as described in R.S. 49:972.

Poverty Impact 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 Impact 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 Rule 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, LA 70130, (504) 568-6820, Ex. 242. She is responsible for responding to inquiries. Written comments will be accepted until 4 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 a.m. at the office of the Louisiana State Board of Medical Examiners, 630 Camp Street, New Orleans, LA 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 FOR ADMINISTRATIVE RULES

RULE TITLE: Mandatory Access and Review of Prescription Monitoring Program Data

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT 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 BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL 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 overdose and addiction.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rules will not affect competition or employment.

Vincent A. Culotta, Jr., M.D.
Executive Director
1710#073

Gregory V. Albrecht
Chief Economist
Legislative Fiscal Office

NOTICE OF INTENT

Department of Health Board of Medical Examiners

Physician Practice; Physician Collaboration with Advanced Practice Registered Nurses (LAC 46:XLV.Chapter 79)

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 State Board of Medical Examiners (board) intends to adopt rules to facilitate physician collaboration with advanced practice registered nurses (APRNs), LAC 46:XLV.7901 et seq. The proposed rules provide for: the scope of the Subchapter (§7901); applicable terms and definitions (§7903); a prohibition against collaboration other than in compliance with the rules (§7905); exceptions (§7907); due diligence (§7909); eligibility and required components of a collaborative practice agreement (§7911); required information (§7913); collaborating physician responsibilities and compensation arrangements (§7915); limitations (§7917); continuous quality improvement and Board access to documents (§7919); and the effect of violations (§7921). The proposed Rule is set forth below

Title 46 PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part XLV. Medical Professions Subpart 3. Practice

Chapter 79. Physician Collaboration with Advanced Practice Registered Nurses

Subchapter A. General Provisions

§7901. Scope

A. The rules of this Chapter govern the practice of physicians in this state who engage in collaborative practice with an advanced practice registered nurse who provides acts of medical diagnosis or prescriptions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(B)(6).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Medical Examiners, LR 44:

§7903. Definitions

A. As used in this Chapter, the following terms shall have the meanings specified.

Act—the Louisiana Medical Practice Act or Act, R.S. 37:1261 et seq.

Advanced Practice Registered Nurse or *APRN*—a licensed registered nurse who is licensed as an advanced practice registered nurse by the Louisiana State Board of Nursing.

Alternate Collaborating Physician or *ACP*—a physician meeting the eligibility requirements of this Chapter who is designated to serve as collaborating physician, in accordance with §7911.A.5 of these rules, when the collaborating physician is unavailable.

Board—the Louisiana State Board of Medical Examiners, as constituted in the Louisiana Medical Practice Act.

Clinical Practice Guidelines—written or electronic documents, jointly agreed upon by the collaborating physician and APRN that describe a specific plan, arrangement, or sequence of orders, steps, or procedures to be followed or carried out in providing patient care in various clinical situations. These may include textbooks, reference manuals, electronic communications and Internet sources.

Collaborating Physician or *CP*—a physician with whom an APRN has been approved to collaborate by the Louisiana State Board of Nursing, who is actively engaged in clinical practice and the provision of direct patient care in Louisiana, with whom an APRN has developed and signed a collaborative practice agreement for prescriptive and distributing authority. A CP shall hold a current, medical license issued by the board, or be otherwise authorized by federal law or regulation to practice medicine in this state, have no pending disciplinary proceedings and practice in accordance with rules of the board.

Collaboration or *Collaborate*—a cooperative working relationship between a physician and APRN to jointly contribute to providing patient care and may include but not be limited to discussion of a patient's diagnosis and cooperation in the management and delivery of health care with each provider performing those activities that he or she is legally authorized to perform.