

Redacted: March 17, 2006

Regular Session, 2006 – House Bill No. 153 – By Rep. Ronnie Johns

A Bill to enact a new law by the Legislature of Louisiana, as follows:

Section 1. Part X-A of Chapter 4 of Title 40 of the Louisiana Revised Statutes of 1950, comprised of R.S. 40:1001 through 1014, is hereby enacted to read as follows:

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Sec. 1004	Establishment of Prescription Monitoring Program
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PART X–A. PRESCRIPTION MONITORING PROGRAM

§1001. Short title

This Section shall be known and may be cited as the "Prescription Monitoring Program Act".

§1002. Purpose

The purpose of this Act is to authorize the development, implementation, operation, and evaluation of an electronic system for the monitoring of controlled substances and other drugs of concern that are dispensed in the state or dispensed to an address within the state. The goal of the program is to improve the state's ability to identify and inhibit the diversion of controlled substances and drugs in an efficient and cost-effective manner and in a manner that shall not impede the appropriate utilization of these drugs for legitimate medical purposes.

§1003. Definitions

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

- (1) "Administer" or "administration" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or any other means.
- (2) "Advisory council" means the entity established in R.S. 40:1005.

- (3) "Board" means the Louisiana Board of Pharmacy.
- (4) "Controlled substance" means 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.
- (5) "Dispense" or "dispensing" means 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.
- (6) "Dispenser" means 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 hospital care.
 - (b) A practitioner who dispenses or distributes no more than a single forty-eight-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 State Board of Wholesale Drug Distributors.
- (7) "Distribute" or "distribution" means the delivery of a drug or device other than by administering or dispensing.
- (8) "Drug" means 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 diseases 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.
- (9) "Drugs of concern" means drugs other than controlled substances as defined by rule which demonstrate a potential for abuse.
- (10) "Patient" means 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.
- (11) "Prescriber" means a licensed health care professional with prescriptive authority.
- (12) "Prescription monitoring information" means data submitted to and maintained by the prescription monitoring program.

(13) "Prescription Monitoring Program" or "PMP" means the program established in R.S. 40:1004.

(14) "Procedure" means 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.

§1004. Establishment of prescription monitoring program

- 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.
- B. In conformity with the Louisiana Public Bid Law, R.S. 38:2211, *et seq.*, the board may contract with a vendor to establish and maintain the electronic monitoring system pursuant to rules promulgated by the board.

§1005. 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 State Board of Examiners of Psychologists.
- (6) The president of the Louisiana State Board of Veterinary Medicine.
- (7) The president of the Louisiana Board of Pharmacy.
- (8) The superintendent of the Louisiana State Police.
- (9) The administrator of the United States Drug Enforcement Administration.
- (10) The speaker of the Louisiana House of Representatives.
- (11) The president of the Louisiana Senate.
- (12) The chairman of the House Committee on Health and Welfare.
- (13) The chairman of the Senate Committee on Health and Welfare.
- (14) The secretary of the Department of Health and Hospitals.
- (15) The president of the Louisiana State Medical Society.
- (16) The president of the Louisiana Dental Association.
- (17) The president of the Louisiana Association of Nurse Practitioners.
- (18) The president of the Optometry Association of Louisiana.
- (19) The president of the Louisiana Veterinary Medical Association.
- (20) The president of the Louisiana Pharmacists Association.
- (21) The president of the Louisiana Independent Pharmacies Association.
- (22) The president of the National Association of Chain Drug Stores.
- (23) The president of the Louisiana Sheriffs' Association.
- (24) The president of the Louisiana District Attorneys Association.
- (25) The president of the Pharmaceutical Research and Manufacturers of America.
- (26) 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 all 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) Proper analysis and interpretation of prescription monitoring information.
- (5) Design and implementation of an evaluation component.
- (6) Potential nominees to the advisory council.

§1006. 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. The information submitted for each prescription shall include, at a minimum, data relative to the identification of the following elements of the transaction:

- (1) Prescriber information, including:
 - (a) Category of licensure and credential number.
 - (b) United States Drug Enforcement Administration registration number.
- (2) Patient, including:
 - (a) Full name.
 - (b) Address.
 - (c) Gender.
 - (d) Date of birth.
- (3) Prescription information, including:
 - (a) Date of issue.
 - (b) Date of dispensing.
 - (c) Days supply dispensed.
 - (d) Whether the prescription is new or a refill.
 - (e) Serial or prescription number assigned by the dispenser.
- (4) Controlled substance or drug information, including:
 - (a) Brand or generic name.
 - (b) National Drug Code for the drug dispensed.
 - (c) Quantity of the controlled substance or drug dispensed.
 - (d) Dosage form.
- (5) Dispenser information, including:
 - (a) Pharmacy permit number or other dispensing credential identifier.
 - (b) United States Drug Enforcement Administration registration number.

B. Each dispenser shall submit the required information in accordance with transmission methods and frequency established by the board.

C. The board may issue a waiver to a dispenser who is unable to submit prescription information by electronic means. The waiver shall state the format and frequency with which the dispenser shall submit the required information.

D. Any person or entity required to report information concerning prescriptions to the board or to its designated agent pursuant to the requirements of this Part shall not be liable to any person or entity for any claim of damages as a result of the act of reporting the information and no lawsuit may be predicated thereon. Any person or entity who submits report information in good faith containing prescription information that is not the subject of the PMP shall not be liable to any person or entity for any claim of damages and no lawsuit may be predicated thereon.

§1007. Access to prescription monitoring information

- A. Except as provided in Subsections C, D, E, and F of this Section, prescription monitoring information submitted to the board shall be protected health information and not subject to public or open records law, including but not limited to R.S. 44:1, *et seq.* Prescription monitoring information shall not be available for civil subpoena nor shall such information be disclosed, discoverable, or compelled to be produced in any civil proceeding nor shall such records be deemed admissible as evidence in any civil proceeding for any reason. Notwithstanding this provision, law enforcement and professional licensing, certification, or regulatory agencies may utilize prescription monitoring information in the course of any investigation and subsequent criminal and administrative proceedings.
- B. The board shall maintain procedures to ensure that the privacy and patient information collected, recorded, transmitted, and maintained is not disclosed to persons or entities except as in Subsections C, D, E, and F of this Section.
- C. The board shall review the prescription monitoring information. If there is reasonable cause to believe a violation of law or breach of professional or occupational standards may have occurred, the board shall notify the appropriate local, state, or federal law enforcement agency or professional licensing, certification, or regulatory agency and shall provide prescription monitoring information required for an investigation.
- D. The board 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 could be used to identify individual patients or persons who received prescriptions from prescribers.
- E. The following persons, after successful completion of the educational courses identified in R.S. 40:1008, 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, for the purpose of providing medical or pharmaceutical care for their patients.
 - (2) Local, state, and federal law enforcement or prosecutorial officials engaged in the administration, investigation, or enforcement of the laws governing controlled substances or other drugs of concern.
 - (3) Designated representatives from the professional licensing, certification, or regulatory agencies charged with supervising those professionals engaged in the prescribing or dispensing of controlled substances or other drugs of concern.
 - (4) Designated representatives from the Louisiana Medicaid program regarding Medicaid program recipients.

- (5) Designated representatives of the board and any vendor or contractor establishing or maintaining the prescription monitoring program.
- F. The board may provide prescription monitoring information to an individual who requests his personal prescription monitoring information in accordance with procedures established by board regulation.
- G. The board and the advisory council shall be immune from civil liability arising from inaccuracy of any of the information submitted to the board pursuant to this Act.

§1008. Education and treatment

- A. The board shall, in consultation with and upon the recommendation of the advisory council, implement the following education courses:
 - (1) An orientation course during the implementation phase of the prescription monitoring program.
 - (2) A course for persons who are authorized to access the prescription monitoring information, but who did not participate in the orientation course.
 - (3) A course for persons who are authorized to access the prescription monitoring information, but who have violated the laws or breached occupational standards involving the prescribing, dispensing, or use of any controlled substances or drugs monitored by the prescription monitoring program.
 - (4) A continuing education course for health care providers or professionals on prescribing practices, pharmacology, and the identification, treatment, and referral of a patient addicted to or abusing controlled substances or drugs monitored by the prescription monitoring program.
- B. The board shall, in consultation with and upon recommendation of the advisory council, implement an educational program to inform the public about the use, diversion and abuse of, addiction to, and treatment for the addiction to controlled substances or drugs monitored by the prescription monitoring program.
- C. The board shall, when appropriate, refer potential or alleged impaired professionals to the appropriate professional licensing, certification, or regulatory agency to ensure intervention, treatment, and ongoing monitoring and follow-up.

§1009. Unlawful acts and penalties

- A. A dispenser who fails to submit prescription monitoring information to the board as required by this Act shall be referred to the appropriate professional licensing, certification, or regulatory agency for administrative sanctions as deemed appropriate by that agency.
- B. A person or entity authorized to possess prescription monitoring information pursuant to this Act who knowingly discloses such information in violation of this Act shall be referred to the appropriate professional licensing, certification, or regulatory agency for administrative sanctions as deemed appropriate by that agency and may, upon criminal conviction, be imprisoned, with or without hard labor, for not more than five years, and in addition, may be fined not more than five thousand dollars.
- C. A person or entity authorized to possess prescription monitoring information pursuant to this Act who uses such information in a manner or for a purpose in violation of this Act shall be referred to the appropriate professional licensing, certification, or regulatory agency for administrative sanctions as deemed appropriate by that agency and may, upon criminal conviction, be imprisoned, with or without hard labor, for not more

than five years, and in addition, may be fined not more than five thousand dollars.

§1010. Evaluation; data analysis; reporting

- 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 drugs monitored by the prescription monitoring program.
- B. The board shall report to the appropriate legislative oversight committees on a periodic basis, but in no case less than annually, the cost benefits and other information contained in Subsection A of this Section.

§1011. Rules and regulations

In accordance with the Administrative Procedure Act, R.S. 49:950, *et seq.*, the board shall promulgate rules and regulations necessary to implement the provisions of this Act.

§1012. Authority to contract

In accordance with the Public Bid Law, R.S. 38:2211, *et seq.*, the board shall have the authority to contract with another agency of this state or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program. Any contractor shall be bound to comply with provisions regarding confidentiality of prescription information in R.S. 40:1007 and further shall be subject to the penalties specified in R.S. 40:1009 for unlawful acts.

§1013. Funding authority

- A. The board shall have the authority to make application for, receive, and administer grant funding from public or private sources for the development, implementation, or enhancement of the prescription monitoring program.
- B. The board shall have the authority to levy and collect an annual fee on controlled dangerous substance permits issued by an agency within the state to physicians, podiatrists, dentists, veterinarians, optometrists, medical psychologists, pharmacies, and any other person authorized by law to prescribe or dispense controlled dangerous substances. A twenty-five-dollar fee shall be levied and collected annually by the board on controlled dangerous substance permits enumerated in Subsection B of this Section.

§1014. Severability

If any provision of this Act or application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this Act which can be given effect without the invalid provisions or applications, and to this end the provisions of this Act are severable.

Section 2. The Louisiana State Law Institute is hereby directed to redesignate and incorporate Parts X-A, X-B, X-C, and X-D of Chapter 4 of Title 40 of the Louisiana Revised Statutes of 1950.

Section 3. This Act [to be] **effective on July 1, 2006**; if vetoed by the governor and subsequently approved by the legislature, this Act shall become effective on July 1, 2006, or on the day following such approval by the legislature, whichever is later.