

State Advocacy Guide to Prescription Drug Monitoring Program Legislation and Regulations

There is currently an epidemic of prescription opioid abuse, misuse and diversion in the U.S. Numerous federal, state and regional legislative and regulatory efforts have been introduced to address this public health crisis. This paper provides an outline of the prescription drug monitoring program provisions in state legislation or regulation that are most relevant to emergency physicians, examples of legislative language from various states related to each of these provisions, and recommendations pertaining to the areas most relevant to emergency physicians.

Most states have laws pertaining to prescription drug monitoring programs (PDMPs)ⁱ. These PDMP laws often contain certain provisions that are particularly relevant to the opioid prescribing practices of emergency physicians.

In general, these provisions can be categorized as follows:

- Funding of the PDMP
- Housing of the PDMP
- Whether Enrollment in the PDMP is Mandated
- Whether Education or Training is Required
- Whether Accessing the PDMP is Mandated
- Use of the PDMP For Data Mining Regarding Physicians
- Whether a Prescriber's Agent May Access the PDMP
- Civil Liability and Immunity
- Whether Data Elicited from the PDMP is Made Part of the Medical Record
- Whether Interstate Linkage/Sharing of Data is Promoted
- How Often Pharmacies are Required to Update Information

These provisions are discussed in detail below and recommendations are made for ACEP chapter consideration when facing legislative initiatives related to these issues in their states. These recommendations are consistent with ACEP's policy statement on electronic prescription monitoring, which reads:

Electronic Prescription Monitoring

Originally approved by the ACEP Board of Directors October 2011

The diversion of controlled substances from medical to non-medical purposes has become a significant public health problem. The American College of Emergency Physicians (ACEP) supports the use of electronic prescription monitoring and believes these systems should:

- Protect patient privacy.
- Not discourage a patient with a genuine medical condition from seeking care.
- Support access to legitimate medical use of controlled substances.
- Ensure accuracy and completion of the data.
- Be voluntary.

- Provide liability protection for the practitioner.
- Minimize burdensome requirements on the physician.
- Utilize a robust monitoring system with intra-state linkages, easily accessible and navigable by practitioners seven days a week, twenty-four hours a day.
- Be limited to appropriate individuals and agencies including physicians, pharmacists and law enforcement.
- Not be used to evaluate a physician's practice.
- Allow physicians to monitor their own prescribing patterns and to identify potential unauthorized use.

ACEP opposes mandatory reporting of potential abuse to law enforcement because such reporting fundamentally conflicts with the appropriate role of physicians in the physician-patient relationship.

KEY PROVISIONS OF PDMPS

A. FUNDING OF PDMPS

Some states fund PDMPS exclusively through fees on prescribers; some states permissively fund through fees on prescribers; and some states explicitly prohibit funding through prescribers. Here are examples of each of these legislative provisions:

REQUIRED FUNDING THROUGH PRESCRIBERS - OREGON:

Oregon Revised Statutes 431.974, Fees ... (2)(a) *In addition to other licensing fees imposed by a board on licensees, a board shall adopt rules imposing a fee of \$25 per year on each person licensed by the board who is authorized to prescribe or dispense controlled substances. A board shall collect the fee at the same time the board collects other licensing fees imposed on licensees.*

(b) *A board shall retain 10 percent of the fees collected under paragraph (a) of this subsection to cover the costs of accounting and collection of the fees.*

(c) *On the first day of each calendar quarter, a board shall transmit 90 percent of the fees collected under paragraph (a) of this subsection during the preceding calendar quarter to the Electronic Prescription Monitoring Fund established in ORS 431.974. [2009 c.799 §8]*

431.974 Electronic Prescription Monitoring Fund. (1) *The Electronic Prescription Monitoring Fund is established in the State Treasury, separate and distinct from the General Fund. The Electronic Prescription Monitoring Fund consists of moneys transmitted to the fund under ORS 431.972 and any other moneys deposited in accordance with law. Interest earned by the fund shall be credited to the fund. Moneys in the fund are continuously appropriated to the Department of Human Services for the purpose of carrying out the provisions of ORS 431.962 to 431.978 and 431.992.*

PERMISSIVE FUNDING THROUGH PRESCRIBERS - COLORADO:

Colorado Revised Statutes Annotated (2012) Title 12. Professions and Occupations Health Care Article 42.5. Pharmacists, Pharmacy Businesses, and Pharmaceuticals Part 4. Electronic Monitoring of Prescription Drugs

§ 12-42.5-405. Prescription drug monitoring fund--creation--gifts, grants, and donations—fee ... (3) *If, based upon the appropriations for the direct and indirect costs of the program, there are insufficient funds to maintain the program, the division may collect an annual fee of no more than seventeen dollars and fifty cents for the fiscal years 2011-2012 and 2012-2013, twenty dollars for the fiscal years 2013-2014 and 2014-2015, and twenty-five dollars for each fiscal year thereafter, from an individual who holds a license from the division that authorizes him or her to prescribe a controlled substance, as defined in section 18-18- 102(5), C.R.S. The division shall set the fee pursuant to section 24-34-105, C.R.S., and shall collect the fee in conjunction with the license renewal fees collected pursuant to section 24- 34-105, C.R.S. Moneys collected pursuant to this subsection (3) are credited to the prescription drug monitoring fund created in subsection (1) of this section.*

EXPLICIT EXCLUSION OF FUNDING BY PRESCRIBERS – KANSAS:

Kansas Statutes Annotated (2012) Chapter 65. Public Health Article 16. Regulation of Pharmacists

§ 65-1684. Same; charges and fees prohibited. *The board shall not impose any charge for the establishment or maintenance of the prescription monitoring program database on a registered wholesale distributor, pharmacist, dispenser or other person authorized to prescribe or dispense scheduled substances and drugs of concern. The board shall not charge any fees for the transmission of data to the database or for the receipt of information from the database, except that the board may charge a fee to an individual who requests the individual's own prescription monitoring information in accordance with procedures adopted by the board.*

B. HOUSING OF PDMPS

Where PDMPS are housed is relevant for emergency physicians because states with programs housed within law enforcement agencies tend to have provisions requiring more general oversight of prescribing practices than states where PDMPS are housed within health-related entities.

C. WHETHER ENROLLMENT IN PDMPs IS MANDATED

A minority of states explicitly require prescribers to enroll in PDMPs.

MANDATED PDMP REGISTRATION BY ALL PRESCRIBERS – ARIZONA:

Arizona Revised Statutes Annotated (2012) Title 36. Public Health and Safety Chapter 28. Controlled Substances Prescription Monitoring Program Article 1. General Provisions

§ 36-2606. Registration; requirements. *A. Beginning November 1, 2007 and pursuant to rules adopted by the board, each medical practitioner who is issued a license pursuant to title 32 and who possesses a registration under the federal controlled substances act must have a current controlled substances prescription monitoring program registration issued by the board.*

D. WHETHER EDUCATION OR TRAINING IS REQUIRED

Some states require education or training in the use of the PDMP or in pain management.

REQUIREMENT THAT USERS OF THE PDMP BE TRAINED – NEVADA:

Nevada Revised Statutes Annotated (2012) Title 40. Public Health and Safety Chapter 453. Controlled Substances Uniform Controlled Substances Act

General Provisions § 453.1545. *2. The Board shall provide Internet access to the database of the program established pursuant to subsection 1 to each practitioner who is authorized to write prescriptions for and each person who is authorized to dispense controlled substances listed in schedule II, III or IV who:*

(a) Elects to access the database of the program; and

(b) Completes the course of instruction described in subsection 7.

7. The Board and the Division shall cooperatively develop a course of training for persons who elect to access the database of the program pursuant to subsection 2 and require each such person to complete the course of training before the person is provided with Internet access to the database pursuant to subsection 2.

E. WHETHER ACCESSING THE PDMP IS MANDATED

Some states have statutes or regulations that *require* a prescriber to access or

check the PDMP database in specified circumstances. Several states *recommend or encourage* prescribers or dispensers to access or check the PDMP database. Some states explicitly provide that neither prescribers nor pharmacists are required to access the PDMP database. Finally, other states have exemptions from accessing the database under certain circumstances.

MANDATE TO CHECK PDMP - NEVADA: Explicit requirement that prescribers check the PDMP before writing a prescription for a controlled substance

Nev. Rev. Stat. Ann. §639.23507. *A practitioner shall, before writing a prescription for a controlled substance listed in schedule II, III or IV for a patient, obtain a patient utilization report regarding the patient for the preceding 12 months from the computerized program established by the Board and the Investigation Division of the Department of Public Safety pursuant to NRS 453.1545 if the practitioner has a reasonable belief that the patient may be seeking the controlled substance, in whole or in part, for any reason other than the treatment of an existing medical condition and:*

1. *The patient is a new patient of the practitioner; or*
2. *The patient has not received any prescription for a controlled substance from the practitioner in the preceding 12 months...*

The practitioner shall review the patient utilization report to assess whether the prescription for the controlled substance is medically necessary.

ENCOURAGEMENT TO CHECK PDMP - ARKANSAS:

S.B. 345, 88th General Assembly, Reg. Sess. (Ark. 2011) (d) *Practitioners are encouraged to access or check the information in the controlled substance database created under this subchapter before prescribing, dispensing, or administering medications.*

EXPLICIT PROVISION THAT PRESCRIBERS ARE NOT MANDATED TO ACCESS THE PDMP – OREGON:

Oregon Rev. Stat. 431 (7) *Nothing in ORS 431.962 to 431.978 and 431.992 requires a practitioner or pharmacist who prescribes or dispenses a prescription drug to obtain information about a patient from the prescription monitoring program. A practitioner or pharmacist who prescribes or dispenses a prescription drug may not be held liable for damages in any civil action on the basis that the practitioner or pharmacist did or did not request or obtain information from the prescription monitoring program. [2009 c.799 §4]*

EXPLICIT PROVISION THAT PRESCRIBERS ARE *NOT* MANDATED TO ACCESS THE PDMP UNDER CERTAIN CIRCUMSTANCES – TENNESSEE:

Tennessee Code Section 53-10-310 (e)(5)(D) *Prescribers are not required to check the database before prescribing or dispensing one of the controlled substances...if the quantity of the controlled substance which is prescribed or dispensed does not exceed an amount which is adequate for a single, seven (7) day treatment period and does not allow a refill.*

F. USE OF THE PDMP FOR DATA MINING REGARDING PHYSICIANS

Some states have legislation authorizing or requiring that data from PDMPs be accessed to obtain information about individual prescribing practices. This is referred to as “data mining.”

AUTHORIZATION TO OBTAIN AND RELEASE INFORMATION ABOUT PHYSICIAN PRESCRIBING PRACTICES – ARIZONA:

Arizona Revised Statutes Annotated (2012) Title 36. Public Health and Safety Chapter 28. Controlled Substances Prescription Monitoring Program Article 1. General Provisions

§ 36-2604. Use and release of confidential information. *C. The board may release data collected by the program to the following:*

- 1. A person who is authorized to prescribe or dispense a controlled substance to assist that person to provide medical or pharmaceutical care to a patient or to evaluate a patient.*
- 2. An individual who requests the individual's own prescription monitoring information pursuant to § 12-2293.*
- 3. A professional licensing board established pursuant to title 32, chapter 7, 11, 13, 14, 15, 16, 17, 18, 21, 25 or 29. Except as required pursuant to subsection B of this section, the board shall provide this information only if the requesting board states in writing that the information is necessary for an open investigation or complaint.*

G. WHETHER A PRESCRIBER’S AGENT MAY ACCESS THE PDMP

Some states allow a prescriber’s designated agent to access the PDMP on behalf of the prescriber under certain conditions.

ACCESS OF PDMP BY AGENT – KENTUCKY:

Baldwin's Kentucky Revised Statutes Annotated (2012) Title XVIII. Public

Health Chapter 218A. Controlled Substances

§ 218A.202 *Electronic system for monitoring controlled substances; required registration and reporting; penalty for illegal use of system; pilot or continuing project; continuing education programs; reports of failure to comply with section; administrative regulations*

(6) The Cabinet for Health and Family Services shall only disclose data to persons and entities authorized to receive that data under this section. Disclosure to any other person or entity, including disclosure in the context of a civil action where the disclosure is sought either for the purpose of discovery or for evidence, is prohibited unless specifically authorized by this section. The Cabinet for Health and Family Services shall be authorized to provide data to:

(e) A practitioner or pharmacist, or employee of the practitioner's or pharmacist's practice acting under the specific direction of the practitioner or pharmacist, who requests information and certifies that the requested information is for the purpose of:

1. Providing medical or pharmaceutical treatment to a bona fide current or prospective patient...

H. CIVIL LIABILITY AND IMMUNITY

Some states explicitly provide that prescribers shall be immune from civil liability for checking or not checking the state PDMP.

IMMUNITY FROM LIABILITY – MARYLAND:

Immunity from liability, duty to check the PDMP or use data obtained therein S.B. 883, 2011 Leg. (Md. 2011)

§21-2A-08. *(B) A prescriber or dispenser, acting in good faith, is not subject to liability or disciplinary action arising solely from:*

- (1) Requesting or receiving, or failing to request or receive, prescription monitoring data from the program; or*
- (2) Acting, or failing to act, on the basis of prescription monitoring data provided by the program.*

IMMUNITY FROM LIABILITY – MINNESOTA:

Minn. Stat. Ann. §152.126. *(b) Nothing in this section shall require a pharmacist, prescriber, or other dispenser to obtain information about a patient from the program, and the pharmacist, prescriber, or other dispenser, if acting in good faith, is immune from any civil, criminal, or administrative liability that might*

otherwise be incurred or imposed for requesting, receiving, or using information from the program.

I. WHETHER DATA ACQUIRED FROM PDMP IS MADE PART OF THE MEDICAL RECORD

Some states prohibit any incorporation of PDMP data into the medical record, while other states actually require that such data be incorporated.

J. WHETHER INTERSTATE LINKAGE OF DATABASES IS ENCOURAGED

Some states specifically encourage or support interstate linkage of prescription monitoring databases.

K. HOW OFTEN PHARMACIES ARE REQUIRED TO UPDATE PRESCRIPTION INFORMATION

States vary regarding the timing within which pharmacies are required to update prescription information, ranging from weekly updates to real-time reporting of information.

RECOMMENDATIONS FOR ACEP CHAPTERS :

In considering the recommendations below, it is important to recognize the rapidly evolving nature of legislative and regulatory activity related to opioid prescribing and prescription drug monitoring. In this highly dynamic environment, chapters should be cognizant that future developments may necessitate new or revised approaches to some of these issues.

With that in mind, and consistent with ACEP's policy statement "Electronic Prescription Monitoring", ACEP chapters are encouraged to consider supporting provisions of PDMP legislation in which PDMPs:

- (1) **Are not funded by prescribers**, though when funding is required that the fees not be overly burdensome and that they be used solely to improve the program and provider enrollment;
- (2) **Are housed within state health agencies**;
- (3) **Do not require enrollment of prescribers**, though when there is mandatory enrollment that the process be streamlined and not overly burdensome;
- (4) **Do not mandate specific training or education**;
- (5) **Do not mandate that prescribers access the database**; though when this is required, that it be only when a prescriber reasonably believes there may be a risk of

diversion or exemptions are made for emergency situations (i.e. a prescription given for a seven-day treatment without a refill).

- (6) **Allow for designated agents to access the PDMP** on a prescriber's behalf;
- (7) **Do not allow mining for data** for individual physician prescribing practices;
- (8) **Explicitly provide immunity from liability** for physician actions taken in regard to the PDMP.
- (9) **Encourage interstate linkage of PDMPs; and**
- (10) **Require prompt and timely updating of information by pharmacies.**

Additional resources:

The website for the National Alliance for Model State Drug Laws provides extremely helpful and easily accessible information: <http://www.namsdl.org>

ⁱ *Please note that in addition to legislation, there are numerous local and state regulations and guidelines pertaining to this subject. These will not be discussed in this paper due to the sheer volume and diversity of such guidelines, regulations, etc.*