Prescription Monitoring Program Task Force
State of Louisiana

October 26, 2005

MINUTES

A meeting of the Prescription Monitoring Program (PMP) Task Force scheduled to meet on Wednesday, October 26, 2005 in Conference Room C on the first floor of the Headquarters of the Louisiana State Police, located at 7919 Independence Blvd. in Baton Rouge, convened at 10:10 a.m. to consider the following:

AGENDA

1. Call to Order
2. Opportunity for Public Comment
3. Consideration of Minutes from August 4, 2005 Meeting
4. Prescription Monitoring Program
   a. Review of Project Performance Measures
   b. Introduction and Review of Draft Legislation
5. Calendar Notes
6. Adjourn

Call to Order
Carl W. Aron, Chairman of the Task Force and President for the Louisiana Board of Pharmacy, called the meeting to order.

Opportunity for Public Comment
No public comments were submitted.

Minutes from August 4, 2005
The minutes from the Task Force's last meeting were accepted by consensus.

The other Task Force representatives present were: Vice Chair Capt. David Staton (Louisiana State Police), Senator Nick Gautreaux (Louisiana Senate), Malcolm Broussard (Executive Director, Louisiana Board of Pharmacy), Donald Hickman (DEA), Alfred Gaudet (Louisiana State Board of Medical Examiners), Dr. Lon Randal (Louisiana Board of Veterinary Medicine), Robert Toups (Louisiana Independent Pharmacists Association), MJ Terrebonne (DHH Medicaid), Dr. Darby Chassion (Louisiana Optometrist Association), John J. Williams (Louisiana District Attorneys Association), Stephanie White (Optometry Association of Louisiana), Peggy Griener (Louisiana Board of Nursing), Ward Blackwell (Louisiana Dental Association), Sgt. Roland Jude Mathews (Louisiana State Police), Brenda Lands (DHH-Office of Addictive Disorders), and Dr. John O'Brien (PhRMA).

Also present: Dr. Ken Hoffman (SAMHSA), Carlos Finalet (General Counsel, Louisiana Board of Pharmacy), and Kathleen Gaudet (Chief Compliance Officer, Louisiana Board of Pharmacy),

Prescription Monitoring Program & Review of Prior Activities

Mr. Broussard provided a summary of the Task Force's last meeting and the Performance Review for the program (*Exhibit A*).

Mr. Broussard directed the Task Force to #8 of the Performance Review: *Identify and quantify prescribers and dispensers of controlled substances* – The numbers have been modified since the last meeting as follows:
Medical Doctors (MD) & Doctors of Osteopathy (DO) = 16,595
Physician Assistants (PA) = 377
Doctors of Podiatric Medicine (DPM) = 198
Advanced Practice Registered Nurse (APRN) = 148
MP = 22
Pharmacies = 1,495
Dispensing Practitioner Certificates = 337

In addition, Ward Blackwell (Louisiana Dental Association) acquired from Barry Ogden (Board of Dentistry) the number of approx. 2,100 dentists in the state.

Review of Project Timeline

Mr. Broussard reviewed the anticipated timeline of the Task Force's legislative mandate (*Exhibit B*). He explained that the anticipated completion of the Task Force Report may be amended to reflect a potential earlier federally mandated deadline in December 2005. Once this is verified, Mr. Broussard will notify the Task Force members.

Draft #2 – PMP Legislation

Draft #2 of the proposed legislation (*Exhibit C*) was circulated for Task Force discussion.

Section 1 – *Short Title*. No modifications were suggested.

Section 2 – *Legislative Findings*. No modifications were suggested.

Section 3 – *Purpose*. No modifications were suggested.

Section 4 – *Definitions*

"*Advisory council*" - While most PMP states do not have an advisory council this draft contains it for the Task Force's consideration.

"*Controlled substance*" – The Task Force will determine whether to include all schedules under the program. Factors to take into account in this determination are resources and whether including all controlled substances would be cost prohibitive.

"*Dispenser*" – The definition is a list of those not included in that definition. Ward Blackwell inquired whether doctors who give a 48-hour supply, usually oral surgeons, would be included in this definition. Mr. Broussard clarified that if they dispense more than a 48-

hour supply that person would fall under the definition of dispenser. The draft will be modified to reflect this concept.

"*Drugs of concern*" – Mr. Broussard suggested a regulation would be best to establish criteria to determine what constitutes a drug of concern. The Task Force agreed to this concept by consensus.

Section 5 – *Establishment of a Prescription Monitoring Program*
Sen. Gautreaux requested clarification on what parameters would be followed in contracting with a vendor to establish/maintain the electronic monitoring system. Mr. Broussard clarified public bid laws would apply. The next draft will explicitly state this requirement.

Section 6 – *Advisory Council* – The Task Force agreed by consensus to the concept and modified the list to parallel the membership established by House Concurrent Resolution No. 98 of the 2005 Louisiana Legislature.

Section 7 – *Reporting of Prescription Monitoring Information*
Mr. Broussard summarized the required data to be reported to the Board: (1) Prescriber; (2) Patient; (3) Prescription; (4) Drug; (5 Dispenser. It is anticipated that the data fields will be expended upon in more detail by regulation. For example, relative to required information on the drug, the regulation will require the drug's strength, brand/generic name, and dosage form. Dr. O'Brien (PhRMA) requested the statue contain these detailed requirements. Senator Gautreaux agreed. Mr. Broussard suggested the next draft itemize those specifics for the Task Force's consideration.

Dr. O'Brien suggested a limitation on liability for reporting. The Task Force added the following to the proposed legislation:

> *"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 Section shall not be liable to any person for any claim of damages as a result of the act of reporting the information and no lawsuit may be predicated thereon."*

Section 8 – *Access to Prescription Monitoring Information*
Mr. Broussard emphasized the provision declaring the information submitted to be restricted information and not subject to public records laws.

Once the Board has *reasonable cause* to believe the confidentiality of any records under the PMP Program has been breached, the Board shall notify the appropriate credentialing agency and law enforcement agency. Sen. Gautreaux asked why the reporting need go to both a credentialing agency and a law enforcement agency. DEA representative Donald Hickman explained that any other way would potentially compromise both administrative and criminal investigations. Mr. Toups explained that DEA currently has the authority to enter a pharmacy without notice and review and/or take records. Criteria must be established as to what determines reasonable cause.

Mr. Williams suggested a provision qualifying PMP reports to be self-proving. Staff will provide the following language for review at the next meeting:

> *"Once prescription monitoring information is signed by a Board representative who attests to its authenticity, then the information is a self-authenticating, self-proving document."*

Subsection D – Pursuant to Sen. Gautreaux's suggestion, the Task Force made the following change:

> *"The Board shall ~~may~~ 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 and/or persons who received prescriptions from prescribers."*

Subsection E – Mr. Williams (LDAA) suggested and the Task Force agreed to modify Subsection E(5) to reference a state judicial district's chief judge or the appropriate federal judge or federal magistrate:

> *"5. A chief judge for a state judicial district court or the appropriate federal judge or federal magistrate ~~Designated representatives of the judiciary~~, pursuant to grand jury subpoena or court order."*

Senator Gautreaux asked if patients will be able to access their own patient information. The current draft does not address that issue. The following is proposed for consideration at the next meeting:

> *"F. The Board may provide prescription monitoring information an individual who requests his personal prescription monitoring information in accordance with procedures established by Board regulation."*

Section 9 – *Education & Treatment.* No modifications were suggested.

Section 10 – *Unlawful Acts & Penalties*
Specific penalties are needed. Mr. Williams (LDAA) will compile proposed penalties for the Task Force's review at a future meeting.

Section 11 – *Evaluation, Data Analysis, and Reporting.* No modifications were suggested.

Section 12 – *Rules and Regulations*
Language will be inserted regarding the requirements under the Louisiana Administrative Procedures Act, La. R.S. 49:950 et seq.

Section 13 – *Authority to Contract*
Language will be inserted regarding the requirements under Louisiana's Public Bid Laws, La. R.S. 38:2211 et seq.

Section 14 – *Severability*. No modifications were suggested.

Section 15 – *Effective Date.* The effective date is yet to be determined.

Calendar Notes
The Task Force's tentative meeting dates for the remainder of Year 2005 are:
Wednesday, November 30, 2005
Wednesday, December 21, 2005

Action Items
Mr. Finalet will research and prepare for dissemination at the next meeting Draft #3 for Louisiana's PMP program.

Adjournment: The Task Force adjourned at approximately 1:15 p.m.

I certify that the foregoing are true and accurate minutes of a meeting of the Prescription Monitoring Task Force for the State of Louisiana, held on the above noted date.

Malcolm Broussard
Executive Director
Louisiana Board of Pharmacy

Prepared by: Carlos M. Finalet, III, General Counsel, Louisiana Board of Pharmacy

Louisiana Board of Pharmacy
Louisiana Controlled Substance Utilization Review Program

Performance Review

	Objective		*Performance Measure*		*Progress*
1	Increase number of stakeholders	A	Number of stakeholders	1-A	Initial = 14 Current = 25
2	Increase understanding of PMP among stakeholders	A	Number of site visits to PMP operations	2-A	Site visits to NV and KY set for 10/30 thru 11/04.
		B	Number of regional and national PMP planning meetings	2-B	NASCSA conference set for 10/16-22.
3	Determine extent of problem related to drug abuse and diversion	A	Number of relevant emergency department (ED) and medical examiner (ME) reports	3-A	Mortality data available for 2001-2003.
		B	Number of admissions to addiction treatment centers for prescription drug abuse	3-B	Admission data available for 2001-2004
		C	State ranking in ARCOS reports	3-C	Rankings available for 1997-2004
4	Develop PMP implementation plan	A	Draft enabling legislation	4-A	LA draft #2 available for review.
5	Identify and adjudicate persons engaged in diversion of controlled substances (CS)	A	Number of persons *investigated* for diversion of CS before and after implementation	5-A	Preliminary data available
		B	Number of persons *arrested* for diversion of CS before and after implementation	5-B	Preliminary data available
		C	Number of persons *prosecuted* for diversion of CS before and after implementation	5-C	Preliminary data available
		D	Number of dosage units of CS diverted by persons who have been prosecuted	5-D	Preliminary data available
6	Develop and/or increase the efficiency of investigational efforts	A	Number of investigations completed per investigator per year before and after implementation	6-A	Preliminary data available
		B	Average number of work hours/days spent per case before and after implementation	6-B	Preliminary data available
7	Increase cooperative efforts between state/local agencies and federal agencies	A	Number of joint investigations conducted	7-A	Data collection still in process
8	Identify and quantify prescribers and dispensers of controlled substances (CS)	A	Number of prescribers of CS	8-A	MD+DO = 16,595 / PA = 377 / DPM = 198 / APRN = 148 /
		B	Number of dispensers of CS	8-B	Rx = 1,495 / DPC = 337 MP = 22

Last update: 10-25-2005

EXHIBIT A

Louisiana Board of Pharmacy
Louisiana Controlled Substance Utilization Review Program

Project Timeline

Stage I – Planning

A. Local Research

Completion: September 2005

Identification of data sources relevant to program objectives, i.e.,

1. adverse health effects, as measured by emergency department visits and medical examiner reports in metropolitan areas other than New Orleans (which is already included in DAWN reports), as well as numbers of admissions to addiction treatment centers for prescription drug abuse,
2. information concerning numbers of persons investigated, arrested, and prosecuted for drug diversion by local and state law enforcement agencies,
3. information concerning efficiency of diversion investigations among law enforcement and regulatory communities, and
4. identification and quantification of prescribers and dispensers.

B. Regional and National Research

Completion: December 2005

Assessment of existing PMP operations in other states:

Site visits to be scheduled in Kentucky and Nevada.

Networking with other states engaged in planning and implementation of programs:

Attendance to regional and national conferences: Alliance for States with Prescription Monitoring Programs in October 2005; National Alliance for Model State Drug Laws in December 2005; National Association of Drug Diversion Investigators in fall 2005.

Stage II – Development

A. Task Force Report

Completion: January 2006

Will summarize results of research and include recommendations for legislation and implementation.

B. Legislation

Completion: July 2006

Session will convene in April and adjourn in July.

Stage III – Implementation

Completion: January 2007

(presumes successful legislation in July 2006 and receipt of implementation grant in October 2006)

Section 1. Short Title

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

Section 2. Legislative Findings

[*insert appropriate information, as may be developed later*]

Section 3. 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 purpose of the system is to improve the state's ability to identify and inhibit the diversion of controlled substances in an efficient and cost effective manner and in a manner that will not impede the appropriate utilization of these drugs for legitimate medical purposes.

Section 4. Definitions

(1) "*Advisory Council*" means the entity established in Section 6 of this Act.
(2) "*Board*" means the Louisiana Board of Pharmacy.
(3) "*Controlled substance*" means [*incorporate federal and state CSA*].
(4) "*Dispenser*" means a person authorized in this state to dispense or distribute to the ultimate user any substance monitored by the system, but shall not include any of the following:
    (a) a pharmacy permitted by the Board as a hospital pharmacy that dispenses or distributes any substance monitored by the system for the purposes of inpatient hospital care, or that dispenses or distributes no more than a 48-hour supply of such substances to patients at the time of discharge from such facility;
    (b) a practitioner or other authorized person who administers such substances upon the lawful order of an authorized prescriber; or
    (c) a wholesale distributor of such substances that is credentialed by the Louisiana Board of Wholesale Drug Distributors.
(5) "*Drugs of concern*" means drugs other than controlled substances which demonstrate a potential for abuse.
(6) "*Patient*" means the person or animal who is the ultimate user of a substance monitored by the system for whom a prescription is issued and/or for whom a substance is dispensed.
(7) "*Prescriber*" means a licensed health care professional with prescriptive authority.
(8) "*Prescription monitoring information*" means information submitted to and maintained by the Prescription Monitoring Program.
(9) "*Prescription Monitoring Program (PMP)*" means the program established under Section 5 of this Act.

Section 5. Establishment of a Prescription Monitoring Program

A. The Board shall establish and maintain, with the consultation 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.

EXHIBIT
tabbies
P C

B. The Board may contract with a vendor to establish and maintain the electronic monitoring system pursuant to rules promulgated by the Board.

Section 6. Advisory Council

A. The Advisory Council shall have the following members, each of whom may appoint a designee:
   1. The President of the Senate;
   2. The Speaker of the House of Representatives;
   3. The Chair of the Senate Committee on Health and Welfare;
   4. The Chair of the House Committee on Health and Welfare;
   5. The Secretary of the Department of Health and Hospitals (DHH);
   6. The Superintendent of the State Police;
   7. The Attorney General;
   8. The Director of the Office of Addictive Disorders in DHH;
   9. The President of the Board of Medical Examiners;
   10. The President of the Board of Dentistry;
   11. The President of the Board of Veterinary Medicine;
   12. The President of the Board of Optometry;
   13. The President of the Board of Examiners of Psychologists;
   14. The President of the Board of Nursing;
   15. The President of the Board of Pharmacy;
   16. The President of the Louisiana State Medical Society;
   17. The President of the Louisiana Dental Association;
   18. The President of the Louisiana Veterinary Medical Association;
   19. The President of the Optometry Association of Louisiana;
   20. The President of the Louisiana Academy of Medical Psychologists;
   21. The President of the Louisiana State Nurses Association;
   22. The President of the Louisiana Pharmacists Association;
   23. The President of the Louisiana Independent Pharmacies Association;
   24. The President of the National Association of Chain Drug Stores;
   25. The President of the Louisiana Sheriffs' Association;
   26. The President of the Louisiana District Attorney's Association;
   27. The President of the Pharmaceutical and Research Manufacturers Association;
   28. The President of the Louisiana Methadone Treatment Association;
   29. The President of the American Civil Liberties Union;
   30. [*Pain management groups?*]
   31. [*Impaired professional groups?*]
   32. [*Professional educational institutions?*]

B. The Board shall seek, and the Advisory Council shall provide, input and advice regarding the development and operation of the electronic monitoring system, including but not limited to such topics as:
   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 Section 9 of this Act;

4. proper analysis and interpretation of prescription monitoring information;
5. design and implementation of an evaluation component; and
6. potential nominees to the Advisory Council.

Section 7. Reporting of Prescription Monitoring Information

A. Each dispenser shall submit to the Board information regarding each prescription dispensed for a drug monitored by the program. The information submitted for each prescription shall include, but may not be limited to, data relative to the identification of the following elements of the transaction:
   1. Prescriber.
   2. Patient
   3. Prescription.
   4. Drug.
   5. Dispenser.

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 that 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.

Section 8. Access to Prescription Monitoring Information

A. Except as indicated in Paragraphs (C), (D), and (E) of this Section, prescription monitoring information submitted to the Board shall be considered protected health information and not subject to public or open records laws.

B. The Board shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted, and maintained is not disclosed to person except as in Paragraphs (C), (D), and (E) 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 law enforcement agency or professional licensing, certification, or regulatory agency, and shall provide prescription monitoring information required for an investigation.

D. The Board may 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 and/or persons who received prescriptions from prescribers.

E. The following persons, after successful completion of the educational courses identified in Section 9, 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 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 judiciary, pursuant to grand jury subpoena or court order.
6. Designated representatives of the Board and any vendor or contractor establishing or maintaining the prescription monitoring program.

F. The Board shall be immune from civil liability arising from inaccuracy of any of the information submitted to the Board pursuant to this Act.

Section 9. Education and Treatment

A. The Board shall, in consultation with the Advisory Council, implement the following education courses:

1. An orientation course during the implementation phase of the PMP.
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 substances monitored by the PMP.
4. A continuing education course for health care professionals on prescribing practices, pharmacology, and the identification, treatment, and referral of patients addicted to or abusing substances monitored by the PMP.

B. The Board shall, in consultation with the Advisory Council, shall implement an educational program to inform the public about the use, diversion and abuse of, and addiction to, substances monitored by the PMP.

C. The Board shall, in consultation with the Advisory Council, when appropriate:

1. work with associations for impaired professionals to ensure intervention, treatment, and ongoing monitoring and follow-up; and
2. ensure that individual patients who are identified and who have become addicted to substances monitored by the PMP receive addiction treatment.

Section 10. Unlawful Acts and Penalties

A. A dispenser who knowingly fails to submit prescription monitoring information to the Board as required by this Act shall be subject to [*insert appropriate administrative, civil, or criminal penalty*].

B. A person authorized to possess prescription monitoring information pursuant to this Act who knowingly discloses such information in violation of this Act shall be subject to [*insert appropriate administrative, civil, or criminal penalty*].

C. A person 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 subject to [*insert appropriate administrative, civil, or criminal penalty*].

Section 11. Evaluation, Data Analysis, and Reporting

A. The Board shall, in consultation with 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 substances monitored by the PMP.

B. The Board shall report to the appropriate legislative oversight committee on a periodic basis, but no less than annually, about the cost benefits and other information noted in Paragraph A of this Section.

Section 12. Rules and Regulations

The Board shall promulgate rules and regulations necessary to implement the provisions of this Act.

Section 13. Authority to Contract

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 Section 8 of this Act, and further, shall be subject to the penalties specified in Section 10 of this Act for unlawful acts.

Section 14. 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 the Act which can be given effect without the invalid provisions or applications, and to this end the provisions of this Act are severable.

Section 15. Effective Date

This Act shall become effective on [*insert date*].