



Louisiana Board of Pharmacy

5615 Corporate Boulevard, 8th Floor
Baton Rouge, Louisiana 70808-2537

www.labp.com



June 5, 2007

Senator Donald E. Hines, MD, President
Louisiana Senate
P. O. Box 94183
Baton Rouge, LA 70804

Re: Regulatory Project 2007-1 ~ Prescription Monitoring Program
Report No. 2 of 3

Dear Senator Hines:

As we indicated in our first project report to you in April 2007, the Board is currently promulgating an entirely new chapter of regulations to implement the program authorized by Act 676 of the 2006 Louisiana Legislature. Subsequent to our Notice of Intent published in the April 20, 2007 edition of the *Louisiana Register*, and in accordance with the Administrative Procedures Act, we conducted a public hearing at the Board office on May 30, 2007. The Board received comments and testimony from over six people. Following its analysis of those comments, the Board determined that a few clarification amendments were in order.

You should find the following documents appended to this letter:

- Notice of Intent
- Summary of Comments at May 2007 Public Hearing and Agency Responses
- Summary of Proposed Amendments to Notice of Intent
- Full Text of Proposed Rule as Amended

Subject to review by the Joint Legislative Oversight Committee on Health and Welfare, the Board proposes to publish the original proposed rule, as amended, as a Final Rule in the July 20, 2007 edition of the *Louisiana Register*. If you have any questions about the enclosed information or our procedures, please contact me directly at 225.925.6481 or mbroussard@labp.com.

For the Board:

Malcolm J. Broussard
Executive Director

NOTICE OF INTENT

Department of Health and Hospitals Board of Pharmacy

LAC 46:LIII.2901 *et seq.*

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Louisiana Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy hereby gives notice of its intent to promulgate an entirely new chapter of regulations relative to the Prescription Monitoring Program. This program was authorized by Act 676 of the 2006 Louisiana Legislature. Further, the Board gives notice of its intent to re-designate the current rule Chapter 29 – Severability as Chapter 33 – Severability, with no changes to the contents of that rule.

In compliance with Act No. 1183 of the 1999 Louisiana Legislature, the impact of this proposed rule on the family has been considered. One of the goals of the program is to identify persons who may be in need of treatment for substance abuse or addiction. To the extent that persons not yet so identified are able to obtain referral and treatment, the Board believes that this program will have a positive impact on the functioning of the family, with probable beneficial effects on family stability and family earnings. The Board does not anticipate any direct effects of this proposed rule on the ability of the family to educate and supervise their children.

Interested persons may submit written comments to Malcolm J Broussard, Executive Director, Louisiana Board of Pharmacy, 5615 Corporate Blvd., 8th Floor, Baton Rouge, LA 70808-2537. He is responsible for responding to inquiries regarding this proposed rule. A public hearing on this proposed rule is scheduled for Wednesday, May 30, 2007 at 9:00 a.m. in the Board office. At that time, 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 12:00 noon that same day.

Malcolm J Broussard
Executive Director
Louisiana Board of Pharmacy

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII – Pharmacists

Chapter 29. Prescription Monitoring Program

Subchapter A. General Operations

§2901. Definitions

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

“Administer” or “administration” means the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or any other means.

“Advisory Council” means the entity established in R.S. 40:1005.

“Board” means the Louisiana Board of Pharmacy.

“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.

“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.

“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 health 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.

“Distribute” or “distribution” means the delivery of a drug or device other than by administering or dispensing.

“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 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” means drugs other than controlled substances as defined by rule which demonstrate a potential for abuse.

“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.

“Prescriber” means a licensed health care professional with prescriptive authority.

“Prescription monitoring information” means data submitted to and maintained by the prescription monitoring program.

“Prescription monitoring program” or “PMP” means the program established in R.S. 40:1004.

“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*.

AUTHORITY NOTE: Promulgated in accordance with R.S. ~~37:1182~~ 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2114 (October 2003), effective January 1, 2004, amended LR

§2903. Authority for program operation

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

§2905. Authority to engage staff

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

§2907. Authority to engage vendors

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

§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 State Board of Examiners of Psychologists.
- (6) The president of the Louisiana Academy of Physician Assistants.
- (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 Pharmacists Association.
 - (20) The president of the Louisiana Independent Pharmacies Association.
 - (21) The president of the National Association of Chain Drug Stores.
 - (22) The president of the Louisiana Sheriffs' Association.
 - (23) The president of the Louisiana District Attorneys Association.
 - (24) The president of the Pharmaceutical Research and Manufacturers of America.
 - (25) 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

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 on a frequency set by the board, which shall be no less than every fourteen days and no more than every seven days.
- 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

§2913. Required data elements

The information submitted for each prescription shall include data relative to the identification of the following elements of the transaction. 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 Controlled Substances in May 1995.

- A. Prescriber information.
 - (1) Name of prescriber.
 - (2) Address of prescriber.
 - (3) Telephone number of prescriber.
 - (4) United States Drug Enforcement Administration (DEA) registration number.
- B. Patient information.
 - (1) Name of patient.
 - (2) Address of patient.

CODING: Words in ~~struck through~~ type are deletions from existing rule; words underscored are additions.

(3) Date of birth of patient.

(4) Social Security number of patient.

C. Prescription information.

(1) Identification number of prescription.

(2) Date of issuance.

(3) Date of fulfillment.

(4) Number of refills authorized on original prescription.

(5) Method of payment for prescription (cash, insurance, or government subsidy).

D. Drug information.

(1) National Drug Code (NDC) number.

(2) Name of drug.

(3) Dosage form of drug.

(4) Strength of drug.

(5) Quantity dispensed.

E. Dispenser information.

(1) Name of pharmacy or practitioner.

(2) Address of dispenser

(3) Telephone number of dispenser.

(4) DEA registration number.

(5) National practitioner identification 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

§2915. Failure to report prescription information

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

Subchapter C. Access to Prescription Monitoring Information

§2917. Authorized direct access users of prescription monitoring information

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:

- A. Persons authorized to prescribe or dispense controlled substances or drugs of concern, for the purpose of providing medical or pharmaceutical care for their patients.
- B. Designated representatives from the professional licensing, certification, or regulatory agencies charged with administrative oversight of those professionals engaged in the prescribing or dispensing of controlled substances or other drugs of concern.
- C. Designated representatives from the Louisiana Medicaid program regarding Medicaid program recipients.
- D. Designated representatives of the board or any vendor or contractor establishing or maintaining 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

§2919. Registration procedures for authorized direct access users

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

- A. The applicant shall successfully complete the program's orientation course, and attach evidence of same to his application to the program.
- B. The applicant shall file an application with the program, using the form supplied by the program for that purpose.
- C. 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.
- D. Upon verification of all requirements, the board shall issue the appropriate credential necessary to access prescription monitoring information.
- E. Upon receipt of information that an authorized user no longer possesses authority to prescribe or

CODING: Words in ~~struck through~~ type are deletions from existing rule; words underscored are additions.

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.

AUTHORITY NOTE: Promulgated by R.S. 40:1011.

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

§2921. Methods of access to prescription monitoring information

- A. Prescribers and dispensers, once properly registered, may solicit prescription monitoring information from the program concerning their patients. 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, 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.

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

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

§2923. Unlawful use or disclosure of prescription monitoring information

If the program receives evidence of inappropriate or unlawful use or disclosure of prescription monitoring information by an authorized user, 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

Subchapter D. Reports

§2925. Release of prescription monitoring information to other entities

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 individual patients or persons who received

CODING: Words in ~~struck through~~ type are deletions from existing rule; words underscored are additions.

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

§2927. Legislative oversight

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

§2929. Program evaluation

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

*

*

*

Chapter ~~29~~ 33. Severability

§~~2901~~ 3301. Severability

...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR

The Notice of Intent for this project was published in the April 20, 2007 edition of the Louisiana Register. The Board received written comments from that day forward through the completion of the public hearing. During the public hearing, which was convened on Wednesday, May 30, 2007 at 9:00 a.m. and concluded at 12:00 noon that same day, the Board received verbal testimony from interested parties. The following is a summary of the comments and testimony received in response to the Notice of Intent.

- 01 letter Kevin Nicholson & Mary Staples, for National Association of Chain Drug Stores (NACDS)
Requested amendments to some of the data elements specified in §2913(A)(1), (4), and (5). Suggested specific amendment to provide for program user manual. Requested a provision for fax-back functionality for users without Internet access to database.
- 02 letter Patrick R. Bernard, DVM, for Louisiana Board of Veterinary Medicine
Suggested specific amendment adding a new section to the rule, clarifying the exemption for veterinarians.
- 03 letter Mary J. Ryan, RPh, for Medco Health Solutions
Suggested specific amendment to §2913(A)(2)(d), to authorize use of health plan identification number as alternative to patient's Social Security number.
- 04 testimony Mary Staples, for National Association of Chain Drug Stores (NACDS)
Reiterated points made in formal letter. Expressed general support for proposed rule.
- 05 testimony Brenda F. Lands, for DHH – Office of Addictive Disorders
Expressed general support for proposed rule. Did not request any amendments.
- 06 testimony Kerry L. Cooley, for Louisiana State Medical Society
Expressed general support for proposed rule.
- With respect to the definitions in §2901:
 - In the definition of the term “patient”, the word ‘person’ should be replaced by ‘individual’.
 - The word ‘prescriber’ is defined, but not the term ‘authorized prescriber’.
 - The word ‘procedure’ references the current year’s version of the cited references; he questioned whether procedures not listed in the current year’s version of the references would be approved or not.
 - The word ‘user’ is not defined.
 - With respect to §2903(A), he questioned whether or not the term ‘distribution’ should not be placed at the end of that paragraph, along with dispenser.
 - With respect to §2907, he questioned the use of the term ‘engage’ in the title, as opposed to ‘contract’.
 - With respect to §2909(C)(6), he questioned why the council should need to add more members.
 - With respect to §2911(C):
 - He suggested changing “If the dispenser” to “In the event the dispenser”...
 - He suggested changing “frequency with which” to “frequency by which.”
 - With respect to §2913:
 - He suggested the absence of a definition of the term ‘transaction’ as used at the end of the first sentence of (A).
 - He suggested the absence of a definition of the term ‘fulfillment’ as used in (3)(c).
 - He questioned the necessity of the information relative to the method of payment as used in (3)(e).
 - He suggested the absence of a definition of the term ‘practitioner’ as used in (5)(a).
 - With respect to §2917:
 - He suggested the absence of a definition of the term ‘user’ as found in the section title.
 - He suggested changing “persons” to “individuals” as used in (A).

- He suggested deleting “other” before the terms “drugs of concern” as found at the end of (2).
- With respect to §2919:
 - He suggested the absence of a definition of the terms “practitioner applicant” and “agency applicant”, as found in (3).
 - He suggested the deletion of “that” as found in the opening of (5).
- With respect to §2921:
 - He suggested the use of singular instead of plural.
 - He suggested confusion as to the intent of (F); does an ‘individual’ refer to a patient, prescriber, or dispenser, or all of the above.
- With respect to §2923:
 - He suggested changing the opening “If” to “When”.
 - He suggested the absence of other categories of personnel identified in §2921, and questioned what sanction, if any, would apply to those persons for the actions contemplated in this section.
- With respect to §2925:
 - He suggested changing the reference to an individual patient, and he suggested the deletion of the term ‘person’.
- With respect to §2927:
 - He questioned why the specific oversight committee was not named.



Louisiana Board of Pharmacy

5615 Corporate Boulevard, 8th Floor
Baton Rouge, Louisiana 70808-2537
www.labp.com



June 4, 2007

Kevin Nicholson
Vice President – Pharmacy Regulatory Affairs
NACDS
P. O. Box 1417-D49
Alexandria, VA 22313-1480

Mary Staples
Regional Director – State Government Affairs
NACDS
1560 E. Southlake Blvd., Suite 230
Southlake, TX 76092

Re: *Response to Comments Submitted at May 30, 2007 Public Hearing*

Dear Mr. Nicholson and Ms. Staples:

Thank you for taking the time to review and comment on our Notice of Intent published in the Louisiana Register on April 20, 2007. You identified several areas of concern. The following information is offered in response to your concerns.

- **§2913 – Required Data Elements**

You identified several data elements for which you believed the reporting to be problematic:

- With respect to Item 1 – Prescriber Information, you suggested the information concerning the name, address, and telephone number was not necessary, since those elements could be easily determined using the prescriber's DEA registration number.
- With respect to Item 2 – Patient Information, you suggested the addition of an alternative identification number to the Social Security number, such as a driver's license number or other state identification number.
- With respect to Item 4 – Drug Information, you suggested the information concerning the name, dosage form, and strength was not necessary, since those elements could be determined using the NDC number.
- With respect to Item 5 – Dispenser Information, you suggested the information concerning the name, address, telephone number, and NPI of the dispenser was not necessary, since those elements could be determined using the dispenser's DEA registration number.

Response:

The Board anticipates the software used by our monitoring program will 'translate' numeric data elements reported by dispensers with electronic dispensing software to the appropriate alpha-numeric data required by users of the monitoring program. Since we have not yet identified the software to be used by the monitoring program, or its capabilities, we believe it appropriate to identify the alpha-numeric data elements. We acknowledge that dispensers reporting numeric data which is then 'translated' – either by the reporter's system or the monitoring program – to the alpha-numeric data required by the monitoring program will be in compliance with the rule.

*

*

*

You suggested a specific amendment to Paragraph A in this section, to wit:

"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 Controlled Substances in May 1995.”

Response:

The Board accepts your suggested amendment, and we will insert it as a clarification.

* * *

You requested the ability to use alternative numbers (also known as default or dummy numbers) in those situations where the patient either does not have a requested number or refuses to provide the requested number.

Response:

We intend to address this procedure in the program’s user manual.

* * *

- *Subchapter C. Access to Prescription Monitoring Information*

You requested the Board to allow alternative means, such as fax-back, for those dispensers without access to the Internet.

Response:

The rule as written does not specify the specific technologies for accessing the program data by authorized users. We intend to construct a web portal to the program’s database. The use of such technology will allow the Board to minimize the staffing requirements. Although we have no objection to enabling fax-back capability, users of such capability may not experience the same turn-around time web-based users will achieve.

* * *

The Board will submit its comprehensive report on the proposed rule to the Joint Legislative Oversight Committee on Health and Welfare within a few days; that report will include your comments and this response. Again, thank you for taking the time to review and comment on our proposed rule.

For the Board:

Malcolm J. Broussard
Executive Director



Louisiana Board of Pharmacy

5615 Corporate Boulevard, 8th Floor
Baton Rouge, Louisiana 70808-2537
www.labp.com



June 4, 2007

Patrick R. Bernard, DVM
President
Louisiana Board of Veterinary Medicine
263 Third Street, Suite 104
Baton Rouge, LA 70801

Re: *Response to Comments Submitted at May 30, 2007 Public Hearing*

Dear Dr. Bernard:

Thank you for taking the time to review and comment on our Notice of Intent published in the *Louisiana Register* on April 20, 2007. You identified one area of concern; the following information is offered in response.

You noted the events surrounding the passage of the enabling statute for this proposed rule, specifically, Act 676 of the 2006 Louisiana Legislature. In particular, the legislature amended the original bill to exclude veterinarians from the reporting requirements for those veterinarians dispensing prescriptions for controlled substances. While the statutory definition of definition was not amended to specifically exclude veterinarians, the legislative intent was clear to exclude veterinarians from the program requirements.

You requested the addition of an entirely new section, to be placed at the end of the proposed rule, to clarify the exemption for veterinarians:

Subchapter E. Exemptions

§2931. Exemptions

A veterinarian licensed by the Louisiana Board of Veterinary Medicine who dispenses, administers, and/or prescribes a controlled substance or drug to a client/patient within the scope of his practice is exempt from the provisions of the prescription monitoring program defined in these rules.

Response:

The Board has agreed to insert the clarification amendment as requested.

* * *

The Board will submit its comprehensive report on the proposed rule to the Joint Legislative Oversight Committee on Health and Welfare within a few days; that report will include your comments and this response. Again, thank you for taking the time to review and comment on our proposed rule.

For the Board:

Malcolm J. Broussard
Executive Director

Pharmacy Program
Tel. 225.922.0852
Fax. 225.925.6499
pharmacy@labp.com

CDS Program
Tel. 225.925.4770
Fax. 225.925.4799
cds@labp.com

Administration
Tel. 225.925.6496
Fax. 225.922.0316
labp@labp.com



Louisiana Board of Pharmacy

5615 Corporate Boulevard, 8th Floor
Baton Rouge, Louisiana 70808-2537

www.labp.com



June 4, 2007

Mary J. Ryan, RPh
Vice President – Pharmacy Regulatory Group
Medco Health Solutions
100 Parsons Pond Drive
Franklin Lakes, NJ 07417

Re: *Response to Comments Submitted at May 30, 2007 Public Hearing*

Dear Ms. Ryan:

Thank you for taking the time to review and comment on our Notice of Intent published in the *Louisiana Register* on April 20, 2007. You identified one area of concern; the following information is offered in response.

With respect to the patient information section in §2913 – *Required Data Elements*, you offered information suggesting privacy and security concerns associated with the use of a patient's Social Security number. You requested a specific amendment of the proposed rule, to wit:

§2913. Required Data Elements

- A. ...
 - 1. ...
 - 2. ...
 - a. – c. ...
 - d. Social Security number or health plan identification number of the patient.

Response:

The Board accepts the information offered relative to privacy and security concerns associated with the use of a patient's Social Security number. They have agreed to authorize the use of a driver's license or other state identification number as an alternative. Further, the Board has agreed to publish a program user manual that may identify additional alternative data for certain required data elements.

* * *

The Board will submit its comprehensive report on the proposed rule to the Joint Legislative Oversight Committee on Health and Welfare within a few days; that report will include your comments and this response. Again, thank you for taking the time to review and comment on our proposed rule.

For the Board:

Malcolm J. Broussard
Executive Director



Louisiana Board of Pharmacy

5615 Corporate Boulevard, 8th Floor
Baton Rouge, Louisiana 70808-2537
www.labp.com



June 4, 2007

Brenda F. Lands
Office of Addictive Disorders
Dept. of Health & Hospitals
P. O. Box 2790
Baton Rouge, LA 70821

Re: *Response to Comments Submitted at May 30, 2007 Public Hearing*

Dear Ms. Lands:

Thank you for taking the time to review and comment on our Notice of Intent published in the *Louisiana Register* on April 20, 2007. You appeared at our public hearing on May 30, offering your unqualified support for the prescription monitoring program. You offered no requests for amendment to the proposed rule.

The Board will submit its comprehensive report on the proposed rule to the Joint Legislative Oversight Committee on Health and Welfare within a few days; that report will include your comments and this response. Again, thank you for taking the time to review and comment on our proposed rule.

For the Board:

Malcolm J. Broussard
Executive Director



Louisiana Board of Pharmacy

5615 Corporate Boulevard, 8th Floor
Baton Rouge, Louisiana 70808-2537
www.labp.com



June 4, 2007

Kerry L. Cooley
La. State Medical Society
6767 Perkins Road
Baton Rouge, LA 70808

Re: *Response to Comments Submitted at May 30, 2007 Public Hearing*

Dear Mr. Cooley:

Thank you for taking the time to review and comment on our Notice of Intent published in the *Louisiana Register* on April 20, 2007. You offered testimony at our public hearing on May 30. Our responses to your concerns are noted below.

- Within the definition of the term 'patient' in §2901, you suggested the replacement of the word 'person' with 'individual', noting 'person' could be misinterpreted as a legal derivative instead of a natural person.
Response:
Given the context of referring to the ultimate user of a controlled substance, the Board is confident the regulated parties understand person to mean an individual.
- Within §2901, you questioned the construction of the term 'procedure.'
Response:
This term is defined as it appears in the enabling statute, Act 676 of the 2006 Louisiana Legislature. Our records indicate, and you may recall, you were the author of this definition during that effort. We will rely on the statutory definition.
- With respect to §2903(A), you questioned whether or not the term 'distribution' should be included with the term 'dispensed.'
Response:
Given the reporting mechanism will only include items dispensed, we respectfully decline to include the term 'distribution' in this section.
- With respect to the section header of §2907, you suggested a stylistic change.
Response:
We accept your suggestion, and will offer the appropriate amendment.
- With respect to §2909(C)(6), you questioned the necessity of additional membership for the Advisory Council.
Response:
This language is taken directly from the enabling statute; it permits the council to identify additional expertise which may be suitable for membership on the council.
- With respect to §2911(C), you suggested two stylistic changes.

Response:

We respectfully decline.

- With respect to §2913(A), you suggested the absence of a definition of the term ‘transaction’, as it appears at the end of the first sentence.

Response:

Given the context of the sentence, the Board is confident the regulated parties understand transaction refers to the prescription dispensed.

- With respect to §2913(A)(3)(c), you suggested the absence of a definition of the term ‘fulfillment’.

Response:

Given the context of the section, the Board is confident the regulated parties understand fulfillment refers to the completion of the commercial transaction.

- With respect to §2913(A)(3)(e), you questioned the necessity of collecting the method of payment.

Response:

When a patient acquires controlled substances with both insurance coverage and by cash payments, some parties believe such an event may merit some level of inquiry. This concept was discussed during the task force meeting you attended.

- With respect to §2913(A)(5)(a), you suggested the absence of a definition of the term ‘practitioner.’

Response:

We agree that the insertion of the word ‘dispensing’ before practitioner would clarify the intent of the proposed rule, and we will offer that amendment.

- With respect to the section header of §2917, you suggested the absence of a definition of the term ‘user.’

Response:

We suggest the contents of the section identify the authorized users of the program data.

- With respect to §2917(A), you suggested the replacement of the term ‘person’ with the term ‘individual’, with the concern that ‘person’ may be misinterpreted to include legal entities.

Response:

Given the context of the section, the Board is confident the regulated parties understand person refers to the individuals identified in the section.

- Within §2917(A)(2), you suggested a stylistic change.

Response:

We respectfully decline.

- Within §2919(A)(3), you suggested the absence of definitions for the terms ‘practitioner applicant’ and ‘agency applicant.’

Response:

Given the context of the section, the Board is confident the regulated parties understand practitioner applicant refers to a practitioner making application to become a registered user of the program and agency applicant refers to a representative of an agency making application to become a registered user of the program.

- With respect to the first sentence of §2919(A)(5), you suggested a stylistic change.

Response:

We respectfully decline.

- With respect to §2921, you suggested a stylistic change.

Response:

We respectfully decline.

- With respect to §2921(F), you suggested the absence of a definition of the term ‘individual’,

questioning whether it referred to a patient, prescriber, dispenser, or all of those.

Response:

Given the context of the section, the Board is confident the regulated parties understand individual refers to anyone.

- With respect to §2923(A), you suggested a stylistic change.

Response:

We respectfully decline.

- With respect to §2923, you suggested some categories of personnel were omitted from provisions for sanctions for unlawful use or disclosure of program information.

Response:

This section directs the program, upon receipt of evidence of inappropriate or unlawful actions by an authorized user, to refer that user to the appropriate agency. The authorized users are enumerated in §2917, and their methods of access are provided for in §2921. The Board respectfully suggests no authorized user has been omitted.

- With respect to §2925, you suggested deletion of the term 'person'.

Response:

We respectfully decline.

- With respect to §2927, you questioned why the current legislative oversight committee was not specified.

Response:

In the event the legislature sees fit to rename their committees, such event will not automatically require the revision of this section of our rule.

The Board will submit its comprehensive report on the proposed rule to the Joint Legislative Oversight Committee on Health and Welfare within a few days; that report will include your comments and this response. Again, thank you for taking the time to review and comment on our proposed rule.

For the Board:

Malcolm J. Broussard
Executive Director

**Regulatory Project No. 2007-1 ~ Prescription Monitoring Program
Summary of Proposed Amendments to Notice of Intent**

§2901. Definitions

Dispenser – ... any of the following:

- a. ... health care;
- b – d ...

§2907. Authority to ~~Engage~~ Contract with Vendors

§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, ...
 - 1. ...
 - 2. Patient Information
 - a – c ...
 - d. ~~Social Security~~ Identification number of patient.
 - 3. ...
 - 4. ...
 - 5. Dispenser Information
 - a. name of pharmacy or dispensing practitioner;

Subchapter E. Exemptions

§2931. Exemptions

A veterinarian licensed by the Louisiana Board of Veterinary Medicine who dispenses, administers, and/or prescribes a controlled substance or drug to a client/patient within the scope of his practice is exempt from the provisions of the prescription monitoring program as defined in these rules.

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.
- 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 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;
 - 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;
 - a practitioner or other authorized person who administers such controlled substance or drug upon the lawful order of a practitioner;
 - a wholesale distributor of such controlled substance or drug that is credentialed by the Louisiana State Board of Wholesale Drug Distributors.
- Distribute or Distribution* – the delivery of a drug or device other than by administering or dispensing.
- Drug* – any of the following:
- 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;
 - any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;
 - 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 which demonstrate a potential for abuse.
- 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. ~~37:1182~~ 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2114 (October 2003), effective January 1, 2004, amended LR

§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

§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

§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

§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 State Board of Examiners of Psychologists;
 6. the president of the Louisiana Academy of Physician Assistants;
 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 Pharmacists Association;
 20. the president of the Louisiana Independent Pharmacies Association;
 21. the president of the National Association of Chain Drug Stores;
 22. the president of the Louisiana Sheriffs' Association;
 23. the president of the Louisiana District Attorneys Association;
 24. the president of the Pharmaceutical Research and Manufacturers of America;
 25. 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

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 on a frequency set by the board, which shall be no less than every fourteen days and no more than every seven days.
- 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

§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 Controlled Substances in May 1995.
 1. Prescriber Information;
 - a. name of prescriber;
 - b. address of prescriber;
 - c. telephone number of prescriber;
 - d. United States Drug Enforcement Administration (DEA) registration number.
 2. Patient Information;
 - a. name of patient;
 - b. address of patient;
 - c. date of birth of patient;
 - d. identification number of patient.
 3. Prescription Information;
 - a. identification number of prescription;
 - b. date of issuance;
 - c. date of fulfillment;
 - d. number of refills authorized on original prescription;
 - e. method of payment for prescription (cash, insurance, or government subsidy).
 4. Drug Information;
 - a. National Drug Code (NDC) number;
 - b. name of drug;
 - c. dosage form of drug;
 - d. strength of drug;
 - e. quantity dispensed.

5. Dispenser Information;
 - a. name of pharmacy or dispensing practitioner;
 - b. address of dispenser;
 - c. telephone number of dispenser;
 - d. DEA registration number;
 - e. national practitioner identification 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

§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

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, for the purpose of providing medical or pharmaceutical care for their patients;
 2. designated representatives from the professional licensing, certification, or regulatory agencies 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.

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

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

§2919. Registration Procedures for Authorized Direct Access Users

- A. Authorized users of prescription monitoring information 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.

AUTHORITY NOTE: Promulgated by R.S. 40:1011.

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

§2921. Methods of Access to Prescription Monitoring Information

- A. Prescribers and dispensers, once properly registered, may solicit prescription monitoring information from the program concerning their patients. 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, 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.

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

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

§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, 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

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 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

§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

§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

Subchapter E. Exemptions

§2931. Exemptions

- A. A veterinarian licensed by the Louisiana Board of Veterinary Medicine who dispenses, administers, and/or prescribes a controlled substance or drug to a client/patient within the scope of his practice is exempt from the provisions of the Prescription Monitoring Program as defined in these rules.

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

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

*

*

*

Chapter 33. Severability

§3301. Severability

- A. In the event any rule, sentence, clause, or phrase or any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof, and such remaining rules or portions thereof shall remain of full force and effect, as if such rule or portions thereof so determined, declared, or adjudged invalid or unconstitutional were not originally a part hereof. It is the intent of the Louisiana Board of Pharmacy to establish rules and regulations that are constitutional and enforceable so as to safeguard the health, safety, and welfare of the people of the State.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR