Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII – Pharmacists

Chapter 29. Prescription Monitoring Program

Subchapter A. General Operations

§2901. Definitions

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

Administer or *Administration* – the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or any other means.

Advisory Council – the entity established in R.S. 40:1005.

Board – the Louisiana Board of Pharmacy.

Controlled Substance – any substance or drug defined, enumerated, or included in federal or state statute or rules, 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 or statute. *Controlled Substance* shall not include distilled spirits, wine, malt beverages, or tobacco.

Delegate – a person authorized by a prescriber or dispenser who is also an authorized user (as described in §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.

Dispense or *Dispensing* – the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

Dispenser – a person authorized by this state to dispense or distribute to the ultimate user any controlled substance or drug monitored by the program, but shall not include any of the following:

a. a pharmacy permitted by the board as a hospital pharmacy that dispenses or distributes any controlled substance or drug monitored by the program for the purposes of inpatient health care;
b. a practitioner who dispenses or distributes no more than a single 48-hour supply of such controlled substance or drug to a patient prior to, or subsequent to, performing an actual procedure on that patient;
c. a practitioner or other authorized person who administers such controlled substance or drug upon the lawful order of a practitioner;
d. a wholesale distributor of such controlled substance or drug that is credentialed by the Louisiana Board of Drug and Device Distributors;

Distribute or *Distribution* – the delivery of a drug or device other than by administering or dispensing.

Drug – any of the following:

a. any substance recognized as a drug in the official compendium, or supplement thereto, designated by the board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;
b. any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;
c. any substance other than food intended to affect the structure or any function of the body of humans or other animals.

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.

Patient – the person or animal who is the ultimate user of a controlled substance or drug monitored by the program for whom a prescription is issued and for whom a controlled substance or drug is dispensed.

Prescriber – a licensed health care professional with prescriptive authority.

Prescription Monitoring Information – data submitted to and maintained by the prescription monitoring program.

Prescription Monitoring Program or *PMP* – the program established in R.S. 40:1004.

Procedure – any dental or medical practice or process described in the current year's version of the American

Dental Association's *Current Dental Terminology* or the American Medical Association's *Code of Procedural Terminology*.

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).

§2903. Authority for Program Operation

A. The board shall establish and maintain, in consultation with and upon the recommendation of the advisory council, an electronic system for the monitoring of controlled substances and drugs of concern dispensed in the state or dispensed to an address in the state.

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).

§2905. Authority to Engage Staff

A. The board shall have the authority to engage a program director and sufficient number of other personnel as may be necessary to accomplish the mission of the program.

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).

§2907. Authority to Contract with Vendors

A. The board shall have the authority to engage vendors to facilitate the collection of the prescription monitoring program data and to facilitate access to the program data by authorized users.

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).

§2909. Advisory Council

A. The advisory council shall consist of the following members, each of whom may appoint a designee:
   1. the president of the Louisiana State Board of Medical Examiners;
   2. the president of the Louisiana State Board of Dentistry;
   3. the president of the Louisiana State Board of Nursing;
   4. the president of the Louisiana State Board of Optometry Examiners;
   5. the president of the Louisiana Academy of Physician Assistants;
   6. the president of the Louisiana Board of Pharmacy;
   7. the superintendent of the Louisiana State Police;
   8. the administrator of the United States Drug Enforcement Administration;
   9. the speaker of the Louisiana House of Representatives;
   10. the president of the Louisiana Senate;
   11. the chairman of the House Committee on Health and Welfare;
   12. the chairman of the Senate Committee on Health and Welfare;
   13. the secretary of the Department of Health and Hospitals;
   14. the president of the Louisiana State Medical Society;
   15. the president of the Louisiana Dental Association;
   16. the president of the Louisiana Association of Nurse Practitioners;
   17. the president of the Optometry Association of Louisiana;
   18. the president of the Louisiana Pharmacists Association;
   19. the president of the Louisiana Independent Pharmacies Association;
   20. the president of the National Association of Chain Drug Stores;
   21. the president of the Louisiana Sheriffs' Association;
   22. the president of the Louisiana District Attorneys Association;

23. the president of the Pharmaceutical Research and Manufacturers of America;
24. the president of the Louisiana Academy of Medical Psychologists;

B. The members of the advisory council shall serve at the pleasure of their respective appointing authorities, eleven of whom shall constitute a quorum for the transaction of business. The members shall elect a chairman and vice chairman whose duties shall be established by the advisory council. The board shall fix a time and place for regular meetings of the advisory council, which shall meet at least quarterly. The advisory council shall establish policies and procedures necessary to carry out its duties.

C. The board shall seek, and the advisory council shall provide, information and advice regarding the development and operation of the electronic monitoring system, including but not limited to the following:
1. which controlled substances should be monitored;
2. which drugs of concern demonstrate a potential for abuse and should be monitored;
3. design and implementation of educational courses identified in R.S. 40:1008;
4. the methodology to be used for analysis and interpretation of prescription monitoring information;
5. design and implementation of a program evaluation component;
6. identification of potential additional members to the advisory council.

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), LR 40:1096 (June 2014).

Subchapter B. Data Collection

§2911. Reporting of Prescription Monitoring Information

A. Each dispenser shall submit to the board information regarding each prescription dispensed for a controlled substance.

B. Each dispenser shall submit the required information by electronic means no later than the next business day after the date of dispensing.

C. If the dispenser is unable to submit prescription information by electronic means, he may apply to the board for a waiver. The board may grant a waiver to that requirement; if so, the waiver shall state the format and frequency with which the dispenser shall submit the required information. The waiver shall expire one year after the date of issue, unless terminated sooner 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 33:1346 (July 2007), amended LR 39:314 (February 2013), LR 41:684 (April 2015).

§2913. Required Data Elements

A. The information submitted for each prescription shall include data relative to the identification of the following elements of the transaction, or alternative data as identified in the board's program user manual. To the extent possible, the data shall be transmitted in the format established by the American Society for Automation in Pharmacy (ASAP) Telecommunications Format for Prescription Monitoring Programs Standard Version 4.2 or a successor.
1. Prescriber Information;
   a. last and first name of prescriber;
   b. United States Drug Enforcement Administration (DEA) registration number, and suffix if applicable, or in the alternative, the national provider identifier (NPI) number, as issued by the United States Centers for Medicare and Medicaid Services (CMS).
2. Patient Information;
   a. last and first name of human patient and middle initial or name if available, or in the event of a veterinary prescription, the client's name and patient's animal species;
   b. complete address of patient;
   c. date of birth of patient;
   d. identification number of patient;
   e. gender code;
   f. species code.
3. Prescription Information;
   a. identification number of prescription;
   b. date of issuance;

c. date of fulfillment;
d. number of refills authorized on original prescription and refill number;
e. method of payment for prescription (cash, insurance, or government subsidy).

4. Drug Information;
   a. National Drug Code (NDC) number;
   b. quantity dispensed;
   c. days supply.
5. Dispenser Information;
   a. DEA registration number, or in the alternative, the national provider identifier (NPI) number.

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).

§2915. Failure to Report Prescription Information

A. A dispenser who fails to submit prescription monitoring information to the board as required shall be referred to the appropriate professional licensing, certification, or regulatory agency for administrative sanctions as deemed appropriate by that agency.

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).

Subchapter C. Access to Prescription Monitoring Information

§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. persons authorized to prescribe or dispense controlled substances or drugs of concern, and their delegates, for the purpose of providing medical or pharmaceutical care for their patients, or for verifying their prescription records;
   2. designated representatives from the professional licensing, certification, or regulatory agencies of this state or another state charged with administrative oversight of those professionals engaged in the prescribing or dispensing of controlled substances or other drugs of concern;
   3. designated representatives from the Louisiana Medicaid program regarding Medicaid program recipients;
   4. designated representatives of the board or any vendor or contractor establishing or maintaining the prescription monitoring program;
   5. prescription monitoring programs located in other states, 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), LR 40:1095 (June 2014).

§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. The applicant shall successfully complete the program's orientation course, and attach evidence of same to his application to the program.
   2. The applicant shall file an application with the program, using the form supplied by the program for that purpose.
   3. The board shall verify the practitioner applicant is in possession of a valid license to prescribe or dispense controlled substances or in the case of an agency applicant, the board shall verify agency representation.
   4. Upon verification of all requirements, the board shall issue the appropriate credential necessary to access prescription monitoring information.

5. 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.
6. 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 by 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).

§2921. Methods of Access to Prescription Monitoring Information

A. Prescribers and dispensers, as well as their delegates, once properly registered, may solicit prescription monitoring information from the program concerning their patients, or for verifying their prescription records. The program may require such users to certify the legitimacy of their inquiry prior to furnishing the requested information.
B. Designated representatives from agencies charged with administrative oversight of prescribers and dispensers of controlled substances may solicit prescription monitoring 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. Designated representatives of the Louisiana Medicaid program, once properly registered, may solicit prescription monitoring information from the program concerning specific recipients. The program may require such users to certify the legitimacy of their inquiry prior to furnishing the requested information.
D. Designated representatives of the board, or any vendor or contractor establishing or maintaining the program, once properly registered, may solicit prescription monitoring information from the program for the purpose of establishing or maintaining the program's database.
E. Upon receipt of one of the following methods of application by local, state, out-of-state, or federal law enforcement or prosecutorial officials, the program may provide prescription monitoring information:
    1. a court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;
    2. a grand jury subpoena; or
    3. an administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided by law enforcement to the board, and further, provided all of the following:
        a. the information sought is relevant and material to a legitimate law enforcement inquiry;
        b. the request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought;
        c. de-identified information, or limited information that does not identify or could not reasonably lead to the identification of an individual patient, could not reasonably be used.
F. Individuals may solicit their own prescription monitoring 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.
G. Program personnel, once properly registered, may solicit prescription monitoring information from the program's database for the purpose of responding to legitimate inquiries from authorized users or other individuals.
H. Prescription monitoring programs located in other states may access prescription monitoring information from the program through a secure interstate data exchange system or health information exchange system 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), LR 40:1095 (June 2014).

§2923. Unlawful Use or Disclosure of Prescription Monitoring Information

A. If the program receives evidence of inappropriate or unlawful use or disclosure of prescription monitoring information by an authorized user or his delegate, the program shall refer that user to the appropriate professional licensing, certification, or regulatory agency for administrative sanctions as deemed appropriate by that agency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1348 (July 2007), amended LR 40:1095 (June 2014).

Subchapter D. Reports

§2925. Release of Prescription Monitoring Information to Other Entities

A. The program shall provide prescription monitoring information to public or private entities, whether located in or outside of the state, for public research, policy, or educational purposes, but only after removing information that identifies or could reasonably be used to identify prescribers, dispensers, and individual patients or persons who received prescriptions from prescribers.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1348 (July 2007), amended LR 39:315 (February 2013).

§2927. Legislative Oversight

A. The board shall report to the appropriate legislative oversight committee on a periodic basis, but in no case less than annually, the cost benefits and other information relevant to policy, research, and education involving controlled substances and other drugs of concern monitored by the program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1348 (July 2007).

§2929. Program Evaluation

A. The board shall, in consultation with and upon recommendation of the advisory council, design and implement an evaluation component to identify cost benefits of the prescription monitoring program and other information relevant to policy, research, and education involving controlled substances and drug monitored by the prescription monitoring program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1348 (July 2007).