Department of Regulatory Agencies

Office of Policy, Research and Regulatory Reform

2010 Sunset Review: Electronic Prescription Drug Monitoring Program and the Prescription Controlled Substance Abuse Monitoring Committee

October 15, 2010

Consumer Protection

Department of Regulatory Agencies

Executive Director's Office
Barbara J. Kelley
Executive Director

Bill Ritter, Jr.
Governor

October 15, 2010

Members of the Colorado General Assembly
c/o the Office of Legislative Legal Services
State Capitol Building
Denver, Colorado 80203

Dear Members of the General Assembly:

The mission of the Department of Regulatory Agencies (DORA) is consumer protection. As a part of the Executive Director's Office within DORA, the Office of Policy, Research and Regulatory Reform seeks to fulfill its statutorily mandated responsibility to conduct sunset reviews with a focus on protecting the health, safety and welfare of all Coloradans.

DORA has completed the evaluation of the Colorado Electronic Prescription Drug Monitoring Program and the Prescription Controlled Substance Abuse Monitoring Advisory Committee. I am pleased to submit this written report, which will be the basis for my office's oral testimony before the 2011 legislative committee of reference. The report is submitted pursuant to section 24-34-104(8)(a), of the Colorado Revised Statutes (C.R.S.), which states in part:

> The department of regulatory agencies shall conduct an analysis of the performance of each division, board or agency or each function scheduled for termination under this section...
>
> The department of regulatory agencies shall submit a report and supporting materials to the office of legislative legal services no later than October 15 of the year preceding the date established for termination….

The report discusses the question of whether there is a need for the regulation provided under Part 7 of Article 22 of Title 12, C.R.S. The report also discusses the effectiveness of the Colorado Board of Pharmacy and Division of Registrations staff in carrying out the intent of the statutes and makes recommendations for statutory and administrative changes in the event this regulatory program is continued by the General Assembly.

Sincerely,

Barbara J. Kelley
Executive Director-

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2010 Sunset Review:
Colorado Electronic Prescription Drug Monitoring Program and the Prescription Controlled Substance Abuse Monitoring Committee

Summary

What Is the Colorado Electronic Prescription Drug Monitoring Program?
The Colorado Electronic Prescription Drug Monitoring Program (PDMP) is an online database that collects designated data on controlled substances dispensed or prescribed within Colorado. Such data include the names of the prescriber and the patient; the name and dosage of the drug prescribed, the quantity supplied, and the number of authorized refills; and the name of the pharmacy where the prescription was filled.

What is the purpose of the PDMP?
The General Assembly created the PDMP to give prescribers a way to monitor patients' use of controlled substances, with the goal of mitigating the abuse of prescription drugs.

What Is Regulated?
The PDMP is under the regulatory authority of the Colorado Board of Pharmacy (Board). Colorado law requires all prescription drug outlets, defined as any resident or non-resident pharmacy outlet registered or licensed in Colorado where prescriptions are compounded and dispensed, to collect data on controlled substance prescriptions dispensed in Colorado, and report such data to the PDMP twice a month.

Who may access the PDMP?
Licensed pharmacists and prescribers—including physicians, dentists, and advanced practice nurses with prescriptive authority—may access the PDMP directly. Representatives of law enforcement may subpoena patient-specific data from the PDMP, provided that the patient is the subject of a bona fide investigation.

What Does It Cost?
In fiscal year 09-10, it cost $272,503 to administer the PDMP, and there were 0.5 full-time equivalent employees associated with the program.

Where Do I Get the Full Report?
The full sunset review can be found on the internet at: www.dora.state.co.us/opr/oprpublications.htm.

Key Recommendations

Continue the PDMP for 11 years, until 2022.
Stakeholders use the PDMP data to improve patient care, investigate illegal activity, and to inform public health initiatives. All of these activities promote the health, safety, and welfare of Coloradans.

Repeal the Prescription Controlled Substance Abuse Monitoring Advisory Committee.
The 11-member Prescription Controlled Substance Abuse Monitoring Advisory Committee (Committee) was created to assist the Board in the initial development and operation of the PDMP. The Committee has met its statutory mandate.

Allow law enforcement agencies and regulatory boards to subpoena prescriber information from the PDMP, provided the prescriber is the subject of a bona fide investigation.
Currently, law enforcement officials may subpoena patient-specific data from the PDMP, provided that the patient is the subject of a bona fide investigation. The law does not allow for the release of prescriber information under any circumstances. This should be changed because prescriber behavior can cause public harm, either by contributing to the abuse of controlled substances or causing actual physical harm to patients; the current data collection process for law enforcement is cumbersome and the data collected incomplete; and the subpoena process adequately protects the privacy of the prescriber. Further, the federal Controlled Substances Act arguably pre-empts the current prohibition on providing prescriber information to law enforcement.

Major Contacts Made During This Review

Colorado Board of Pharmacy
Colorado Dental Association
Colorado Medical Society
Colorado Pharmacists Society
Colorado Prescription Drug Task Force
Denver Office of Drug Strategy
U.S. Drug Enforcement Administration
North Metro Task Force
Peer Assistance Services
Prescription Controlled Substance Abuse Monitoring Advisory Committee
Purdue Pharma LP
Rx Plus

What is a Sunset Review?

A sunset review is a periodic assessment of state boards, programs, and functions to determine whether or not they should be continued by the legislature. Sunset reviews focus on creating the least restrictive form of regulation consistent with protecting the public. In formulating recommendations, sunset reviews consider the public's right to consistent, high quality professional or occupational services and the ability of businesses to exist and thrive in a competitive market, free from unnecessary regulation.

Sunset Reviews are Prepared by:
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Background

Introduction

Enacted in 1976, Colorado's sunset law was the first of its kind in the United States. A sunset provision repeals all or part of a law after a specific date, unless the legislature affirmatively acts to extend it. During the sunset review process, the Department of Regulatory Agencies (DORA) conducts a thorough evaluation of such programs based upon specific statutory criteria[1] and solicits diverse input from a broad spectrum of stakeholders including consumers, government agencies, public advocacy groups, and professional associations.

Sunset reviews are based on the following statutory criteria:

- Whether regulation by the agency is necessary to protect the public health, safety and welfare; whether the conditions which led to the initial regulation have changed; and whether other conditions have arisen which would warrant more, less or the same degree of regulation;
- If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms and whether agency rules enhance the public interest and are within the scope of legislative intent;
- Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures and practices and any other circumstances, including budgetary, resource and personnel matters;
- Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;
- Whether the composition of the agency's board or commission adequately represents the public interest and whether the agency encourages public participation in its decisions rather than participation only by the people it regulates;
- The economic impact of regulation and, if national economic information is not available, whether the agency stimulates or restricts competition;
- Whether complaint, investigation and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession;
- Whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action;
- Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

[1] Criteria may be found at § 24-34-104, C.R.S.

Not all of these criteria apply to sunset reviews of programs that do not regulate professions or occupations. However, DORA must still evaluate whether a program needs to exist to protect the public health safety and welfare; whether the level of regulation established for the program is the least restrictive consistent with the public interest; whether the state administers the program efficiently and effectively; and whether administrative and statutory changes are necessary to enhance the public interest.

Sunset Process

Programs scheduled for sunset review receive a comprehensive analysis. The review includes a thorough dialogue with agency officials and other stakeholders. Anyone can submit input on any upcoming sunrise or sunset review via DORA's website at: www.dora.state.co.us/pls/real/OPR_Review_Comments.Main.

The Colorado Electronic Prescription Drug Monitoring Program (PDMP), administered by the Colorado Board of Pharmacy (Board) pursuant to Part 7 of Article 22 of Title 12, Colorado Revised Statutes (C.R.S.), shall terminate on July 1, 2011, unless continued by the General Assembly. During the year prior to this date, it is the duty of DORA to conduct an analysis and evaluation of the Board pursuant to section 24-34-104, C.R.S.

The purpose of this review is to determine whether the PDMP should be continued for the protection of the public and to evaluate the performance of the Board and staff of the Division of Registrations (Division). During this review, the Board and the Division must demonstrate that the PDMP serves to protect the public health, safety or welfare, and that it is the least restrictive program consistent with protecting the public. DORA's findings and recommendations are submitted via this report to the legislative committee of reference of the Colorado General Assembly.

Methodology

As part of this review, DORA staff attended Board meetings, interviewed Division staff, interviewed officials with local and federal law enforcement, interviewed health care providers, reviewed Colorado statutes and Board rules, and reviewed the laws of other states.

Prescription Drug Monitoring Programs

Generally speaking, a prescription drug monitoring program is an electronic database that collects designated data on controlled substances dispensed or prescribed within a given state. Such data usually include the names of the prescriber and the patient; the name and dosage of the drug prescribed, the quantity supplied, and the number of authorized refills; and the name of the pharmacy where the prescription was filled. State governments generally house prescription drug monitoring programs within a state administrative, regulatory or law enforcement agency. As of July 2010, 34 states had prescription drug monitoring programs in place, and seven other states had enacted legislation to create them.[2]

Although most prescription drug monitoring programs are funded at least partially by grants from the U.S. Department of Justice (DOJ), the DOJ does not administer any prescription drug monitoring programs or establish standards for data collection or access. Consequently, programs vary considerably from state to state. Some areas of variation include:

- **Substances monitored.** Some prescription drug monitoring programs monitor only Schedule II drugs (i.e., those with a high potential for abuse), while others monitor Schedules III through V (i.e., those with a lower potential for abuse) in addition to Schedule II drugs.
- **Level of access**. Some prescription drug monitoring programs allow law enforcement to access the database directly, while others require law enforcement to supply a court order or subpoena to access data.
- **Proactive versus reactive.** In proactive prescription drug monitoring programs, a state regulatory or law enforcement agency monitors program data to detect patterns that might indicate prescription drug abuse or fraud, and may open an investigation based on its observations. Reactive programs prohibit regulatory agencies or law enforcement from accessing data unless a person is already under investigation for a drug offense.
- **Timeliness of data.** In many prescription drug monitoring programs, the data are only updated once or twice a month. There are, however, a few states—most notably California—that require pharmacies to upload the data once a week.

Colorado's PDMP is a "reactive" program housed at the Board. The data are updated twice monthly. Only licensed pharmacists, licensed prescribers, and Division staff responsible for administering the PDMP may access the data directly. Law enforcement may request data on patients (but not prescribers), via a subpoena or court order, only if the patients are the subject of a bona fide investigation.

Colorado-licensed prescription drug outlets started uploading data to the PDMP in July 2007, and the online database went live for queries in February 2008.

[2] U.S. Department of Justice, Drug Enforcement Administration. *Questions and Answers: State Prescription Drug Monitoring Programs*. Retrieved on September 20, 2010, from http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm

Legal Framework

History of Regulation

The General Assembly created the Colorado Electronic Prescription Drug Monitoring Program (PDMP) in 2005, with the passage of House Bill 05-1130. The purpose of the PDMP was to prevent prescription drug abuse by creating a database of all prescriptions for controlled substances that are filled in Colorado. The database would allow prescribers to monitor patients' use of controlled substances, with the goal of mitigating the abuse of prescription drugs. The bill made implementation of the PDMP contingent upon receiving sufficient funding via gifts, grants, and donations.

In 2007, the General Assembly passed Senate Bill 07-204, which authorized the Colorado Board of Pharmacy (Board) to supplement funding for the PDMP by charging all prescribers of controlled substances—i.e., dentists, nurses with prescriptive authority, optometrists, physicians, physician assistants, podiatrists, and veterinarians—a surcharge of up to $7.50 per year. Prescribers would pay the surcharge when renewing their licenses, that is, once every two years.

As of August 2010, the prescriber fee is set at $7.50 per year.

Summary of Statute

Part 7 of Article 22 of Title 12, Colorado Revised Statutes (C.R.S.), creates the PDMP and places it under the regulatory authority of the Board, which is housed within the Division of Registrations (Division), Colorado Department of Regulatory Agencies (DORA).

The Prescription Controlled Substance Abuse Monitoring Advisory Committee (Committee) assists the Board in designing, operating, and maintaining the PDMP, including developing access and security protocols.[3] The Committee consists of the following 11 members:[4]

- The Division Director or his or her designee;
- A pharmacist appointed by the Board;
- Three physicians appointed by the state Medical Board, one of which is a pain specialist or addiction specialist;
- A dentist appointed by the Board of Dental Examiners;
- A veterinarian appointed by the Board of Veterinary Medicine;
- The director of the Division of Alcohol and Drug Abuse (now the Division of Behavioral Health) in the Colorado Department of Human Services or his or her designee; and
- Three persons appointed by the Committee, one of whom is a representative of law enforcement.

[3] § 12-22-703(2), C.R.S.
[4] § 12-22-703(1), C.R.S.

Committee members receive no compensation and are not reimbursed for expenses associated with their service.[5]

The Board is responsible for developing a database to track prescriptions for controlled substances written in Colorado. "Controlled substances" refers to drugs that have a currently accepted medical use and fall into one of the following categories:[6]

- **Schedule II** drugs have a high potential for abuse, and such abuse can lead to severe psychological or physical dependence. Schedule II drugs include morphine, fentanyl, and oxycodone.[7]
- **Schedule III** drugs have a lesser potential for abuse, and such abuse can lead to moderate or low physical dependence, or high psychological dependence. Examples of Schedule III drugs include secobarbital, anabolic steroids, and ketamine.[8]
- **Schedule IV** drugs have a low potential for abuse, and such abuse may lead to limited physical dependence or psychological dependence. Schedule IV drugs include diazepam and phenobarbital.[9]
- **Schedule V** drugs have a low potential for abuse, and such abuse may lead to limited physical dependence or psychological dependence. Schedule V drugs include medications containing low dosages of codeine.[10]

The PDMP must track, at a minimum, the following information for each prescription:[11]

- The date the prescription was dispensed;
- The name of the patient and the prescriber;
- The name and amount of the controlled substance;
- The method of payment (e.g., cash or health insurance); and
- The name of the dispensing pharmacy.

The law further authorizes the Board to collect: [12]

> …any other data elements needed to determine whether a patient is visiting multiple prescribers or pharmacies, or both, to receive the same or similar medication.

[5] § 12-22-703(3), C.R.S.
[6] § 12-22-702(3), C.R.S.
[7] § 18-18-204, C.R.S.
[8] § 18-18-205, C.R.S.
[9] § 18-18-206, C.R.S.
[10] § 18-18-207, C.R.S.
[11] § 12-22-704(1), C.R.S.
[12] § 12-22-704(1)(f), C.R.S.

By rule, these additional data elements include, but are not limited to:[13]

- The number of refills authorized for each prescription;
- The patient's sex, date of birth, and address;
- The prescriber's U.S. Drug Enforcement Administration (DEA) registration number; and
- The number—assigned by either the DEA or the National Association of Boards of Pharmacy— assigned to the dispensing pharmacy.

Prescription drug outlets, defined as any resident or non-resident pharmacy outlet registered or licensed in Colorado where prescriptions are compounded and dispensed,[14] are responsible for collecting the data and reporting it to the Board.[15] Licensed hospitals, hospital pharmacies dispensing controlled substances for chart orders or in amounts less than or equal to a 24-hour supply, and certified emergency medical services personnel do not have to submit data to the PDMP.[16] By law, the data transmission process cannot require the prescription drug outlet to enter data more than once per patient per prescription.[17]

Prescription drug outlets must report data to the PDMP twice each month.[18]

If the prescription drug outlet does not dispense any controlled substances for the reporting period, it must enter a "zero" entry or it will be considered non-compliant.[19]

Prescription drug outlets that cannot report data to the PDMP due to a lack of technology may apply to the Board for a waiver from the reporting requirements. The Committee determines whether a waiver shall be granted.[20]

The following people may directly access PDMP data:[21]

- Board staff responsible for administering the PDMP;
- Licensed practitioners with the statutory authority to prescribe controlled substances, as long as:
    - The query relates to a current patient to whom the practitioner is prescribing or considering prescribing any controlled substance; or
    - Such practitioners are engaged in a legitimate program to monitor patients' controlled substance abuse; and
- Licensed pharmacists with the statutory authority to dispense controlled substances, if the query relates to a current patient to whom the pharmacist is dispensing or considering dispensing a controlled substance.

[13] Board of Pharmacy Rule 23.00.40.
[14] § 12-22-702(7), C.R.S.
[15] § 12-22-708(1), C.R.S.
[16] § 12-22-709(1), C.R.S.
[17] § 12-22-704(2), C.R.S.
[18] Board of Pharmacy Rule 23.00.30.
[19] Board of Pharmacy Rule 23.00.30.
[20] § 12-22-709(2), C.R.S.
[21] § 12-22-705(3), C.R.S.

Law enforcement officials may request PDMP data from the Board via an official court order or subpoena, as long as the information released is specific to a patient who is the subject of a bona fide investigation.[22]

The Board must provide a means of sharing PDMP data with out-of-state health care practitioners and law enforcement officials meeting the above requirements.[23]

Individuals who have been prescribed controlled substances may request from the Board their own PDMP data.

The Board may provide PDMP data to a public or private entity for the purpose of bona fide research or education, so long as such information does not identify patients, prescribers, or dispensers.[24]

Anyone who knowingly releases, obtains, or attempts to obtain PDMP data in violation of the law is subject to a civil fine of not less than $1,000 and not more than $10,000 for each violation. Fines paid are deposited in the Prescription Drug Monitoring Fund.[25]

Prescription drug outlets that fail to report data as required by law and rule may be subject to Board discipline.[26]

Prescribers who have in good faith prescribed a controlled substance to a patient, shall not be held liable for information submitted to the PDMP. Prescribers, pharmacists, and prescription drug outlets that have in good faith submitted data to the PDMP, shall not be held liable for doing so.[27]

Section 12-22-706(3), C.R.S., directs the Board to seek gifts, grants, and donations to support the PDMP. The Board must report annually to the Health and Human Services Committees in the Colorado House of Representatives and Senate regarding the gifts, grants, and donations requested, of whom they were requested, and the amounts received. If there is insufficient funding for the PDMP, the Board may charge all prescribers of controlled substances a fee of up to $7.50 per year to offset the costs of the PDMP. Prescribers pay the fee every two years, when renewing their licenses.[28]

[22] § 12-22(705)(3)(e), C.R.S.
[23] § 12-22-705(6), C.R.S.
[24] § 12-22-705(5), C.R.S.
[25] § 12-22-707, C.R.S.
[26] § 12-22-125(1)(c), C.R.S.
[27] § 12-22-708(2), C.R.S.
[28] § 12-22-706(5), C.R.S.

Program Description and Administration

The Colorado Board of Pharmacy (Board) has regulatory authority over the Colorado Electronic Prescription Drug Monitoring Program (PDMP). The Board contracts with GHS Data Management to administer the PDMP database and manage the collection of the data. Staff of the Division of Registrations (Division) within the Department of Regulatory Agencies (DORA) oversees the day-to-day operation of the PDMP, acts as a liaison with the software vendor, and seeks grant funding to support the PDMP.

Funding of the PDMP

The PDMP has two funding sources:

- Federal grant funds from the Harold Rogers Prescription Drug Monitoring Program administered by the U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Assistance; and
- Fees collected from licensed prescribers of controlled substances. The fee is currently set at $7.50 per prescriber per year. Prescribers pay the fee every other year as part of their license renewal ($15 every two years).

Table 1 shows the funding sources, total expenditures, and the number of full-time equivalent (FTE) employees associated with the PDMP since its inception in 2006.

Table 1
Fiscal Information

Fiscal Year	Federal Grant Money	Prescribers Fees	Total Program Expenditure	FTE
06-07	$50,814	$0	$50,814	0
07-08	$220,442	$34,376	$254,818	1
08-09	$172,622	$101,026	$273,648	1
09-10	$0	$272,503	$272,503	0.5*

* In FY 09-10, staffing was sporadic. From October 1, 2009 through March 6, 2010, the PDMP had no dedicated staff. As of July 2010, the PDMP has 0.7 FTE.

During fiscal year 06-07, the Board was in the process of developing the PDMP. Program expenditures increased dramatically when the PDMP went live in fiscal year 07-08. The Board pays the vendor $188,300 per year for the maintenance of the PDMP, with the balance of the expenditures consisting of salaries, legal fees, and general operating costs.

The Board obtained a federal grant for the initial implementation of the PDMP. The Board received a second federal grant in fiscal year 08-09; however, this grant was primarily intended to fund enhancements to the program, and only a portion could be spent on routine maintenance costs. Consequently, the PDMP has relied primarily on the prescriber surcharge to maintain the PDMP. As reflected in the table above, the amount of money collected from prescribers varies considerably from year to year, depending on how many prescribers renew in a given year.[29]

The remainder of the second federal grant was to be spent on two system enhancements: upgrading the upload software that prescription drug outlets use, and implementing a system for sharing PDMP data with other states in accordance with national standards.

The Board did not implement these changes in fiscal year 09-10, however. The Board chose to delay the first enhancement because it determined that upgrading the software would first require prescription drug outlets to upgrade their computer hardware, and the Board did not want to impose additional costs during the economic downturn. The second enhancement was delayed because the Alliance of States with Prescription Monitoring Programs was still in the process of developing national standards for interstate data-sharing. In light of these delays, Board staff requested and received an extension until August 2011 to implement these enhancements. For this reason, there was no federal grant money spent in fiscal year 09-10.

The FTE reflected in the table above was for a Program Assistant II position that was allocated exclusively to the PDMP. In March 2010, the Division made staffing changes to accommodate a new regulatory program that was assigned to the Division. Consequently, the following classified positions staff the PDMP:

- Program Director of the Board, 0.2 FTE Pharmacy III. Responsible for general oversight of the PDMP and for seeking grant funding.
- PDMP Administrator, 0.5 FTE Technician IV. Responsible for the day-to-day operation of the PDMP, such as ensuring prescription drug outlets comply with reporting requirements, and fulfilling data requests from law enforcement and other agencies.

Recall that the PDMP is supported by not only funds from the prescriber surcharge but also federal grants and, potentially, private gifts, grants, and donations. Based on the uncertainty of future grant revenue, the Division decided to maintain staffing of the PDMP at 0.7 FTE, even though 1.0 FTE were actually allocated. In the future, the Division will continue to evaluate the staffing level of the PDMP in concert with available revenue across all funding sources, including the extent of gift and grant activity.

[29] Licensed prescribers renew their licenses at staggered two-year intervals; for example, physicians renew in May of odd-numbered years, and dentists renew in February of even-numbered years. The number of renewing individuals for each license type varies considerably: there are over 20,000 licensed physicians and only about 5,000 licensed dentists.

Use of the PDMP

The statute authorizes licensed pharmacists and licensed prescribers to access the PDMP directly. Those wishing to do so must register on the Colorado PDMP website. When registering, pharmacists and prescribers must provide their license number (or, in the case of registered nurses with prescriptive authority, authority number), Social Security number, and birth date. Prescribers must also provide their U.S. Drug Enforcement Administration (DEA) registration number. These data must match the information in DORA's licensing system or access to the PDMP is denied.

Table 2 shows the number of registered users of the PDMP by license type.

Table 2
Number of PDMP Registered Users
(July 2010)

License Type	Number of Registered Users
Pharmacists	1,412
Physicians	3,504
Physician Assistants	748
Optometrists	16
Registered Nurses with Prescriptive Authority	1,754
Veterinarians	7
Dentists	699
Podiatrists	27
TOTAL	8,167

Among licensed professionals, registered nurses with prescriptive authority are by far the most likely to register for the PDMP, with over 85 percent registering. Roughly 17 percent of all licensed physicians and 14 percent of dentists have registered. Veterinarians have the lowest registration rate, with only 7 of 4,021 practitioners registering.

Table 3 shows the number of queries submitted by registered users since the system was available for queries in February 2008.

Table 3
Number of PDMP Queries by Registered Users

Fiscal Year	Number of Queries
07-08*	34,760
08-09	132,537
09-10	182,818

*Data reflect February 1 through June 30, 2008.

Based on the available data, the number of queries to the PDMP has risen steadily.

Out-of-state practitioners and consumers who have been prescribed a controlled substance may access PDMP data by submitting a request to the Board. Representatives of law enforcement may request data via subpoena.

Table 4 shows the number of data requests submitted by out-of-state practitioners, consumers, the DEA, and representatives of other law enforcement agencies since the system was available for queries in February 2008.

Table 4
Number of Data Requests

Fiscal Year	Requester				
	Out-of-State Practitioners	Consumers	DEA	Other Law Enforcement Agencies	Total Requests
07-08*	6	0	0	4	10
08-09	13	10	123	13	159
09-10	16	19	190	15	240

*Data reflects February 1 through June 30, 2008.

Over the past three fiscal years, the number of data requests in every category has risen. The DEA is responsible for the most data requests by a considerable margin.

Disciplinary Actions Against Non-Compliant Prescription Drug Outlets

The Board may take disciplinary action against prescription drug outlets that fail to report data as required by law. The Board may also take action against any person who knowingly releases, obtains, or attempts to obtain PDMP data in violation of the law.

Table 5 shows, for the three fiscal years indicated, the final actions the Board took against licensed pharmacists and pharmacies for violating the PDMP statutes.

Table 5
Final Actions Taken Relating to Violations of the PDMP Law

Type of Action	FY 07-08*	FY08-09	FY 09-10
Letters of Admonition	0	0	1
Relinquishments	1	16	10
Fines	0	24	42
Total Fine Amount	$0	$120,000	$235,000
Dismissals	19	7	17
Dismissals with confidential Letters of Concern	23	52	107

*Data reflects February 1 through June 30, 2008.

With the exception of the single letter of admonition issued in fiscal year 09-10, which was issued to a pharmacist for misuse of PDMP data, the disciplinary actions reflected in the table above were taken against prescription drug outlets for failure to report data to the PDMP as required by law.

The high number of dismissals in the first year of the PDMP reflects an adjustment period for participating prescription drug outlets reporting data. As pharmacies became accustomed to the reporting schedule and the Internet application used to upload data, compliance increased.

The relinquishments were primarily by prescription drug outlets located outside Colorado that filled prescriptions for Colorado patients via mail order. These outlets, given the choice between paying a substantial fine or relinquishing their registration, (and thereby discontinuing service to Colorado patients), found that relinquishment made more financial sense.

The spike in the number of fines, as well as the number of dismissals with letters of concern, from fiscal year 08-09 to 09-10 reflects the tiered disciplinary structure the Board has in place. For example, the Board typically sends a letter of concern to a prescription drug outlet after a first incident of non-compliance, but levies a fine against that outlet for subsequent offenses.

Prescription drug outlets that lack the technology to report data to the PDMP may apply to the Board for a waiver from the reporting requirements. Since the PDMP was created, the Board has waived the reporting requirements for two prescription drug outlets.

Analysis and Recommendations

Recommendation 1 – Continue the Colorado Electronic Prescription Drug Monitoring Program for 11 years, until 2022.

The Colorado Electronic Prescription Drug Monitoring Program (PDMP) is an online database that tracks specific information about all prescriptions for controlled substances dispensed in the state of Colorado. The statutes governing the PDMP are located in Part 7 of Title 12, Article 22, Colorado Revised Statutes (C.R.S.). The PDMP falls under the regulatory authority of the Colorado Board of Pharmacy (Board).

The legislative declaration of the PDMP statute recognizes that the abuse of prescription drugs "exceeds or rivals the abuse of illicit drugs."[30] Statistics gathered over the course of this review indicate that prescription drug abuse has continued to rise since the General Assembly passed House Bill 05-1130. According to Peer Assistance Services, which focuses on the prevention and treatment of substance abuse in Colorado, the number of Colorado residents admitted for treatment for prescription opioid abuse rose from 305 in 2000 to 1,062 in 2008, an increase of nearly 300 percent. Further, the number of yearly deaths related to the most commonly used prescription drugs nearly doubled from 298 in 2000 to 562 in 2008.

Clearly, the problem of prescription drug abuse still exists.

The primary question of this review is whether the PDMP exists to protect the public health, safety, and welfare.

There are three primary stakeholder groups who use PDMP data.

Licensed prescribers of controlled substances, including physicians, physician assistants, dentists, and nurses with prescriptive authority, use the PDMP to check the prescription history of their patients.

According to information gathered over the course of this review, emergency room (ER) personnel are among the most frequent users of the PDMP. In a typical scenario, a new patient is admitted to the ER. The ER physician checks the PDMP to see what, if any, controlled substances the patient might have in his or her system before administering any additional medications. In instances like these, the use of PDMP data can prevent harmful drug interactions and accidental overdoses.

[30] § 12-22-701(1)(a), C.R.S.

Prescribers can also use the PDMP to detect drug-seeking behavior. In a typical scenario, a patient calls a dentist late on a Friday night, saying that his or her usual dentist is unavailable and he or she needs a supply of pain medication to get through the weekend. In reviewing the patient's PDMP record, the dentist discovers the patient had been prescribed multiple controlled substances by several different healthcare providers. While this information in itself does not prove the patient is "doctor shopping," the dentist can use the data to inform his or her clinical decisions. If the dentist finds that the patient is engaging in drug-seeking behavior, the dentist would be able to refer the patient for substance abuse treatment. Prescribers' use of the PDMP helps prevent accidental overdoses and identify patients with possible substance abuse issues, and allows prescribers to provide better patient care.

Law enforcement officials do not have direct access to the PDMP data, but they may subpoena PDMP records for specific patients if the request is made as part of a bona fide investigation. Consider, for example, that the U.S. Drug Enforcement Administration (DEA) is investigating a person on the suspicion that he or she is seeking multiple prescriptions of a controlled substance, then selling the pills on the street. The DEA could subpoena that person's PDMP record to verify the number and type of prescriptions that person had in his or her name. The PDMP data in itself does not conclusively prove a person's guilt or innocence. Rather, it serves as one of many data sources that law enforcement can use over the course of an investigation.

Researchers, such as academics and public health officials, do not have direct access to the PDMP data, but may request from the Board aggregate data that do not identify the names of patients, prescribers, or dispensers. Researchers use these aggregate data to track prescribing trends over time. They also can look at the data side-by-side with data on deaths due to overdose and emergency room and drug treatment program admissions to detect patterns of abuse in the larger community. Knowledge of these patterns can help substance abuse treatment centers better serve patients, and shape public health policy.

The Board's contract with the current PDMP vendor is due to expire in 2012. An 11-year sunset date will give the Board ample time to select a vendor via the request for proposals process, develop system requirements and enhancements, implement the upgraded system, and resolve any glitches before undergoing the next sunset review.

Stakeholders may use the PDMP data to improve patient care, detect illegal activity, and to inform public health initiatives. All of these activities promote the health, safety, and welfare of Coloradans.

For these reasons, the General Assembly should continue the PDMP for 11 years, until 2022.

Recommendation 2 – Repeal the Prescription Controlled Substance Abuse Monitoring Advisory Committee.

Section 12-22-703, C.R.S., creates the Prescription Controlled Substance Abuse Monitoring Advisory Committee (Committee). The 11-member Committee was created to assist the Board in the development and operation of the PDMP, and included healthcare providers, at least one member of law enforcement, and representatives of state agencies.

The Committee held its first meeting on May 9, 2007. In fiscal years 08-09 through 09-10, the Committee met a total of three times. The Program Director for the Board, although not a Committee member, facilitated and attended all Committee meetings.

- On August 4, 2008, four members attended via teleconference.
- On November 5, 2008, eight members attended via teleconference.
- On June 3, 2009, one member attended via teleconference.

For the past two fiscal years there have been no revenues or expenditures associated with the Committee, and the Committee has made no advisory proposals to the Board.

Within the first six months of the PDMP development project, the Committee provided guidance to the Board. Ultimately, however, the Board selected a software vendor that had already developed a similar program in another state, and was consequently familiar with the basic system requirements for the PDMP. The vendor was able to modify its existing program to meet Colorado's needs. Once the vendor was selected, the Board no longer required the Committee's guidance.

By advising the Board in the early development stages of the PDMP, the Committee met its statutory mandate. Since the Committee has served its purpose, the General Assembly should repeal the Committee.

Recommendation 3 – Allow law enforcement agencies and regulatory boards to subpoena prescriber information from the PDMP, provided the prescriber is the subject of a bona fide investigation.

When the PDMP was created, the General Assembly narrowly defined the purpose of the PDMP. Recognizing the extent of prescription drug abuse in the United States and the fact that patients sometimes deceive prescribers in order to obtain controlled substances, the stated purpose of the PDMP is to provide a way for a prescriber to determine a patient's history with prescribed controlled substances.[31]

[31] § 12-22-701(1)(c), C.R.S.

In light of this stated purpose, the law places strict limits on who may access PDMP data. Currently, only Board staff and licensed prescribers and pharmacists may access the online database directly. Law enforcement officials may request patient-specific data, provided that patient is the subject of a bona fide investigation.

The law does not allow for the release of prescriber information under any circumstances.

Interviews with local and federal law enforcement officials, as well as representatives of the Office of Investigations within the Division of Registrations (Division) —which investigates complaints on behalf of the regulatory boards that license prescribers—revealed that forbidding access to prescriber data creates administrative inefficiency. The lack of access forces law enforcement officials to resort to a manual, scattershot data collection process that is described in detail below. The manual process delays the investigative process, and can consequently pose a public health risk. This justifies permitting law enforcement officials and professional regulatory boards to subpoena prescriber-specific data from the PDMP.

Prescriber behavior can cause serious harm to the public. The Office of Diversion Control at the DEA publishes on its website a list of physicians who have been investigated, arrested, and ultimately prosecuted for crimes relating to controlled substances since 2003.[32] While cases resulting in a criminal conviction are extremely rare—according to the list, there have been only 221 cases nationwide in seven years, only three of which occurred in Colorado—this list provides a critical glimpse at the kind of harm a prescriber can cause. Most of the cases on the list involve physicians prescribing controlled substances outside the scope of professional practice, sometimes in exchange for money, or unlawfully distributing such substances. In the more egregious cases, there is serious patient harm: in 11 cases, physicians prescribed such high doses of controlled substances that patients suffered serious injury or death. A jury found one particular physician responsible for the overdose deaths of five patients.

Again, these cases are extremely rare, and the vast majority of prescribers practice and prescribe appropriately. But it is indisputable that prescribers can cause harm to patients. It is in the public interest to assure that prescribers who are breaking the law are investigated and removed from practice efficiently.

Law enforcement officials are able to investigate such prescribers with or without PDMP prescriber data. However, the limitation slows down the investigation and means that the data collected is frequently incomplete. To illustrate the effect of the ban on the release of PDMP prescriber data, consider this example.

[32] U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control. *Cases Against Doctors.* Retrieved on October 13, 2010, from http://www.deadiversion.usdoj.gov/crim_admin_actions/doctors_criminal_cases.pdf

A prescriber is allegedly selling prescriptions for a Schedule II controlled substance, i.e., a drug with high potential for abuse. The prescriber sells the drugs either to addicts or to individuals with the intent to sell.

Law enforcement or regulatory officials become aware of the problem, through undercover work, a newspaper article, or any other means. They open an investigation.

Next, the officials need to determine what controlled substances the prescriber has prescribed, and to whom. As a first step, they can interview the prescriber, or ask him or her to voluntarily provide patient records. This can reveal good information, but the prescriber may omit or refuse to provide information.

Alternatively, law enforcement officials may subpoena the records of all prescriptions written by the prescriber from each pharmacy which might have filled those prescriptions. It is relatively easy to obtain such records from the larger corporate pharmacies with many locations statewide. However, to form a complete picture of the prescriber's prescribing behavior within the state, it would be necessary to subpoena records from the nearly 1,000 prescription drug outlets in Colorado. Needless to say, this would be an extremely inefficient and time-consuming process, and is not a viable alternative. Instead, law enforcement can make educated guesses about which pharmacies might have pertinent prescriber data, and subpoena records accordingly. However, this can often result in incomplete data.

The Division’s Office of Investigations faces the same difficulties as law enforcement in obtaining these data, even though it is housed in the same agency as the PDMP.

There is one final way of obtaining comprehensive prescription information, but it is available only to the DEA. Every healthcare provider must obtain a DEA registration number before he or she may prescribe medications. This means that every prescriber is under the regulatory authority of the DEA. The DEA would have the authority to visit the prescriber's office and inspect all patient records. This would give a complete picture of the prescriber's prescribing history.

In order to get information on the controlled substances a person has prescribed, law enforcement must either rely on witness interviews or subpoena prescriber data from every pharmacy that has conceivably filled a prescription the prescriber has written. The DEA alone has the ability to inspect the records of all of a prescriber's patients, but unless the prescriber has all patient records electronically, this requires many hours of sifting through patient files.

This poses a considerable administrative burden for law enforcement and for the Office of Investigations. The delay caused by this inefficient data gathering process slows down the investigation considerably, meaning that it takes longer to close cases. It takes longer to remove bad actors from practice, and longer to clear the innocent of wrongdoing.

If law enforcement and regulatory officials were able to subpoena prescriber data from the PDMP, they could receive—in a single, centralized report—data that would otherwise take considerable time and resources to gather.

An argument against providing law enforcement and the Office of Investigations access to prescriber data is that such officials would be tempted to go on "fishing expeditions," that is, to browse through prescriber records looking for certain prescribing behavior, then target prescribers who display that behavior. However, recall that law enforcement officials would not be granted direct access to the PDMP. They would only be able to obtain prescriber data from the PDMP by submitting a prescriber-specific subpoena to the Board. This is the same standard that has been in place for patient data since the PDMP was created.

Moreover, law enforcement and regulatory personnel access confidential or sensitive data on a daily basis. Whether such personnel work for the federal, state, or local government, they must sign confidentiality agreements and are forbidden by law from misusing sensitive or confidential information.

Another concern is that fear of punishment by law enforcement or regulatory officials would have a chilling effect on the aggressive management of pain. In other words, prescribers might become leery of prescribing controlled substances for fear of becoming subject to scrutiny. However, because a prescriber would already have to be the subject of an investigation before his or her data could be subpoenaed, law enforcement and regulatory officials would have to possess additional evidence suggesting that the prescriber was prescribing inappropriately. The PDMP data would be simply one data element amongst many to consider in the context of an investigation. The data would serve to corroborate or contradict information received from other sources, and would be as likely to eliminate suspicion as to confirm it.

The current system prohibits the release of prescriber data under any circumstances. This should be changed because:

- Prescriber behavior can cause public harm, either by contributing to the abuse of controlled substances or causing actual physical harm to patients;
- The current data collection process for law enforcement is cumbersome and the data collected incomplete; and
- The subpoena process adequately protects the privacy of the prescriber.

Finally, the federal Controlled Substances Act arguably pre-empts the current prohibition on providing prescriber information to law enforcement.

The General Assembly should permit representatives of law enforcement and state professional regulatory boards to subpoena prescriber-specific data from the PDMP, provided that prescriber is the subject of a bona fide investigation.

Recommendation 4 – Remove the cap on the surcharge paid by prescribers.

In 2007, the General Assembly granted the Board the power to assess a surcharge of no more than $7.50 per year on the license renewal of each licensed prescriber. This surcharge was intended to support the PDMP if funding from other sources, such as federal grants, were to become insufficient.

Since the surcharge was created, it has been set at the maximum of $7.50 per year.

When the General Assembly authorized the surcharge, it included statutory language requiring the surcharge to be set pursuant to section 24-34-105, C.R.S. This statutory provision directs cash-funded programs—meaning those that are funded by fees rather than by a General Fund allocation—to adjust their fees every year based on their direct and indirect costs, and projected revenues. The fee-setting process is intended to assure that fees are adequate to support a program without creating a surplus exceeding 16.5 percent of its annual expenditures.

Typically, a cash-funded program may increase fees if expenses increase, thereby assuring its survival.

With the PDMP, however, it does not work this way. If the appropriated cost of the PDMP were to rise—for example, if the federal grant money was no longer available—the Division would not be able to increase the charge enough to support the program, due to the $7.50-cap.

The surcharge is currently the sole stable funding source for the PDMP. The federal grant monies that have supported the PDMP since its inception could disappear at any time. Further, according to Board staff responsible for seeking gifts, grants, and donations to support the PDMP, there is more grant money available for states that are either implementing a new prescription drug monitoring program, or enhancing an existing one. It is considerably more difficult to secure money to simply maintain an existing program. In the absence of federal grant money, the only way to keep Colorado's PDMP running would be to increase the surcharge.

Eliminating the surcharge cap would assure the long-term viability of the PDMP.

An argument against eliminating the cap is that the PDMP might start accumulating excessive revenues. However, the core purpose of the fee-setting process established in section 24-34-105, C.R.S., is to assure that cash-funded programs collect only enough money to continue to operate while maintaining a modest cash reserve. Further, all monies in the PDMP cash fund would be still subject to appropriation by the General Assembly, which retains ultimate authority over the State budget.

The fee-setting and appropriations processes assure that there are adequate checks and balances in place to prevent unwarranted increases in spending on the PDMP. Removing the cap would assure the long-term viability of a program which many prescribers highly value.

Therefore, the General Assembly should remove the $7.50-cap on the surcharge the Board may charge prescribers for the funding of the PDMP.

Recommendation 5 – Require all fines collected for misuse of PDMP data to be deposited in the General Fund.

Section 12-22-707, C.R.S., authorizes the Board to fine any person who inappropriately accesses or releases PDMP data between $1,000 and $10,000 per violation. The section directs that such fines be deposited in the PDMP's cash fund.

Statutes governing other regulatory programs within the Division—including those regulating pharmacists and prescription drug outlets—typically require fines collected to be deposited in the General Fund. To make the PDMP's fining provision consistent with those of other programs within the Division, the General Assembly should require all fines to be deposited in the General Fund.

Recommendation 6 – Amend the statute to clarify that the PDMP tracks all prescriptions for controlled substances that are dispensed in Colorado.

Section 12-22-704(1), C.R.S., states that the purpose of the PDMP is to "track prescriptions written for controlled substances in Colorado." This wording is misleading, however, because the PDMP tracks only prescriptions that have actually been dispensed.

For the sake of clarity, this provision should be revised to clarify that the PDMP tracks prescriptions for controlled substances that have actually been dispensed.

Administrative Recommendation 1 – Require prescription drug outlets to report data to the PDMP every seven days.

Under Board Rule 23.00.30, prescription drug outlets must upload data to the PDMP twice a month. The Board should change this rule to require data uploads every seven days. This should not pose an undue burden to the reporting outlets, since they are now familiar with the reporting process and the software. Moving to a more frequent reporting schedule would provide more thorough and timely data to prescribers, thereby allowing them to make more informed clinical decisions and thereby improving patient care.

Another advantage to moving to a weekly reporting schedule is that it would make Colorado eligible for another major source of federal funding. The National All Schedules Prescription Electronic Reporting Act (NASPER) is a grant program administered by the U.S. Department of Health and Human Services. NASPER awards grants to states seeking to create a prescription drug monitoring program or enhance an existing one. In order to qualify for NASPER funding, a prescription drug monitoring program must meet certain criteria, including a weekly reporting schedule.

For these reasons, the Board should change the data submission timeline from twice a month to once a week.