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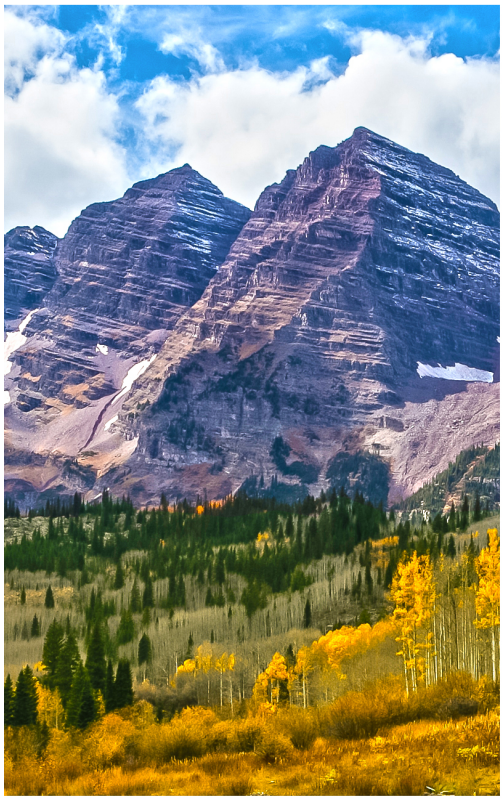
COLORADO PRESCRIPTION DRUG MONITORING PROGRAM



MARCH 2021

PERFORMANCE AUDIT

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DIANNE E. RAY, CPA
STATE AUDITOR

March 31, 2021

Members of the Legislative Audit Committee:

This report contains the results of a performance audit of the Department of Regulatory Agencies (Department), Prescription Drug Monitoring Program. The audit was conducted pursuant to Section 2-3-103, C.R.S., which authorizes the State Auditor to conduct audits of all departments, institutions, and agencies of state government, and Section 2-7-204(5), C.R.S., which requires the State Auditor to annually conduct performance audits of one or more specific programs or services in at least two departments for purposes of the SMART Government Act. The report presents our findings, conclusions, and recommendations, and the responses of the Department.

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REPORT HIGHLIGHTS

COLORADO PRESCRIPTION DRUG MONITORING PROGRAM
PERFORMANCE AUDIT, MARCH 2021

DEPARTMENT OF REGULATORY AGENCIES

KEY CONCERN

The Prescription Drug Monitoring Program (PDMP), within the Department of Regulatory Agencies (Department), is not operating as effectively as members of the General Assembly intended to help improve patient care, detect illegal activity, and prevent prescription drug abuse or misuse in Colorado, in accordance with the program's statutory purpose.

KEY FINDINGS

- Since the PDMP has been in place, recorded overdose deaths from prescription opioids rose significantly in Colorado, from 246 deaths in 2008 to 433 deaths in 2019.
- In 2018 and 2019, PDMP data showed 8,700 patients in Colorado with prescription histories that indicated doctor shopping for opioids because they each received one or more opioid prescriptions from 10 or more prescribers, which is nearly 10 times the average. For example, 20 patients got an average of 73 opioid prescriptions from at least 25 different doctors and 10 different pharmacies. Yet, the PDMP does not refer such patients to law enforcement.
- The State does not use PDMP data to identify and address overprescribing, although PDMP data showed 85 Colorado medical professionals who each prescribed more than 3,000 opioids in Calendar Years 2018 and 2019, which was 26 times the number of opioids as the average prescriber. Most of the 85 prescribers were in family medicine, internal medicine, and nurse practitioners, and their prescribing trends indicate "pill mills," or the prescribing of more opioids than patients need.
- 18 percent of Colorado's 34,679 prescribers were not registered to use the PDMP database, as statute requires, which may hamper their ability to provide quality care and ensure patients receive safe amounts of opioids. The PDMP also does not track whether prescribers query the database before issuing a second opioid prescription to a patient, as statute requires, so it is unclear whether prescribers comply.
- Most pharmacies did not submit prescription data to the PDMP within 1 business day, as rules require. Colorado pharmacies submitted about 5.5 million prescriptions (35 percent) an average of 6 business days late. When pharmacies are untimely submitting data, the PDMP database is not an accurate and complete tool that prescribers can use to monitor their patients' prescription histories.

BACKGROUND

- Each state has a PDMP to help combat the misuse, abuse, and diversion of controlled substance prescription drugs, like opioids.
- In 2008, Colorado's PDMP was created to electronically track and monitor prescriptions to help prevent their misuse, allow prescribers to review their patients' prescription histories, and help law enforcement and regulatory boards investigate potentially harmful prescribers.
- Since 2014, statute has required Colorado pharmacists to submit data on all dispensed controlled substances to the PDMP database, and has required Colorado prescribers and pharmacists to query the PDMP database to help monitor prescription drug use.
- The State Pharmacy Board regulates Colorado pharmacies, sets rules related to the PDMP, and issues best practice guidance for PDMP database users.

KEY RECOMMENDATIONS

- Improve the effectiveness of the PDMP by working with the General Assembly on statutory changes that would require prescribers to query the PDMP database before prescribing each opioid.
- Enforce the requirements that prescribers and pharmacists register to use and query the PDMP database.
- Enforce statutory limits on opioid prescriptions and develop enforcement mechanisms for noncompliant prescribers.
- Ensure pharmacies comply with rules to timely submit data on prescriptions to the PDMP database.

The Department of Regulatory Agencies agreed with the audit recommendations.

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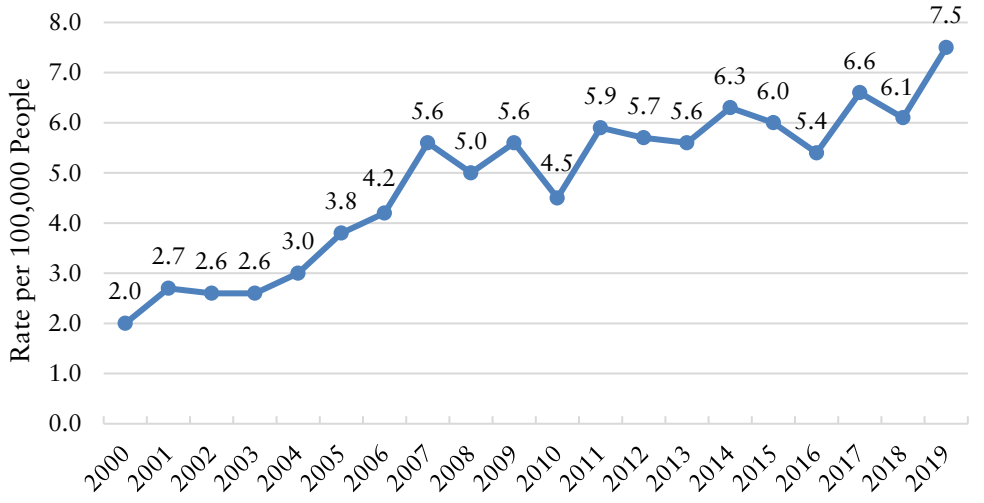
CHAPTER 1
OVERVIEW

In 2019, an estimated 16.3 million people in the United States (U.S.) misused prescription drugs at least once during the year, which equated to about 6 percent of Americans 12 years and older [Substance Abuse and Mental Health Services Administration, 2020]. Furthermore, between 2000 and 2019, opioid prescription drugs, which are primarily used to treat pain, have contributed to more than 243,000 overdose deaths nationwide, or one-half of all opioid overdose deaths during those years [Centers for Disease Control and Prevention (CDC), 2020].

Prescription opioids, such as hydrocodone and oxycodone, have important medical uses, but stimulate the reward centers in the brain, which can lead to misuse and abuse. Health professionals refer to the trend in opioid prescription-related deaths and misuse as an opioid crisis. As shown in EXHIBIT 1.1, in Colorado, deaths involving prescription opioids have steadily increased over the 19 years, from 2 deaths per 100,000 people in 2000 to 7.5 deaths in 2019 [Colorado Department of Public Health and Environment (CDPHE), 2020].

EXHIBIT 1.1. PRESCRIPTION OPIOID DRUG OVERDOSE DEATHS IN COLORADO PER 100,000 PEOPLE CALENDAR YEARS 2000 THROUGH 2019



SOURCE: Office of the State Auditor analysis of CDPHE data.

A controlled substance is a drug or chemical that is regulated because it can have a detrimental effect on a person's health and welfare. To help federal and state governments monitor the manufacturing, distribution, and possession of controlled substances, the U.S. Drug Enforcement Administration (DEA) categorizes each into one of five schedules, or categories, based on whether the drug is commonly used for medical treatment, the potential for a person to abuse the drug, and the likelihood that it will cause dependence when abused [21 USC 812(b) 1-5]. As shown in EXHIBIT 1.2, some prescription opioids are categorized as Schedule 2 drugs, meaning they have a medical use, but pose a high danger of abuse and dependence.

EXHIBIT 1.2. FEDERAL SCHEDULE OF CONTROLLED SUBSTANCES

SCHEDULE	FEDERAL DEFINITION	EXAMPLES
1	Substances with no currently accepted medical use in the U.S. and a high potential for abuse.	Illegal opioids including heroin, ecstasy (3,4-methylenedioxymethamphetamine), LSD (lysergic acid diethylamide), methaqualone, and peyote.
2	Substances with a medical use, a high potential for abuse, and that may lead to severe psychological or physical dependence.	Prescription opioids such as codeine, fentanyl (Duragesic®), hydrocodone, hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), morphine, opium, and oxycodone (OxyContin®, Percocet®). Stimulants such as amphetamine (Adderall®) and methylphenidate (Ritalin®).
3	Substances with a medical use, less potential for abuse compared to Schedule 1 or 2 substances, and that may lead to moderate or low physical dependence or high psychological dependence.	Prescription opioids containing no more than 90 milligrams of codeine per dose, such as Tylenol with Codeine®, and non-opioids such as benzphetamine (Didrex®), ketamine, and anabolic steroids.
4	Substances with a medical use and low potential for abuse compared to Schedule 3 substances.	Benzodiazepines such as alprazolam (Xanax®), diazepam (Valium®), and lorazepam (Ativan®).
5	Substances with a medical use, low potential for abuse compared to Schedule 4 substances, and that primarily contain limited quantities of certain narcotics.	Prescription opioid cough medicine containing no more than 200 milligrams of codeine per 100 milliliters or per 100 grams, such as Robitussin AC® and Phenergan with Codeine®.

SOURCE: DEA, federal regulations 21 USC 812(b)1-5.

In Colorado, a medical professional may issue their patients prescriptions for Schedule 2 through 5 controlled substances if the prescriber is licensed to practice medicine in the State and holds a DEA registration, or license. According to Prescription Drug Monitoring Program (PDMP) data, as of December 2019, there were about 34,680 individuals licensed to practice medicine in Colorado who held a DEA license to prescribe controlled substances.

Every state has some type of PDMP that helps combat the misuse, abuse, and diversion of prescription drugs for illicit use. PDMPs track and monitor controlled substance prescription data. Medical professionals who prescribe (prescribers) and pharmacists are often required to access the PDMP data in their state to review patients'

prescription histories and help limit instances in which a patient receives potentially dangerous amounts or combinations of prescription drugs.

COLORADO'S PDMP

In 2008, Colorado's PDMP was implemented to provide electronic monitoring of controlled substance prescriptions to help address prescription drug misuse that can occur when a patient receives prescriptions from multiple prescribers. For example, PDMP monitoring can help make prescribers aware when a patient is receiving similar prescriptions from other prescribers during a similar period of time, which is commonly known as "doctor shopping" [Legislative declaration for Section 12-280-401(1), C.R.S.]. Colorado's PDMP was also implemented to help law enforcement and regulatory boards "efficiently investigate practitioner behavior that is potentially harmful to the public."

Colorado's PDMP database tracks and monitors statewide data on the prescriptions dispensed by Colorado pharmacies. For each prescription, the PDMP database tracks the controlled substance type, dosage, days' supply, and date dispensed; patient name and address; prescriber and pharmacist name and address; and sometimes the prescriber's specialty. The PDMP database does not contain information on patients' health needs or medical conditions, such as medical diagnostic codes.

Since 2014, statute has required Colorado prescribers and pharmacists to use the PDMP database to inform them of patients' prescription histories, as follows:

- **PRESCRIBERS.** All Colorado prescribers who have a federal DEA license to prescribe controlled substances must register as users of the PDMP database [Section 12-280-403(2)(a), C.R.S.] and must query the database to review the prescription histories for most patients before prescribing them a second opioid [Section 12-280-404(4)(a), C.R.S.]. This query requirement is waived under certain circumstances, such as if the patient is in a hospital, nursing, or

correctional facility; is a cancer patient; or is undergoing palliative or hospice care. Prescribers who specialize in certain fields such as surgery, hospice and palliative care, and oncology can serve these types of patients, and therefore, can be exempt from the PDMP database query requirement. In addition, veterinarians can query the PDMP database if they are concerned that their patient's owner is diverting the controlled substances they have prescribed for the animal. However, veterinarians are not required to use the PDMP database. According to PDMP data, as of December 2019, about 28,460 prescribers were registered to use Colorado's PDMP database.

- **PHARMACISTS.** All Colorado pharmacists must register as users of the PDMP database to review the data as they determine is necessary [Section 12-280-403(2)(a), C.R.S.], and all pharmacies are required to submit prescription records to the PDMP database for all controlled substance prescriptions that they dispense [3 CCR 719-1 23.00.30]. According to PDMP data, as of December 2019, there were 6,110 Colorado pharmacists registered to use Colorado's PDMP database.

In addition to containing prescription history, the PDMP database provides prescribers and pharmacists monthly patient alerts to inform them when a patient for whom they have written or dispensed prescriptions has exceeded a threshold of multiple prescriptions from multiple prescribers and pharmacies in a given time period [Section 12-280-404(8), C.R.S.]. Patients who exceed the threshold may be at a greater risk of doctor shopping. In the fourth quarter of Calendar Year 2019, the PDMP sent prescribers and pharmacists patient alerts for about 345 patients. The PDMP database also generates quarterly report cards for prescribers, which summarize their opioid prescribing activity compared to their peers in the same role (e.g., physician, dentist, optometrist) and specialty (e.g., internal medicine or geriatric care). The report cards notify prescribers when their prescribing is outside of the norm in their fields to help inform their decision-making [Section 12-

280-404(9), C.R.S.]. In the fourth quarter of 2019, the PDMP sent 15,482 report cards to prescribers.

ADMINISTRATION AND OVERSIGHT

Colorado's PDMP is administered, or overseen, by the following:

THE DEPARTMENT OF REGULATORY AGENCIES (DEPARTMENT) administers Colorado's PDMP and contracts with a vendor, Appriss, to manage the PDMP database and certain aspects of the program. Appriss is a data analytics and software company that developed and maintains the PDMP databases in 37 other states. Colorado's contract with Appriss requires it to collect controlled substance prescription data from pharmacies, clean and validate the data, and make it available to prescribers and pharmacists registered to use the database. The Department also licenses and regulates all medical professionals, and manages the PDMP database registration process by checking that registered prescribers have active Colorado medical licenses in good standing and DEA licenses to prescribe controlled substances. As of February 2021, the Department had 2.25 full-time equivalent employees (FTE) within its Division of Professions and Occupations, including a part-time PDMP Director, a PDMP Administrator, and a grant-funded and temporary PDMP Analyst, who are assigned to carry out these PDMP responsibilities and monitor the Appriss contract.

THE PHARMACY BOARD, within the Department, protects consumers by regulating and licensing pharmacies, pharmacists, and certain pharmacy staff in Colorado, as well as other entities such as drug manufacturers and wholesalers. The Pharmacy Board also promulgates rules related to the PDMP and best practice guidance for PDMP database users [Sections 12-280-403 and 404, C.R.S.]. For example, the Pharmacy Board sets thresholds for prescribers to consider when determining patient drug needs and works with the Department and other healthcare profession regulatory boards to establish policy on maximum opioid dosages, known as morphine milligram equivalent, or "MME" dosages.

THE COLORADO CONSORTIUM FOR PRESCRIPTION DRUG ABUSE PREVENTION (CONSORTIUM) was created in 2013 to meet the statutory requirement for a taskforce to help reduce prescription drug abuse [Section 12-280-409(1), C.R.S.]. The Consortium is a statewide interagency network that studies and implements ways to reduce prescription drug abuse in Colorado, and includes a PDMP Taskforce. As of August 2020, the PDMP Taskforce had 116 members, including the PDMP Director, doctors, nurses, epidemiologists, and various other community members and stakeholders. The PDMP Taskforce submits an annual report to the Department and the General Assembly on recommendations to improve Colorado's PDMP [Section 12-280-409(2), C.R.S.].

OTHER PRESCRIPTION DRUG AUTHORITIES

SIX COLORADO HEALTHCARE PROFESSION REGULATORY BOARDS regulate various types of prescribers of controlled substances: the Colorado Medical Board, Dental Board, Podiatry Board, Board of Nursing, Board of Optometry, and Board of Veterinary Medicine. In addition to regulating their respective practice areas, these boards have adopted statewide guidelines for healthcare professionals on prescribing opioids.

CDPHE monitors prescription drug use trends in Colorado using PDMP data. In 2016, CDPHE also shared with the Department a portion of federal grant funds from the CDC to pilot integrating the PDMP database with a sample of prescribers' electronic health records to allow those prescribers to easily access the database.

THE PRESCRIPTION DRUG MONITORING PROGRAM TRAINING AND TECHNICAL ASSISTANCE CENTER (PDMP ASSIST), within the nonprofit Institute for Intergovernmental Research, measures the performance of PDMPs nationwide and seeks to increase their effectiveness to combat the misuse, abuse, and diversion of prescription drugs. PDMP Assist also provides training and best practice identification to states, federal agencies, and other stakeholders such as public health professionals.

FEDERAL AGENCIES. The CDC issues guidance to health care providers on controlled substance prescriptions, which many state PDMPs use to monitor prescription drug use and prescribing habits of prescribers. The CDC evaluates the effectiveness of state PDMPs and outlines best practices for them. The National Institutes of Health (NIH), within the U.S. Department of Health and Human Services, conducts research, including on opioid abuse, to enhance Americans' health. The Substance Abuse and Mental Health Services Administration has a mission to reduce the impact of substance abuse and mental illness on communities, and is also within the U.S. Department of Health and Human Services.

FUNDING

In Fiscal Years 2017 through 2019, the Department received about $621,000 annually for Colorado's PDMP, from federal grants and cash funds. The federal grants averaged $337,000 annually in these years, and were from the U.S. Department of Justice and the CDC. The PDMP cash funds, averaging $284,000 annually in these years, were from a portion of prescriber licensure fee revenue and were used for PDMP operations.

AUDIT PURPOSE, SCOPE, AND METHODOLOGY

We conducted this performance audit pursuant to Section 2-3-103, C.R.S., which authorizes the State Auditor to conduct audits of all departments, institutions, and agencies of the state government, and Section 2-7-204(5), C.R.S., the State Measurement for Accountable, Responsive, and Transparent (SMART) Government Act. Audit work was performed from January 2020 through February 2021. We appreciate the cooperation and assistance provided by Department management and staff during this audit.

We conducted this audit in accordance with generally accepted government auditing standards. Those standards require that we plan

and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The objectives of this audit were to evaluate the extent to which (1) Colorado prescribers and pharmacists register and utilize the PDMP as statutorily required, (2) the Department ensures the PDMP operates in accordance with statutory and contractual requirements, and (3) the State could better leverage its PDMP to mitigate opioid misuse and abuse.

To accomplish our audit objectives, we performed the following audit work:

- Reviewed Colorado statutes and regulations relevant to the electronic monitoring of prescription drugs.
- Reviewed national data on prescription drugs, the opioid crisis, and overdose trends from the CDC and the NIH for Calendar Years 2000 through 2019, and from the Substance Abuse and Mental Health Services Administration for Calendar Year 2019, the most recent data available.
- Reviewed prescribing guidelines from the CDC; reports on national best practices related to PDMPs and opioid prescribing, such as from the CDC and PDMP Assist; and annual reports from the Consortium and the PDMP Taskforce for 2019 and 2020.
- Interviewed staff from the Department, the Consortium, CDPHE, as well as representatives from the Colorado regulatory boards responsible for oversight of opioid prescribers and/or dispensers including the Medical Board, Dental Board, Podiatry Board, Board of Nursing, Board of Optometry, Board of Veterinary Medicine, and Pharmacy Board, and reviewed these boards' policies.

- Reviewed the Department's contract with the PDMP vendor Appriss, the Department's contract management procedures, and State Fiscal Rules on contract management.

- Reviewed the Department's SMART Government Act performance plan for Fiscal Year 2020.

- Analyzed PDMP financial data from the Colorado Operations Resource Engine, the State's accounting system.

- Analyzed Department data on prescribers with DEA licenses to prescribe controlled substances in the state of Colorado.

- Analyzed 15.6 million prescription records that pharmacies submitted to Appriss for its review prior to uploading them into the PDMP database in Calendar Years 2018 and 2019.

- Analyzed patient de-identified data from the PDMP database for Calendar Years 2018 and 2019, which included about 15.4 million controlled substance prescriptions dispensed in Colorado, prescribers and pharmacists registered to use the database, patient alerts, and prescriber queries of the database. During the audit, we identified some limitations with these data due to the structure of the PDMP data and the Department's lack of direct access to it. Specifically, the PDMP data that the Department obtained from its vendor Appriss, included about 790,000 prescription records (about 5 percent of the 15.4 million) that were not matched to a patient because the data did not show a patient identifier code, so our analysis excluded these unmatched records. However, we do not believe that the exclusion of these records limited our ability to address the audit objectives or draw conclusions.

As required by auditing standards, we planned our audit work to assess the effectiveness of those internal controls that were significant to our audit objectives. Specifically, our work reviewed the internal control components and underlying principles shown in EXHIBIT 1.3, based on guidance issued by the U.S. Government Accountability Office.

EXHIBIT 1.3. SIGNIFICANT INTERNAL CONTROL COMPONENTS AND UNDERLYING PRINCIPLES REVIEWED DURING THE AUDIT

Control Environment ▪ Exercise Oversight Responsibility ▪ Establish Structure, Responsibility, and Authority ▪ Enforce Accountability	**Control Activities** ▪ Design Control Activities ▪ Design Activities for the Information System ▪ Implement Control Activities
Risk Assessment ▪ Assess Fraud Risk ▪ Identify, Analyze, and Respond to Change	**Information and Communication** ▪ Use Quality Information ▪ Communicate Internally ▪ Communicate Externally
	Monitoring ▪ Perform Monitoring Activities ▪ Evaluate Issues and Remediate Deficiencies

SOURCE: Office of the State Auditor analysis of internal controls, as specified in the U.S. Government Accountability Office, Standards for Internal Control in the Federal Government (Green Book).

Our conclusions on the effectiveness of those controls that were significant to our audit objectives, as well as specific details about the audit work supporting our findings, conclusions, and recommendations, are described in the remainder of this report.

A draft of this report was reviewed by the Department, and we have incorporated its comments into the report where relevant. The written responses to the recommendations and the related implementation dates are the sole responsibility of the Department.

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CHAPTER 2

PDMP OPERATIONS AND EFFECTIVENESS

Colorado's Prescription Drug Monitoring Program (PDMP) was implemented to help prevent prescription drug misuse and abuse, and is administered by the Department of Regulatory Agencies (Department). The State Board of Pharmacy (Pharmacy Board) within the Department, promulgates rules related to the PDMP [Section 12-280-404, C.R.S.]. Colorado's PDMP uses an electronic controlled substance prescription database, known as the PDMP database, to track statewide data on the controlled substance prescriptions dispensed by pharmacies; these data are available to medical practitioners who prescribe in Colorado, as well as pharmacists working in Colorado, to help inform prescribing habits and identify potential misuse and abuse of prescription drugs. The Department contracts with the vendor, Appriss, to develop and administer the PDMP database, and collect and maintain the State's prescription data.

Currently, Colorado's PDMP helps keep prescribers informed of their own prescribing habits and their patients' prescription histories, can be used to inform pharmacists of potential misuse of prescription drugs, and can be subpoenaed by regulatory boards and law enforcement when they are conducting an active investigation of a prescriber or a patient. However, our audit found that the PDMP is not operating as effectively as it could in accordance with statutory intent, to help the State prevent prescription drug abuse, misuse, and diversion [Section 12-280-401, C.R.S.].

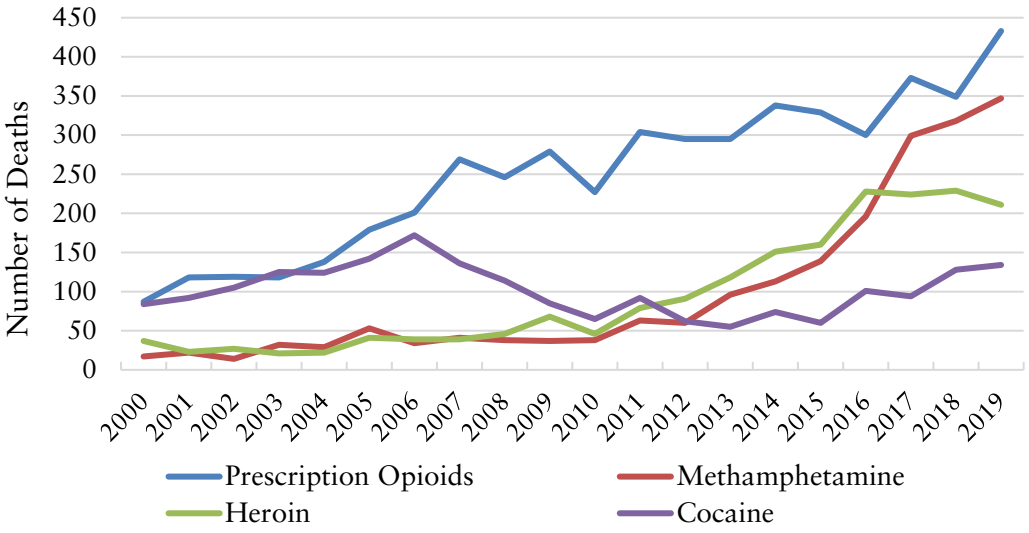
The remainder of this chapter includes findings and recommendations to improve PDMP operations, the usefulness of the PDMP database, and Department and Pharmacy Board oversight.

IMPROVING THE EFFECTIVENESS OF COLORADO'S PDMP

According to the Centers for Disease Control and Prevention (CDC), high rates of opioid prescribing have contributed to the current United States (U.S.) opioid epidemic and an increase in overdose deaths across the country [CDC, 2020]. Opioid overdose deaths in the U.S. rose dramatically in the past 2 decades, from about 8,400 overdose deaths in 2000 to more than 50,000 overdose deaths in 2019. About 30 percent of those deaths in 2019 (about 15,000) involved prescription opioids [National Institute on Drug Abuse, National Institutes of Health (NIH), 2020].

Colorado has also experienced the effects of the prescription opioid epidemic. Between Calendar Years 2000 and 2019, Colorado deaths due to prescription opioids rose 398 percent, and they remain the most frequent subcategory of drug overdose deaths in the state. EXHIBIT 2.1 displays drug overdose deaths in Colorado due to prescription opioids compared to deaths from other common drug overdoses.

EXHIBIT 2.1. COMMON DRUG OVERDOSE DEATHS IN COLORADO, BY TYPE CALENDAR YEARS 2000 THROUGH 2019



SOURCE: Office of the State Auditor analysis of Colorado Department of Public Health and Environment (CDPHE) data.

The CDC, Drug Enforcement Administration (DEA), and Prescription Drug Monitoring Program Training and Technical Assistance Center (PDMP Assist) have identified prescription drug monitoring programs as one of the most effective state-level tools to address opioid abuse, misuse, and overdose. These organizations identify PDMPs as effective tools, in part, because of their ability to limit "doctor shopping," when a patient receives opioids from multiple prescribers who are unaware that the patient is receiving opioids from others.

HOW WERE THE RESULTS OF THE AUDIT WORK MEASURED?

In 2005, House Bill 05-1130 established Colorado's PDMP to help promote the health, safety, and welfare of Coloradans, and the PDMP was implemented in 2008. According to statute, the intent of the PDMP is to provide electronic monitoring of controlled substance prescriptions for the following purposes:

- **ALLOW PRESCRIBERS TO VIEW A PATIENT'S PRESCRIPTION HISTORY.** The intent was to help practitioners "discover the extent of each patient's requests for drugs and whether other providers have prescribed similar substances during a similar period of time" and prevent "the deception of authorized practitioners where patients seek controlled substances for treatment and the practitioner is unaware of the patient's other medical providers and treatments" (i.e., doctor shopping) [Section 12-280-401, C.R.S.].

- **HELP PREVENT PRESCRIPTION DRUG MISUSE.** The intent was to allow education and intervention to help prevent and reduce occurrences of controlled substance misuse and abuse [Section 12-280-404(8), C.R.S.]. In line with this legislative intent, the CDC recommends that states use their PDMPs to help prescribers avoid prescribing dangerous combinations of opioids and other types of prescription drugs. However, the CDC's only specific guidance and warnings about prescribing combinations of opioids and other drugs, relate to benzodiazepines. Benzodiazepines, also called benzos, are a type of sedative used to treat anxiety, seizures, and other conditions, and include the brand drugs Valium and Xanax. In 2015, the CDC stated that, "PDMPs are promising tools, allowing health care providers to see patients' prescription histories to inform their prescribing decisions. However, a PDMP is useful…only if they check the system before prescribing and checking the PDMP prior to prescribing opioid pain relievers and benzodiazepines is particularly important" [CDC, 2015]. In 2016, the CDC again stated that prescribers should "…avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible" because the CDC has found that concurrent opioid and benzodiazepine prescriptions can be lethal to patients [CDC, 2016].

- **ALLOW REGULATORY BOARDS AND LAW ENFORCEMENT TO EFFICIENTLY INVESTIGATE PRESCRIBERS THAT POTENTIALLY HARM THE PUBLIC [SECTION 12-280-401, C.R.S.].** In order to investigate potentially harmful prescriber behavior, regulatory boards and law enforcement would need to receive PDMP information on prescribers who may be harming the public. For example, the CDC

> suggests that PDMPs provide "unsolicited reports on high-risk providers and patients to…regulatory boards, as well as law enforcement under certain circumstances."

To help accomplish legislative intent, in 2014, House Bill 14-1283 implemented some nationally-recognized best practices at the time, such as requiring Colorado prescribers and pharmacists to register as users of the PDMP database and allowing prescribers to delegate access to the PDMP database to their staff to query the database on their behalf. Also in 2014, the Pharmacy Board implemented a rule requiring pharmacies to submit data on the controlled substances they dispensed to the database on a daily basis.

WHAT AUDIT WORK WAS PERFORMED AND WHAT PROBLEMS WERE IDENTIFIED?

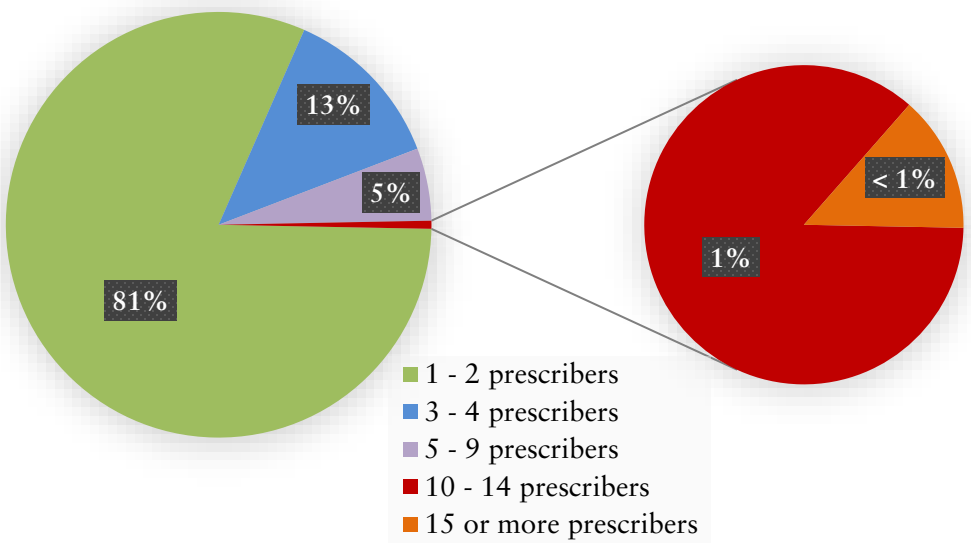
We reviewed the State's design of the PDMP and how it works in practice to assess its effectiveness at achieving the legislative intent of preventing the misuse of prescription drugs, specifically opioids. We compared Colorado's PDMP to other PDMPs nationwide and to best practices identified by the CDC and PDMP Assist and employed by other states to monitor prescription opioids and controlled substance use. We also reviewed the 15.4 million dispensed controlled substance prescription records from the PDMP database from Calendar Years 2018 and 2019, 7 million of which were for opioids.

Overall, we found Colorado's PDMP is not effective, as currently designed, to fully achieve legislative intent or CDC recommendations, or to help ensure compliance with statutory requirements. Specifically, the PDMP does not sufficiently help address or prevent the following:

- **DOCTOR SHOPPING.** In our analysis of PDMP database prescription data, we identified patients with prescription histories that may indicate doctor shopping based on the number of opioid prescriptions they received from different prescribers and different pharmacies. Of the 1.4 million Colorado patients with opioid

prescriptions in Calendar Years 2018 and 2019, there were almost 8,700 patients who received opioid prescriptions from 10 or more prescribers during this time period, and about 1,200 patients who received opioid prescriptions from 15 or more prescribers. Conversely, as EXHIBIT 2.2 shows, the vast majority of Colorado patients (81 percent) who received opioid prescriptions during the same 2 years obtained them from only one or two prescribers.

EXHIBIT 2.2. NUMBER OF OPIOID PRESCRIBERS PER PATIENT CALENDAR YEARS 2018 AND 2019



SOURCE: Office of the State Auditor analysis of data from the PDMP database.

To illustrate examples of Colorado patients who appear to doctor shop by visiting many prescribers to obtain large numbers of opioid prescriptions, EXHIBIT 2.3 summarizes information for 20 patients who obtained opioid prescriptions from many different prescribers, along with the number of prescriptions they received and number of pharmacies that dispensed the prescriptions to them. These 20 patients obtained the most opioid prescriptions that were from at least 25 different doctors and at least 10 different pharmacies, which indicates patients who appear to be doctor shopping. If these prescribers were spread evenly throughout the 2-year period, then, on average, each of the 20 patients obtained opioids from a different prescriber every 3 weeks.

EXHIBIT 2.3. COLORADO PATIENTS WITH MOST OPIOID PRESCRIBERS AND MANY PRESCRIPTIONS AND PHARMACIES CALENDAR YEARS 2018 AND 2019

PATIENT	NUMBER OF PRESCRIBERS	NUMBER OF PHARMACIES	NUMBER OF OPIOID PRESCRIPTIONS
1	55	21	154
2	41	12	80
3	39	15	50
4	38	11	90
5	38	20	64
6	36	10	58
7	36	11	54
8	34	10	72
9	33	17	76
10	33	11	57
11	30	12	65
12	29	17	82
13	28	13	89
14	28	14	50
15	27	12	81
16	27	27	50
17	26	16	104
18	26	17	61
19	26	13	58
20	25	14	65
TOTAL	**655**	**293**	**1,460**
AVERAGE	**33**	**15**	**73**

SOURCE: Office of the State Auditor analysis of data from the PDMP database.

In 2018 and 2019, the 20 patients shown in EXHIBIT 2.3 visited a total of 607 unique prescribers, predominately from the Denver metro area. These 607 prescribers had a range of specialties, but the PDMP data showed that most were emergency medical doctors (19 percent), dentists (18 percent), or family medicine providers (12 percent), and the remaining prescribers had different specialties or had no specialty listed in the PDMP.

- **OPIOID MISUSE BY PATIENTS.** We identified Colorado patients who may not be doctor shopping, but appear to misuse or abuse opioid prescriptions based on the high number of prescriptions they have received. EXHIBIT 2.4 summarizes information for 20 patients who received the highest numbers of opioid prescriptions and obtained opioids from at least eight prescribers and five pharmacies in

Calendar Years 2018 and 2019, according to the PDMP database, which would indicate that they are misusing opioids. These 20 patients have prescription histories that, if spread evenly over the 2-year period, indicate that they received an opioid prescription on average every 5 days. The PDMP database does not include sufficient information to determine whether some of these patients have diagnoses that would indicate they may need more opioids than the typical patient; some of these 20 patients could have been exempt from the statutory limits on opioids because they were receiving palliative care or treatment for cancer.

EXHIBIT 2.4. COLORADO PATIENTS WITH THE HIGHEST NUMBER OF OPIOID PRESCRIPTIONS, AND MULTIPLE PRESCIBERS AND PHARMACIES CALENDAR YEARS 2018 AND 2019

PATIENT	NUMBER OF OPIOID PRESCRIPTIONS	TOTAL DAYS' SUPPLY OF OPIOIDS[1]	NUMBER OF PRESCRIBERS	NUMBER OF PHARMACIES
1	274	1,602	12	7
2	196	1,579	12	9
3	180	1,453	10	5
4	156	1,932	9	7
5[2]	154	1,372	55	21
6	149	1,494	17	26
7	141	1,271	12	8
8	136	1,679	9	8
9	136	1,962	9	6
10	131	1,011	8	5
11	123	1,697	16	5
12	122	673	24	13
13	121	2,771	13	7
14	118	862	12	6
15	115	2,297	9	5
16	112	1,658	24	7
17	107	1,840	21	7
18	106	552	13	6
19	106	1,851	13	5
20	106	727	9	7
TOTAL	**2,789**	**30,283**	**307**	**170**
AVERAGE	**139**	**1,514**	**15**	**9**

SOURCE: Office of the State Auditor analysis of data from the PDMP database.
[1] According to the Department, some of the high supply days shown in the PDMP data could be due to data entry errors by pharmacists.
[2] Patient 5 is the same as Patient 1 in Exhibit 2.3. Otherwise, there are no overlapping patients between the two exhibits.

- **SOME PATIENTS RECEIVE DANGEROUS COMBINATIONS OF OPIOIDS AND BENZODIAZEPINES.** PDMP data for Calendar Years 2018 and 2019 showed that 12,839 prescribers had prescribed a benzodiazepine when the patient already had an opioid prescription from a different prescriber, and 17,420 prescribers had prescribed an opioid when the patient already had a benzodiazepine prescription from a different prescriber.

  EXHIBIT 2.5 lists the 20 Colorado prescribers who prescribed the most opioid and benzodiazepine prescriptions concurrently when they were also being prescribed by other prescribers. In other words, EXHIBIT 2.5 counts each time a prescriber "created" a concurrency

by prescribing an opioid to a patient who already had a benzodiazepine prescription from another prescriber, or vice versa. This exhibit excludes prescribers specializing in the exempt fields of pain management, hospice and palliative care, oncology, and surgery, and concurrencies in which the opioid and benzodiazepine were prescribed by the same prescriber.

EXHIBIT 2.5. NON-EXEMPT PRESCRIBERS WHO CREATED AN OPIOID-BENZODIAZEPINE CONCURRENCY WITH OTHER PRESCRIBERS CALENDAR YEARS 2018 AND 2019

PRESCRIBER	PRESCRIBER'S SPECIALTY LISTED IN PDMP DATA	CONCURRENT OPIOID OR BENZODIAZEPINE PRESCRIPTIONS	NUMBER OF PATIENTS
1	Nurse Practitioner	1,709	242
2	Not registered [1]	1,228	134
3	Internal Medicine	873	180
4	Nurse Practitioner	804	114
5	Not listed [2]	755	170
6	Not listed [2]	732	128
7	Physical Medicine and Rehabilitation	674	109
8	Nurse Practitioner	637	82
9	Preventive Medicine	603	99
10	Internal Medicine	518	97
11	Not registered [1]	510	273
12	Family Medicine	499	315
13	Family Medicine	498	119
14	Not listed [2]	492	124
15	Family Medicine	456	83
16	Nurse Practitioner	444	98
17	Nurse Practitioner	442	96
18	Physical Medicine and Rehabilitation	421	97
19	Family Medicine	415	269
20	Family Medicine	408	150
TOTAL	**-**	**13,118**	**2,979**
AVERAGE	**-**	**656**	**149**

SOURCE: Office of the State Auditor analysis of data from the PDMP database.
[1] This prescriber is not registered with the PDMP, a violation of Section 12-280-403(2)(a), C.R.S.
[2] This prescriber is registered with the PDMP, but does not have a specialty entered, a violation of Section 12-280-404(3)(b), C.R.S.

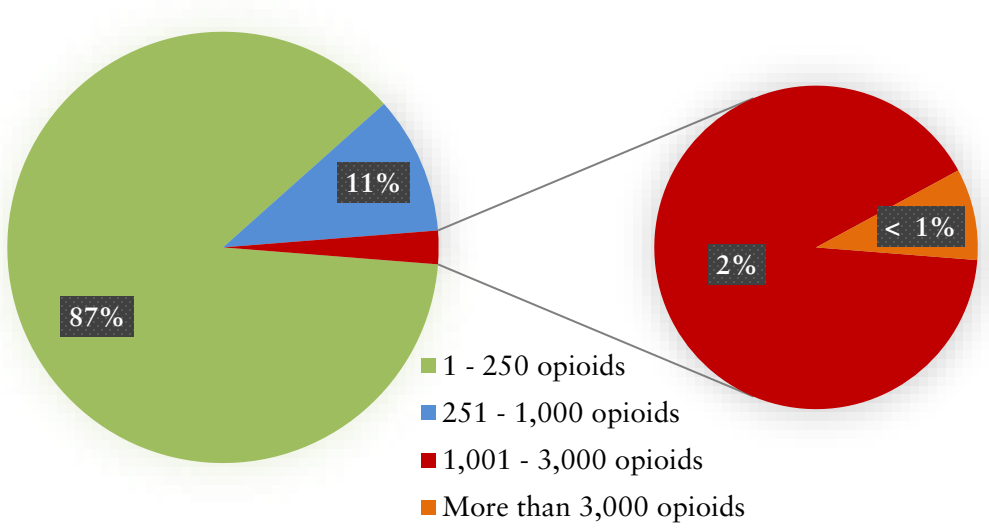
Furthermore, we identified 516 instances in Calendar Years 2018 and 2019 in which a single prescriber prescribed more than 20 opioid prescriptions to a single patient who already had a benzodiazepine prescription, creating a concurrency. For example,

in one instance, a single prescriber prescribed 97 opioid prescriptions to a patient who already had a benzodiazepine prescription.

- **SOME PRESCRIBERS ISSUE SIGNIFICANTLY MORE OPIOID PRESCRIPTIONS THAN AVERAGE.** PDMP data shows some prescribers with prescribing trends that may be harmful to patients. For example, of the approximately 37,000 non-exempt prescribers who prescribed an opioid in Colorado in Calendar Years 2018 or 2019, we identified 85 who prescribed at least 26 times the number of opioids as the average for all other prescribers. Non-exempt prescribers are those who should comply with statute to review the PDMP database before prescribing a second opioid prescription and limit the amount of opioids they prescribe to their patients because they do not have a specialty of hospice, pain management, oncology, or surgery.

  These 85 prescribers had a range of specialties, but most were family medicine (38 percent), internal medicine (19 percent), and nurse practitioners (13 percent); the remaining prescribers had different specialties or had no specialty listed in the PDMP data. These 85 prescribers each prescribed more than 3,000 opioids, compared to all other prescribers, who prescribed an average of 115 opioids each. This distribution is shown in EXHIBIT 2.6. According to the Department, some of these prescribers may have prescribed appropriately based on their patients' diagnoses.

EXHIBIT 2.6. NUMBER OF OPIOIDS PRESCRIBED PER COLORADO PRESCRIBER CALENDAR YEARS 2018 AND 2019



SOURCE: Office of the State Auditor analysis of data from the PDMP database.

EXHIBIT 2.7 provides more details on the 20 non-exempt prescribers who prescribed the most opioids in Calendar Years 2018 and 2019, along with the number of patients who received these prescriptions.

EXHIBIT 2.7. NON-EXEMPT PRESCRIBERS WHO PRESCRIBED THE MOST OPIOIDS CALENDAR YEARS 2018 AND 2019

PRESCRIBER	PRESCRIBER'S SPECIALTY LISTED IN PDMP DATA	NUMBER OF OPIOID PRESCRIPTIONS	NUMBER OF PATIENTS	AVERAGE NUMBER OF PRESCRIPTIONS PER PATIENT
1	Nurse Practitioner	12,575	1044	12.0
2	Not Registered[1]	7,861	496	15.8
3	Nurse Practitioner	7,508	886	8.5
4	Not listed[2]	7,205	565	12.8
5	Physical Medicine and Rehabilitation	6,683	596	11.2
6	Family Medicine	6,513	355	18.3
7	Preventative Medicine	6,122	503	12.2
8	Nurse Practitioner	5,924	720	8.2
9	Nurse Practitioner	5,913	752	7.9
10	Addiction Specialist	5,836	1,228	4.8
11	Physical Medicine and Rehabilitation	5,803	599	9.7
12	Internal Medicine	5,776	282	20.5
13	Internal Medicine	5,504	613	9.0
14	Family Medicine	5,503	582	9.5
15	Family Medicine	5,382	730	7.4
16	Family Medicine	5,129	461	11.1
17	Not listed[2]	4,942	659	7.5
18	Not listed[2]	4,915	516	9.5
19	Internal Medicine	4,895	906	5.4
20	Physical Medicine and Rehabilitation	4,871	477	10.2
TOTAL	-	**124,860**	**12,970**	-
AVERAGE	-	**6,243**	**649**	**11**

SOURCE: Office of the State Auditor analysis of data from the PDMP database.
[1] This prescriber is not registered with the PDMP, a violation of Section 12-280-403(2)(a), C.R.S.
[2] This prescriber is registered with the PDMP but does not have a specialty entered, a violation of Section 12-280-404(3)(b), C.R.S.

- **REGULATORY BOARDS AND LAW ENFORCEMENT INVESTIGATIONS.** Without a court order or subpoena, the Department does not provide regulatory boards or law enforcement any information from the PDMP database that would allow them to investigate potentially unlawful behavior by prescribers or patients. Providing such information to regulatory boards and law enforcement would help them meet the statutory intent of identifying healthcare providers whose prescribing habits fall significantly outside of the norms for their specialty or patients who appear to be doctor shopping.

WHY DID THESE PROBLEMS OCCUR?

The PDMP was meant to improve patient care and detect illegal activity, but in practice, Colorado has not designed its PDMP as an effective tool to address doctor shopping, opioid misuse, dangerous combinations of opioid and benzodiazepine prescriptions, or overprescribing of opioids, nor does it aid regulatory boards and law enforcement in addressing these problems for the following reasons:

- **Insufficient database query requirements.** Colorado does not require prescribers to query the PDMP in the most effective way to prevent doctor shopping and concurrent opioid and benzodiazepine prescriptions. To help inform practitioners' prescribing habits, statute requires prescribers to query the PDMP database only before issuing a ***second*** opioid prescription, but does not require query for the first opioid or any subsequent opioid prescriptions after the second. The CDC evaluates PDMPs nationwide and ranked Colorado's PDMP database as "ineffective" in the category of use because Colorado does not require prescribers to query the PDMP database before every opioid prescription. Additionally, Colorado does not require prescribers to query the PDMP database before prescribing a benzodiazepine. For the PDMP to be rated effective by the CDC, Colorado would have to require prescribers to query the database at least before the first opioid prescription and the first benzodiazepine prescription because these are best practices that other states have adopted to promote consistent use of PDMP databases by prescribers and to realize the benefits associated with such use. According to a 2020 PDMP Assist report, other states that require prescribers to check their PDMP database for every prescription have resulted in increased queries of databases and better outcomes, such as decreases in morbidity and mortality related to prescription drug misuse.

- **No requirements for the Department to monitor PDMP data for potentially unlawful behavior and report to regulatory boards or law enforcement.** Due to a lack of clear statutory authority, the Department does not use PDMP data to

identify and refer a patient's possible inappropriate opioid or other prescription drug use to law enforcement for investigation. Additionally, the Department does not use PDMP data to identify prescribers who fall outside statutory limits or norms for prescribing opioids for their type of practice and refer the prescribers to the appropriate regulatory board or law enforcement for investigation.

Currently, the PDMP database is used only as a healthcare tool in Colorado. The Department sends unsolicited reports to prescribers and pharmacists alerting them if their patients meet criteria for inappropriate drug use, such as multiple prescribers and pharmacies in a short time period. The Department also uses the PDMP database to generate report cards for prescribers, which alert them when their prescribing habits fall outside the norm compared to their peers and for their fields, to help reduce overprescribing. There is not a process or criteria to use the PDMP data for any other monitoring purpose.

Statute also limits regulatory board and law enforcement access to the PDMP database, making it only available to PDMP staff and law enforcement and regulatory boards when they obtain a court order or subpoena during an investigation [Section 12-280-404(3), C.R.S.]. While the use of Colorado's PDMP database as a healthcare tool is important, the CDC and PDMP Assist advocate that states actively manage PDMP data to mitigate the opioid crisis by using it to identify inappropriate drug use and prescribing habits and address the issues without waiting for an overdose or another harmful outcome.

Many other states have implemented best practices that would help address the problems we identified, which Colorado has not implemented, including requiring prescribers to query the PDMP database before prescribing any opioid and before prescribing a benzodiazepine, and allowing the PDMP to make unsolicited reports on prescriber and patient behavior to regulatory boards and law enforcement. EXHIBIT 2.8 summarizes five different PDMP best

practices that have been implemented by other states, but not in Colorado, as of December 2020.

EXHIBIT 2.8. STATES' PDMP BEST PRACTICES AS OF DECEMBER 2020

STATE	REQUIRE DATABASE QUERY BEFORE *EACH* OPIOID PRESCRIPTION	REQUIRE DATABASE QUERY BEFORE *FIRST* OPIOID PRESCRIPTION	ALLOW UNSOLICITED REPORTS TO REGULATORS	ALLOW UNSOLICITED REPORTS TO LAW ENFORCEMENT	REQUIRE DATABASE QUERY BEFORE BENZO PRESCRIPTION
Alabama	•	•			
Alaska	•	•	•		
Arizona	•	•	•	•	•
Arkansas	•	•	•		•
California		•			•
Colorado					
Connecticut		•			•
Delaware	•	•	•	•	•
Florida	•	•	•	•	
Georgia		•	•	•	•
Hawaii	•	•			
Idaho			•	•	
Illinois		•	•		
Indiana		•	•	•	•
Iowa	•	•			
Kansas			•	•	
Kentucky		•			
Louisiana		•	•		
Maine		•	•		•
Maryland		•			•
Massachusetts	•	•	•	•	•
Michigan	•	•	•		•
Minnesota					•
Mississippi		•	•	•	
Missouri [1]			•	•	
Montana			•		
Nebraska					
Nevada		•	•	•	
New Hampshire		•	•		
New Jersey		•	•	•	•
New Mexico		•	•		•
New York	•	•	•	•	
North Carolina		•	•		
North Dakota		•	•	•	
Ohio		•	•	•	•
Oklahoma		•	•		•
Oregon					
Pennsylvania	•	•	•		•
Rhode Island		•			
South Carolina	•	•	•	•	
South Dakota			•	•	
Tennessee		•	•		•
Texas	•	•	•	•	•
Utah		•	•		
Vermont		•	•		•
Virginia		•	•	•	
Washington	•	•			
West Virginia		•	•	•	
Wisconsin	•	•	•	•	•
Wyoming	•	•	•	•	
TOTAL	17	41	37	22	21

SOURCE: Office of the State Auditor analysis of PDMP Assist data.

[1] Missouri does not operate a state program, but St. Louis County administers a PDMP database that covers 84 percent of the state's population.

Implementing these best practices in Colorado would help the Department, regulatory boards, and law enforcement better address opioid misuse, abuse, and diversion by allowing the PDMP to identify various types of risky behavior, including when a patient is doctor shopping and receiving prescriptions from multiple prescribers; when a prescriber repeatedly, significantly deviates from prescription limits and best practices or writes an unusually high number of prescriptions for controlled substances; or when a prescriber has a high number of suspected doctor shoppers among their patients.

WHY DO THESE PROBLEMS MATTER?

When Colorado does not sufficiently utilize the PDMP to help prevent doctor shopping and patients from obtaining high numbers of opioids, Coloradans have more opportunity to misuse opioids, which can often lead to death. Since 2008 when the PDMP was implemented, recorded overdose deaths from prescription opioids have increased by 76 percent in Colorado. CDPHE recorded 433 prescription opioid deaths in 2019, up from 246 deaths in 2008. When prescribers are not required to check a patient's prescription history in the PDMP database before prescribing every opioid, patients are able to go to multiple prescribers and obtain one opioid prescription from each without triggering Colorado's requirement for prescribers to query the PDMP database, which may be one factor contributing to further opioid misuse.

Compared to populations in other states that have implemented PDMP best practices, Coloradans also have more of an opportunity to misuse opioids and may be prescribed dangerous combinations of drugs. For example, when prescribers are able to prescribe an opioid or benzodiazepine concurrently, it is possible that patients, especially those who doctor shop, could have one or more dangerous combinations of opioid or other prescriptions. We were unable to identify any statistics on prescription overdose deaths in Colorado that involved opioids and benzodiazepines, but nationwide in 2017, benzodiazepines were involved in 33 percent of all prescription opioid overdose deaths.

When PDMP data are not used to identify and address overprescribing, the PDMP is a less effective tool to combat "pill mills," which are when doctors prescribe opioids to patients who do not need them or prescribe more than patients need to address their pain. Pill mill prescribers typically do not spend sufficient time with their patients to assess them, but rather see many more patients than the average prescriber and prescribe many more prescriptions in a day. When the State does not effectively monitor and address pill mills, the prescribers involved fuel misuse and the illegal drug trade [NIH, 2010].

RECOMMENDATION 1

The Department of Regulatory Agencies (Department) should work with the General Assembly to improve the effectiveness of Colorado's Prescription Drug Monitoring Program (PDMP) in meeting its legislative intent to address prescription drug misuse, abuse, and diversion by proposing that the General Assembly consider whether statute should be amended to require:

A Prescribers to check the PDMP database before prescribing each opioid and, at least, before prescribing each benzodiazepine.

B The Department to develop criteria to identify patients who appear to be doctor shopping, and based on the criteria, refer those patients to law enforcement, as appropriate.

C The Department to develop criteria to identify prescribers who fall significantly outside of prescribing norms and limits for their specialty, and based on the criteria, refer them to the appropriate regulatory board or law enforcement for investigation, as appropriate.

RESPONSE

DEPARTMENT OF REGULATORY AGENCIES

A AGREE. IMPLEMENTATION DATE: JANUARY 2023.

The Department will work to improve the effectiveness of Colorado's Prescription Drug Monitoring Program (PDMP) with the General Assembly in January 2022 and/or through rulemaking. Specifically, the Department will work to require prescribers to check the PDMP before prescribing each opioid and at least before prescribing each benzodiazepine in connection with related recommendations and in consideration of legislative, rulemaking, technical, and fiscal impacts. Should the General Assembly move forward with the recommendation, rulemaking may not conclude until January 2023, extending the implementation timeline.

B AGREE. IMPLEMENTATION DATE: JANUARY 2023.

The Department will work with the General Assembly in January 2022 to provide authority, and/or work through rulemaking, to develop criteria to identify patients who appear to be doctor shopping, and based on the criteria established, refer those patients to law enforcement in connection with related recommendations and in consideration of legislative, rulemaking, policy and fiscal impacts. Further, the Department may also revisit existing criteria based on the Board of Pharmacy's statutory authority (12-280-404, C.R.S.) for sending unsolicited reports, as the Board of Pharmacy is currently tasked with setting the confidential thresholds that identify such patients to prescribers. The implementation timeline is based upon the ability for potential legislation, stakeholder, and rulemaking processes. Should the General Assembly move forward with the recommendation, rulemaking may not conclude until January 2023, extending the implementation timeline.

C AGREE. IMPLEMENTATION DATE: JANUARY 2023.

The Department will work with the General Assembly in January 2022 to provide the Board of Pharmacy authority to develop criteria to identify prescribers who fall significantly outside of prescribing norms and limits for their specialty in connection with related recommendations and in consideration of legislative, rulemaking, policy and fiscal impacts. Such criteria could clarify the current limitations on enforcement set out in 12-280-404(9), C.R.S. The Department will also consider potential pathways to resolve the existing challenge of ensuring that every licensed prescriber submits to the Department, and keeps updated, their specialty. The timeline is based upon the ability for potential legislation and stakeholder and rulemaking processes. Should the General Assembly move forward with the recommendation, rulemaking may not conclude until January 2023, extending the implementation timeline.

PDMP REGISTRATION

Prescribers and pharmacists must apply to register with the PDMP as a database user by entering their DEA and Department-assigned professional license numbers on Appriss' website. Department staff review and approve PDMP database registrations to ensure that only licensed professionals can access the database. After a prescriber is registered, they can access the PDMP database to search and review a patient's historical prescription information. Pharmacies are required to submit information for all of the controlled substances that they dispense to the PDMP database [3 CCR 719-1, Section 23.00.30]. Once a pharmacist is registered, they can query a patient's prescription history if they suspect misuse or abuse of prescription drugs.

The Pharmacy Board develops criteria for indicators of misuse, abuse, and diversion of controlled substances and, based on those criteria, the Department uses the PDMP database to notify prescribers and pharmacists about patients who are potentially misusing or abusing opioids [Section 12-280-404(8), C.R.S.]. These statutorily required patient alerts are emailed to registered prescribers and pharmacists, and mailed to unregistered prescribers and pharmacists when a patient for whom they write or dispense prescriptions has too many prescribers or pharmacies. These alerts are meant to help identify patients who obtain unnecessarily large amounts of opioids from multiple prescribers without the prescribers' knowledge (i.e., doctor shopping).

WHAT WAS THE PURPOSE OF THE AUDIT WORK AND HOW WERE THE RESULTS MEASURED?

In the legislative declaration establishing Colorado's PDMP, the General Assembly acknowledges that prescription drug misuse is a significant problem that occurs, in part, due to prescribers being unaware of a patient's other medical providers and prescriptions. [Section 12-280-401(1)(b), C.R,S.]. To address this legislative

declaration, statute requires certain prescribers and all pharmacists in Colorado to register as PDMP database users, as follows:

- **PRESCRIBER REGISTRATION.** Statute requires that all Colorado prescribers who are licensed by the Department to practice medicine and hold DEA licenses to prescribe controlled substances, register with the PDMP and maintain a database user account [Section 12-280-403(2)(a), C.R.S.]. Statute requires that, at a minimum, prescribers are to query the PDMP database before prescribing the second opioid to most patients [Section 12-280-404(4)(a), C.R.S.].

- **PHARMACIST REGISTRATION.** Statute requires all Colorado pharmacists to register with the PDMP database as users [Section 12-280-403(2)(a), C.R.S.]. Statute allows registered pharmacists to query the PDMP database on a patient to whom the pharmacist is dispensing or considering dispensing a controlled substance or is providing clinical patient care services [Section 12-280-404(3)(f), C.R.S.]. Upon query of the PDMP database, if the pharmacist has a concern about dispensing a controlled substance to a patient, the pharmacist could decide not to dispense the prescription or could contact the prescriber to get more information.

WHAT PROBLEMS DID THE AUDIT WORK IDENTIFY AND WHY DO THEY MATTER?

We reviewed the Department's PDMP database registration data for Colorado DEA licensed prescribers and pharmacists in Calendar Years 2018 and 2019. Overall, we found that many prescribers and pharmacists who are required to register as PDMP database users are not registered.

UNREGISTERED PRESCRIBERS. We found that 6,223 of the 34,679 prescribers (18 percent) with current professional licenses in Colorado and DEA licenses were not registered with the PDMP database in 2018 and 2019. Lack of registration may hamper prescribers' ability to provide the best medical care to their patients and their ability to

identify patients who may be at-risk of misuse or abuse of prescription drugs. Specifically:

- When a prescriber is unregistered, they cannot query the PDMP database to ensure that patients receive safe amounts of opioids. In 2018 and 2019, there were 2,754 unregistered prescribers who gave approximately 185,000 patients about 314,500 opioid prescriptions. Without access to the PDMP database, these unregistered prescribers would not know the extent to which their patients have previously existing opioid prescriptions from different prescribers. Furthermore, we identified 218 of the 2,754 unregistered prescribers who prescribed an opioid for a total of 278 patients who met the Pharmacy Board criteria to have a patient alert, meaning the patients were potentially misusing or abusing opioids. Had these prescribers been registered as PDMP database users, they would have received more timely patient alerts by email, instead of by mail, that could have informed their decisions to prescribe additional opioids to these patients.

- When a prescriber is unregistered, they cannot access the PDMP database to determine if patients may be misusing or abusing opioids, or are receiving concurrent opioids and benzodiazepines. We identified 1,427 unregistered prescribers who prescribed 15,822 opioid prescriptions to more than 8,800 patients in 2018 or 2019 after a different prescriber had already prescribed a benzodiazepine for the patient, which is a sedative such as Valium. Guidance from the CDC states, "Physicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible." This is due to studies showing a higher death rate for individuals receiving opioids and benzodiazepines concurrently than those only receiving opioids [CDC, 2016].

- When a prescriber does not register to access the PDMP database, it can constitute unprofessional conduct. In 2018 and 2019, about 37,660 of the 314,500 opioid prescriptions issued by unregistered prescribers (12 percent) were the second opioid prescription that the patients had received in a year, and those prescribers could not have

queried the PDMP database before prescribing the second opioid, as required [Section 12-280-404(4)(a), C.R.S.]. Statute states that the failure of DEA licensed prescribers to query the PDMP database for a second opioid prescription constitutes unprofessional conduct and is subject to disciplinary action [Section 12-30-109(1)(b), C.R.S.].

UNREGISTERED PHARMACISTS. We found that 219 of the 6,329 pharmacists (3 percent) with current licenses in Colorado were not registered with the PDMP database in 2018 and 2019, as required. When a pharmacist is not registered as a user of the PDMP database they cannot access it, such as to check if they suspect a patient is misusing or abusing opioids.

WHY DID THESE PROBLEMS OCCUR?

LACK OF CONTROLS TO ENSURE REGISTRATION. The Department lacks an automated system control to ensure that all prescribers and pharmacists register with the PDMP database, as required. For example, the Department's licensure system does not check that a prescriber or pharmacist is registered as a PDMP database user before it renews their professional licenses. Department staff told us that during the license renewal process, prescribers must self-report that they have registered, but there is no verification by the Department. In October 2020, Department management told us that it was in the process of procuring a new licensure system that would compel prescribers and pharmacists to register with the PDMP database as a condition of renewing their licenses. Design of the new licensing system is scheduled to begin in January 2021, but a new system will not be integrated with the PDMP database until the summer of 2022.

While the Department waits to implement its new licensing system, it has to rely on manual controls to ensure prescribers and pharmacists register for the PDMP database. However, the Department does not have sufficient manual controls to ensure registration. For example, the Department's current licensure system produces a report showing all prescribers with DEA licenses and the PDMP database has a report of all database users, but Department staff do not compare the two reports

to identify unregistered prescribers so that they can be notified and required to register. Likewise, the Department does not have a process to identify pharmacists who are not registered. Department staff told us that they believe some individual pharmacists are not registered because their pharmacies upload prescription data for all of their pharmacists in aggregate into the PDMP database using one account, so each individual pharmacist may not register. However, the Department could not provide evidence of this or tell us how often pharmacists are not registered because their pharmacies upload all prescription information.

No enforcement mechanism to ensure registrations. Colorado does not have any rules, policies, or penalties that establish the Department's, nor five of the six relevant health care profession boards', authority for enforcement of the registration requirement, and there are no repercussions in the statute for a prescriber who does not register. Representatives from the six healthcare profession boards that oversee prescribers that should register to use the PDMP database—the Pharmacy, Medical, Dental, Nursing, Optometry, and Podiatry Boards—told us that enforcement is their responsibility, yet only the Dental Board has rules that establish a fine for dentists who do not register for the PDMP database. Nonetheless, Dental Board representatives told us it has not fined any dentists for failing to register, although 930 of the 6,223 (15 percent) unregistered prescribers we identified were dentists.

We reviewed PDMP practices in other states and identified 22 other states that have penalties for prescribers who do not register or query their PDMP databases within certain timeframes, as required by their state laws and regulations, and four states that also define a prescriber's lack of registration to use their PDMP database as unprofessional conduct. Penalties in other states primarily include fines or possible disciplinary action by the appropriate regulatory board.

RECOMMENDATION 2

The Department of Regulatory Agencies should ensure that Colorado prescribers and pharmacists register as users of the Prescription Drug Monitoring Program (PDMP) database, as statutorily required, so that they can use it to help prevent opioid misuse and abuse, by:

A Implementing controls, such as automated controls in the new licensure system and manual processes until the new system is implemented, to identify licensed prescribers and pharmacists who are unregistered as PDMP database users, notify them of their noncompliance, and require them to register, such as before they can renew their professional licenses.

B Working with the healthcare profession boards to develop and implement mechanisms to enforce prescribers and pharmacists to register, such as a fine for those who do not comply with the registration requirement, within a certain amount of time of obtaining or renewing a professional license.

RESPONSE

DEPARTMENT OF REGULATORY AGENCIES

A AGREE. IMPLEMENTATION DATE: JULY 2023.

The Department is currently in the contracting phase of acquiring a vendor to develop and implement a new licensing system and is preparing a Request for Proposal (RFP) for the PDMP database. The Department will work with the newly contracted licensing system vendor to ensure automated controls exist to identify and require licensed and DEA-registered prescribers and licensed pharmacists to register with the PDMP as soon as possible, and clarify corresponding requirements in the PDMP RFP, potentially resulting in an extended implementation timeline. Until such time, the

Department will research and develop manual pathways of registration enforcement. Additionally, although complete implementation is anticipated to occur in 2023, the Department will pursue increasing registration through pathways including, but not limited to notifying unregistered licensees of noncompliance and requiring PDMP registration at renewal, sending communication through effective and efficient channels to licensees regarding the requirement and potential enforcement outcomes, as well as working with the current and future vendor in utilizing potentially available technological pathways to support this recommendation and requirement.

B AGREE. IMPLEMENTATION DATE: JULY 2023.

The Department will work to align the collaboration of healthcare profession boards to develop and implement enforcement rules or policies respective to the registration requirement with the estimated completion timeline of the new licensing system and in consideration of legislative, policy, and fiscal impacts. Until such time, the potential manual pathway(s) discussed in the Department's Response 2A may provide a resolution until the licensing system is implemented. The Department will work to align the necessary registration interoperability requirements with the new licensing system, where possible, to enhance the pathways towards enforcement of registration. Additionally, the Department's contract with the current PDMP vendor ends in 2022. Requirements for the upcoming PDMP RFP are in development; resulting in implementation of the new contract by September 2023 and a potentially extended timeline for implementation of this recommendation.

COMPLIANCE WITH OPIOID PRESCRIPTION REQUIREMENTS

A prescription drug monitoring database can be an effective control against opioid misuse and abuse in two key areas. First, prescribers can use a database as a health care tool to review a patient's prescription history prior to prescribing an opioid, including determining whether other medical providers have already prescribed the patient an opioid, to ensure they do not accidently prescribe dangerous combinations of opioids and other controlled substances. Second, prescribers can use a prescription drug monitoring database as a tool to help prevent patients from doctor shopping, as it allows them to see a patient's prescription history and avoid giving an opioid prescription to a patient who has received opioid prescriptions from other doctors.

Prescribers who are registered to use the PDMP database can access it through Appriss' online portal, the Prescription Monitoring Program (PMP) Aware website, or through the prescribers' electronic health record system if a prescriber has purchased integrated access from Appriss. When a prescriber purchases integrated access, Appriss creates an electronic gateway from the prescriber's system to the PDMP database so that prescribers can access the database without performing extra steps, such as logging into a separate website. Prescribers query the PDMP database using patient information, such as name and date of birth.

HOW WERE THE RESULTS OF THE AUDIT WORK MEASURED?

The purpose of the audit work was to assess whether prescribers comply with statutory requirements to control opioid abuse and misuse in the state, as follows:

- **PRESCRIBERS MUST QUERY THE PDMP DATABASE BEFORE PRESCRIBING A SECOND OPIOID.** Statute requires each prescriber to query the PDMP database prior to prescribing a second opioid prescription to a patient, unless the patient meets an exception as defined in statute [Sections 12-280-404(4)(a) and 12-30-109(1)(a), C.R.S.]. Exceptions include when the patient is in a hospital setting or correctional facility, and/or is being treated for cancer or receiving palliative care. Statute provides that if the prescriber repeatedly fails to comply with the query requirement, it constitutes unprofessional conduct and is grounds for discipline [Section 12-30-109(1)(b), C.R.S.].

- **PRESCRIBERS MUST LIMIT INITIAL OPIOID PRESCRIPTIONS.** Statute states, "An opioid prescriber shall not prescribe more than a 7 day supply of an opioid to a patient who has not had an opioid prescription in the last 12 months by that opioid prescriber, and may exercise discretion to include a second fill for a 7 day supply" [Section 12-30-109(1)(a), C.R.S.]. These limits do not apply if, in the judgment of the prescriber, the patient:

  - Has chronic pain longer than 90 days or past the time of normal healing, as determined by the opioid prescriber, or following transfer of care from another opioid prescriber who has the same specialty and also prescribed an opioid to the patient;
  - Has been diagnosed with cancer and is experiencing cancer-related pain;
  - Is experiencing post-surgical pain that is expected to last more than 14 days; or
  - Is undergoing palliative or hospice care focused on providing the patient with relief from symptoms, pain, and stress resulting from a serious illness, and the opioid prescriber is a physician, physician assistant, or advanced practice registered nurse.

  In line with statute, five of Colorado's healthcare profession boards that oversee opioid prescribers—the Dental, Medical, Nursing, Optometry, and Podiatry Boards—have issued guidance that

prescribers limit the amount and duration of opioids prescribed to first time opioid users.

WHAT AUDIT WORK WAS PERFORMED AND WHAT PROBLEMS WERE IDENTIFIED?

- **IT IS UNCLEAR WHETHER PRESCRIBERS QUERY THE PDMP DATABASE BEFORE SECOND OPIOID PRESCRIPTIONS, AS REQUIRED.** The Department could not provide information on the extent to which prescribers utilize the PDMP database by querying it before prescribing a second opioid prescription, as statute requires. The Department only estimates how often prescribers query the PDMP database for any prescription, which it determines by dividing the total number of instances that prescribers queried the database by the total number of all controlled substance prescriptions pharmacies dispensed, not just opioids. The Department obtains the total queries and total prescriptions dispensed from a PDMP database utilization report. The Department estimates that between January 2018 and March 2019, prescribers queried the PDMP database for between 22 and 41 percent of all controlled substance prescriptions each month. However, the Department's estimate does not show the extent to which prescribers comply with statute by querying the PDMP database before prescribing a second opioid prescription, nor does it account for duplicative queries for the same prescription or prescriptions that are exempt from the query requirement.

  In accordance with Section 12-280-409(2), C.R.S., the Department's Executive Director has asked the PDMP Taskforce, within the Colorado Consortium for Prescription Drug Abuse Prevention, to examine opportunities and weaknesses related to the PDMP annually, and recommend improvements to make the PDMP database a more effective tool for prescribers and pharmacists and to reduce prescription drug abuse in the state. In its 2019 report, the PDMP Taskforce estimated the number of queries made by prescribers using a modified version of the Department's

methodology that excluded duplicative queries and estimated that prescribers queried the PDMP database for between 16 percent and 34 percent of all controlled substance prescriptions each month between January 2018 and March 2019.

- **SOME PRESCRIBERS DID NOT ADHERE TO STATUTORY LIMITS ON INITIAL OPIOID PRESCRIPTIONS.** We reviewed the PDMP database records for the 6.7 million opioid prescriptions dispensed in Calendar Years 2018 and 2019. Since the PDMP data does not include sufficient information, such as a patient's diagnosis, we could not definitively exclude all patients who met one of the statutory exception criteria. To account for some of these exceptions, we excluded prescriptions for patients who had prior opioid prescriptions in 2018 or 2019, and those issued by a prescriber who specialized in oncology, surgery, or gerontology and identified 885,100 prescriptions that may have been subject to the 7-day supply statutory limit. Of these, we identified approximately 28,100 prescriptions (3 percent) for which prescribers appeared to have exceeded the 7-day supply limit for first opioid prescriptions, as shown in EXHIBIT 2.9. For example, we identified 818 patients who received prescriptions that supplied between 6 and 18 months of opioids, far exceeding the statutory limit.

EXHIBIT 2.9. SUMMARY OF FIRST OPIOID PRESCRIPTIONS EXCEEDING STATUTORY LIMITATIONS

Prescription Duration	Number of Prescriptions Exceeding Limit	Number of Prescribers [1]	Number of Patients Receiving Prescriptions [2]	Percentage of Prescriptions
8 to 29 days	11,368	4,894	11,297	41%
30 to 59 days	12,198	5,737	12,127	43%
60 to 179 days	3,703	2,099	3,695	13%
180 to 540 days	825	574	818	3%
Total	**28,094**	**8,965** [3]	**27,884** [3]	**100%**

SOURCE: Office of the State Auditor analysis of PDMP data.
[1] Some prescribers issued prescriptions that fell into each of the prescription duration categories shown in rows one through four so they are counted more than once in these rows.
[2] Some patients received prescriptions that fell into each of the prescription duration categories shown in rows one through four so they are counted more than once in these rows.
[3] Totals for the number of prescribers and number of patients exclude duplicates, so the columns do not total.

Some of the prescriptions in Exhibit 2.9 may have been appropriate as they may have met one of the statutory exception criteria, but we could not determine the extent to which this was the case. In addition, according to the Department, there may have been instances where pharmacists incorrectly entered the prescription data needed to determine statutory compliance, such as the number-of-days' supply of the prescription or number of authorized refills, into the PDMP database.

WHY DID THESE PROBLEMS OCCUR?

Lack of PDMP database functionality. The Department does not have a process to monitor whether prescribers comply with statute by querying the PDMP database before prescribing a second opioid. The PDMP database maintains prescription data and query records separately, and does not have the functionality to track if prescribers are querying, as required by Sections 12-280-404(4)(a) and 12-30-109(1)(a), C.R.S. According to the PDMP Taskforce, Appriss has developed database functionality in other states that, if purchased in Colorado, would enable the Department to tie prescriber queries to specific prescriptions and monitor whether prescribers query the PDMP database before prescribing a second opioid. This functionality would

be particularly helpful to allow the Department to monitor prescriber compliance with statute. Department staff told us that Appriss cannot provide a cost estimate for adding this functionality in Colorado because it would need the specifications of the design changes to the PDMP database to make an estimate. Additionally, the Department has not identified a funding source to make such a purchase; currently the PDMP is funded primarily through prescriber license fees. The Department stated that it plans to request proposals for the PDMP database contract in Fiscal Year 2022 to evaluate options for database contractors, and may be able to add this functionality when it executes a new contract.

Furthermore, the PDMP database lacks the functionality to identify first opioid prescriptions that exceed the statutory supply limits. Department staff told us that they cannot identify prescriptions that are exempt from statutory supply limits because the PDMP database does not collect patient diagnoses information. At least four other states collect this information by including codes for patient diagnosis in their PDMP databases. Department staff indicated reluctance to add diagnosis codes to the PDMP database to keep that type of patient information confidential, although the PDMP database already contains other protected health care information about patients. Alternatively, it may be possible for the PDMP database to track exempt prescriptions without collecting patient diagnosis information, such as by adding a check box to the PDMP database that the prescriber could mark to attest that the prescription is to treat a condition that is exempt from statutory requirements. At least one other state has check box functionality in their PDMP database to indicate specific information about prescription records.

USING THE PDMP DATABASE CAN BE TIME CONSUMING FOR SOME PRESCRIBERS, WHICH MAY LIMIT THEIR QUERIES. In 2019, the Department and the PDMP Taskforce reported to the General Assembly that one hurdle in prescribers utilizing the PDMP database is the amount of time it takes to query the database through the PMP Aware website because it can take up to 30 mouse clicks to access the database.

The Department has not developed a method to help address this inefficiency.

One option to make querying efficient for prescribers is integration of their electronic health records with the PDMP database, which could streamline querying to about two mouse clicks. Appriss reported that about 10,700 (34 percent) of the 31,400 PDMP database registered prescribers in Colorado had integrated access between July 2019 and December 2020. However, prescribers must pay to obtain integrated access. Appriss charges each prescriber who has integrated access to the PDMP database $50 annually. Alternatively, Appriss estimated the cost of providing the Department an enterprise license to integrate all Colorado prescribers currently registered to use the PDMP database, including those who are already integrated, would be $475,000 annually, or $15.14 annually per prescriber. If the Department were to make querying efficient by facilitating statewide integration of prescribers' health records with the PDMP database, the Department could pay for the integration by increasing the state licensing fee for prescribers, or pursue grant funding as it has in the past when it paid to pilot integrating small numbers of prescribers to test whether integration improved prescriber PDMP database utilization. The Department's evaluation of the integration pilot found that, with integrated access, prescribers used the PDMP database more often and issued fewer opioid prescriptions and for shorter durations.

LACK OF DATA ENTRY CONTROLS IN THE PDMP DATABASE. Pharmacists may not always accurately fill in the PDMP database fields for data on a prescription's number-of-days' supply or authorized refills because the database does not limit the days' supply or refill amounts that pharmacists can input into fields or flag anomalous entries, such as extremely high numbers. For example, we identified two prescriptions that had 99 refills indicated in the PDMP database, but the Department told us that the refill counts were data entry errors after verifying with the pharmacies. Therefore, these fields may not always accurately reflect the amount of controlled substances provided to a patient. Without these data entry controls, the Department has less assurance of the

accuracy of the PDMP database data on opioid prescriptions that exceed statutory limits.

LACK OF MONITORING AND ENFORCEMENT BY HEALTHCARE PROFESSION BOARDS. We interviewed representatives from the five healthcare profession boards that oversee professions with a statutory requirement to query the PDMP database and are responsible for developing and enforcing rules and policies for their respective professions—the Medical, Dental, Nursing, Optometry, and Podiatry Boards. We requested information about how the boards enforce the statutory requirement for prescribers to query the database before prescribing a second opioid prescription, and discipline prescribers who repeatedly fail to comply in line with Section 12-30-109(1)(b), C.R.S. All of the representatives stated that if a prescriber does not query the PDMP database as required, it would only be brought to their attention through a complaint; none of the representatives were aware of their boards receiving any such complaint. In addition, all of the boards' representatives stated that they do not monitor and enforce the 7-day statutory supply limit for first opioid prescriptions. Furthermore, none of the boards have developed a schedule of enforcement mechanisms in rules or otherwise that can be used, such as sending letters of admonition or issuing fines, in situations where a board determines that a prescriber is not consistently complying with statutory requirements related to the PDMP. Statutory change may be needed to clarify the Department's authority to share PDMP data with these boards so that they are able to enforce the requirements that are in statute and rule.

WHY DO THESE PROBLEMS MATTER?

When prescribers do not adhere to statutory requirements designed to protect patients from opioid abuse and misuse, they may endanger the health and wellness of their patients. Querying the PDMP database can help prevent instances where one patient receives multiple prescriptions for the same or similar drugs prescribed by multiple doctors. Furthermore, when prescribers do not query the PDMP database they cannot review a patient's prescription history. One of the leading best practices identified by the Prescription Drug Monitoring Program

Training and Technical Assistance Center (PDMP Assist) is for prescribers to search the database before prescribing a controlled substance. This is because these searches have been shown to change prescribers' behavior that has resulted in decreased morbidity and mortality stemming from drug use and abuse and decreased "multiple-provider episodes," which are incidents when one patient is prescribed the same or similar drugs by multiple prescribers at the same time. For example, PDMP Assist identified significant decreases, between 50 percent to 82 percent, in multiple-prescriber episodes after states adopted mandatory queries of the PDMP database.

Additionally, prescribers who do not adhere to the statutory limits on initial opioid prescriptions increase their patients' risk of opioid dependency and increase the risk of a patient receiving an excessive dosage. CDC studies indicate that the duration of an initial opioid prescription can be a major factor in influencing whether a patient develops a dependency on opioids. The CDC recommends prescribing opioids for the shortest duration possible and states that 3 to 7 days is often a sufficient supply to address acute pain. Furthermore, according to the National Institute on Drug Abuse, opioids can be a gateway to heroin; whereas 80 percent of heroin users state that they had misused prescription opioids before transitioning to heroin.

RECOMMENDATION 3

The Department of Regulatory Agencies should ensure that prescribers comply with statute to query the Prescription Drug Monitoring Program (PDMP) database and adhere to statutory limits on opioid prescriptions by:

A Working with its PDMP database contractor to implement the functionality to, at a minimum:

i. Track and monitor whether prescribers query the database before prescribing a second opioid prescription.

ii. Identify patients who are exempt from queries and state prescribing limits.

iii. Identify prescribers that exceed statutory prescribing limits.

iv. Implement controls to ensure data accuracy in fields needed to determine statutory compliance, such as days' supply and refill fields.

B Implementing a method(s) to make querying the PDMP database more efficient. This may include, but should not be limited to, implementing a method to help integrate DEA licensed prescribers' electronic health records in the State with the PDMP database.

C Working with the General Assembly to clarify, as needed, the Department's authority to share PDMP data with healthcare profession boards.

D Working with the relevant healthcare profession boards to implement processes to notify the boards of prescribers who do not comply with the statutory requirement for querying the PDMP database or with limits on opioid prescriptions, and developing enforcement mechanisms for prescribers with ongoing noncompliance.

RESPONSE

DEPARTMENT OF REGULATORY AGENCIES

A AGREE. IMPLEMENTATION DATE: JULY 2023.

The Department's PDMP contract ends in 2022. The Department will work to ensure requirements are included in the PDMP RFP that reflect the recommendations within 3A(i-iv), potentially extending implementation as noted in Response 2B. The Department will also work with the current vendor to administer these recommendations as a contract amendment, if possible based on technical, fiscal, and contract considerations. The Department anticipates an extended timeline to ensure implementation of all areas are addressed through the RFP and contracting phase.

B AGREE. IMPLEMENTATION DATE: JULY 2023.

Currently, the PDMP is accessible to all registered users through a web-browser portal. The Department will pursue method(s) to make it more efficient, including integration pathways, to determine which may be most effective to make querying the PDMP database more efficient within the Department's purview. Healthcare organizations that choose to directly integrate their electronic health record with the PDMP work directly with the vendor to implement integration, which may come at a cost. The Department will take into consideration various challenges of implementing integration and improvement strategies, including legislative, fiscal, and best practice policy factors to refine requirements of the pending RFP based upon the timeline highlighted in Response 2B.

C AGREE. IMPLEMENTATION DATE: JANUARY 2023.

The Department will work with the General Assembly to clarify, as needed, the Department's authority to share PDMP data with healthcare profession boards. As noted in the other responses, the Department's work in this area contemplates impact based upon legislative, policy, rulemaking and fiscal considerations.

D AGREE. IMPLEMENTATION DATE: SEPTEMBER 2023.

The Department will work with relevant healthcare profession boards, to the statutory and technological extent possible, to implement notification processes and enforcement mechanisms related to prescribers who do not comply with PDMP querying requirements or statutory limits on opioids prescriptions. The Department will explore solutions to current challenges that exist, including the lack of collection by the PDMP of diagnostic information necessary to identify when non-compliance with requirements would be allowed under statutory exceptions. Such efforts may be focused in the pending RFP for the PDMP, which may result in an extended timeline for implementation as noted in Response 2B. Given the need to allow for collaboration, the timeline is extended.

PHARMACIES' SUBMISSION OF PRESCRIPTION DATA TO THE PDMP DATABASE

Colorado pharmacies submit data on the controlled substance prescriptions that they dispense (prescription data) to the State's PDMP database via Appriss. Pharmacies use their information technology systems to submit these prescription data automatically, such as by submitting data on all of the prescriptions dispensed in a 24-hour period to Appriss by the following business day. Pharmacies are exempt from reporting under certain circumstances, such as when the prescription was dispensed by a hospital or emergency medical personnel.

As required by its contract, Appriss reviews the data that pharmacies submit using a proprietary method to correct data entry errors made by pharmacists, to ensure the PDMP database correctly tracks each prescription's strength and duration and each patient's prescriptions. For example, a patient who has one prescription under the name Jonathan Smith and another under John Smith, but has the same address, date of birth, and prescriber, would be matched by Appriss so that the PDMP database tracks all prescriptions for this patient. If a pharmacy submits data with significant errors, such as missing patient information or an incorrect prescriber license number, then Appriss sends an automated daily email to the pharmacy for up to 30 days, and asks it to submit corrected data. Once it has accurate data, Appriss uploads it into the PDMP database, making it accessible to prescribers and pharmacists.

The Pharmacy Board promulgates rules to help ensure pharmacies submit data for the PDMP database timely. In May 2020, the Department began monitoring timeliness using a PDMP database delinquency report that identifies pharmacies that do not submit data. If a pharmacy does not dispense a controlled substance prescription during a given day, it has the option to send Appriss a "zero report" stating that none were dispensed, and therefore, there are no prescription data to submit for that day. The Department contacts each

pharmacy that fails to submit prescription data or a zero report for 5 consecutive days, to determine if the pharmacy is delinquent in submitting data and resolve any problems.

WHAT AUDIT WORK WAS PERFORMED AND HOW WERE THE RESULTS MEASURED?

We reviewed Department data on the 15.6 million dispensed controlled substance prescriptions, which 1,361 pharmacies submitted to the PDMP database in Calendar Years 2018 and 2019. We assessed whether pharmacies submitted these data timely, as required by the following Pharmacy Board rules:

- "Every prescription drug outlet must ensure that all controlled substance dispensing transactions are reported to the [PDMP database] on a daily basis by no later than the outlet's next regular *business* day" [emphasis added] [3 CCR 719-1, Section 23.00.30]. To measure pharmacy compliance with this rule, we compared each prescription's sale date showing when it was dispensed to the date the pharmacy submitted the prescription data.

- "Any errors identified by the PDMP [contractor] shall be corrected and resubmitted by the prescription drug outlet within 30 *calendar* days of original dispensing date of the affected prescription(s)" [emphasis added] [3 CCR 719-1, Section 23.00.50(a)]. To measure pharmacy compliance with this rule, we reviewed pharmacy submission data to identify prescription records that were not submitted within 30 days, and reviewed Appriss' report on pharmacy data submission errors in November and December 2019 showing if and when the pharmacies corrected the errors and resubmitted the data.

WHAT PROBLEMS DID THE AUDIT WORK IDENTIFY?

Overall, we found that pharmacies did not consistently comply with Pharmacy Board rules, as follows:

PHARMACIES DID NOT CONSISTENTLY SUBMIT DATA TIMELY. In Calendar Years 2018 and 2019, a total of 1,229 of the 1,361 pharmacies did not submit data for about 5.5 million of the 15.6 million prescription records (35 percent) by the end of the next business day, as required. On average, these pharmacies submitted prescription data 6 business days late, but almost one-half of noncompliant pharmacies submitted some data more than 3 months late, as shown in EXHIBIT 2.10.

EXHIBIT 2.10. SUMMARY OF PHARMACIES' TIMELINESS OF PRESCRIPTION DATA SUBMISSION CALENDAR YEARS 2018 AND 2019

TIMELINESS OF SUBMISSION, IN BUSINESS DAYS	NUMBER OF PRESCRIPTIONS (PERCENTAGE)	NUMBER OF PHARMACIES SUBMITTING (PERCENTAGE)[1]
On-time, within 1 day	10,057,152 (64.7%)	1,319 (97%)
2 to 6 days late	5,261,414 (33.8%)	1,189 (87%)
7 to 30 days late	113,337 (0.7%)	1,020 (75%)
31 to 90 days late	51,299 (0.3%)	669 (49%)
91 days or more late	69,080 (0.5%)	557 (41%)
TOTAL	**15,552,282 (100%)**	**1,361 (100%)**

SOURCE: Office of the State Auditor analysis of PDMP pharmacy upload data.
[1] The sum of the percentages in this column do not equal 100 percent because pharmacies made multiple submissions of data at varying timeframes.

Furthermore, we found that 42 pharmacies (3 percent) never submitted data to the PDMP database timely during Calendar Years 2018 and 2019.

Department staff told us that they believe the primary reason pharmacies submitted prescription data late is because the data contained errors that needed to be corrected. However, neither the Department nor Appriss could provide data or documentation to support this statement.

PHARMACIES DID NOT ALWAYS CORRECT AND RESUBMIT DATA TIMELY. We identified 714 pharmacies that did not correct and resubmit data with errors within the required 30 calendar days at least once during Calendar Years 2018 and 2019. Altogether, these 714 pharmacies took between 31 and 820 days to resubmit up to 120,400 prescription records that originally had errors. Neither the Department nor Appriss could provide additional information on prescription records that pharmacies resubmitted due to an error because Appriss only maintains data for corrected errors for 30 days.

EXHIBIT 2.11 shows the 10 pharmacies that were the least timely resubmitting prescriptions that had errors to the PDMP database.

EXHIBIT 2.11. PHARMACIES THAT WERE LEAST TIMELY RESUBMITTING DATA
CALENDAR YEARS 2018 AND 2019

	AVERAGE NUMBER OF CALENDAR DAYS TO RESUBMIT DATA	NUMBER OF PRESCRIPTIONS
Pharmacy 1	431	6,022
Pharmacy 2	323	658
Pharmacy 3	279	3,181
Pharmacy 4	239	354
Pharmacy 5	198	1,290
Pharmacy 6	196	118
Pharmacy 7	177	16
Pharmacy 8	137	4,904
Pharmacy 9	130	798
Pharmacy 10	120	12
TOTAL	-	17,353

SOURCE: Office of the State Auditor analysis of PDMP pharmacy upload data.

We also found that no action was taken, either by the Department and Appriss, or the Pharmacy Board, when pharmacies did not correct their errors and resubmit the data within the 30-day requirement. We reviewed Appriss' report of the pharmacy data submissions with errors that were still pending correction in November and December 2019, which totaled 306 submissions in those months. We found that all 306 submissions were not in the PDMP database as of October 2020, meaning that the pharmacies never corrected and resubmitted these data.

WHY DID THESE PROBLEMS OCCUR?

MONITORING OF DELINQUENT PHARMACIES WAS LACKING, AND ZERO REPORTING NOT REQUIRED. Prior to May 2020, there was no process, within the Department, by Appriss, or by the Pharmacy Board, to reliably identify pharmacies that were delinquent submitting prescription data. As a result, the Department did not follow-up with pharmacies to ensure that they submitted data timely. The Department told us that it was not monitoring delinquent pharmacies prior to May 2020 because it was time consuming to determine when pharmacies were actually delinquent and which pharmacies had not dispensed controlled substances. In May 2020, the Department began using a PDMP database report that lists pharmacies that have not submitted any controlled substance data to the database in the previous 5 days. The Department told us that it now uses that report to follow-up with pharmacies if they appear to be delinquent submitting data. However, the Department continues to make it optional for pharmacies to submit zero reports specifying that they did not dispense controlled substances in the previous 24 hours so the Department cannot identify all pharmacies that are out of compliance with rules requiring data submission. For example, only about one-half of pharmacies (778 of the 1,331) regularly provided a zero report in October and November 2019. According to PDMP Assist, 22 other states *require* pharmacies to submit zero reports to their PDMP so that those states can better monitor to ensure their PDMP databases contain timely and complete data.

NO PROCESS TO ENSURE PHARMACIES CORRECT AND RESUBMIT DATA THAT HAVE ERRORS. Although the PDMP database automatically emails pharmacies with data errors every day for 30 days to notify them that they need to correct and resubmit the data, there is no process, within the Department, by Appriss, or by the Pharmacy Board, to verify that the pharmacies have corrected and resubmitted the data. In addition, neither the Department nor the Pharmacy Board use Appriss' error report to monitor pharmacy compliance and to verify that pharmacies have corrected all errors and resubmitted the data.

THE DEPARTMENT AND THE PHARMACY BOARD HAVE NOT ESTABLISHED PENALTIES FOR PHARMACY NONCOMPLIANCE WITH RULES. The Pharmacy Board rules do not contain any enforcement mechanisms or penalties for pharmacies that do not comply with prescription data submission rules.

WHY DO THESE PROBLEMS MATTER?

Monitoring and enforcement are important to ensure prescribers and pharmacists can rely on the prescription data to identify all of the controlled substance prescriptions dispensed to patients, in line with statutory intent. When the Department does not ensure that pharmacies submit prescription data to the PDMP database timely, or correct data with errors and resubmit it timely, the PDMP database is not an accurate and complete tool that prescribers can use to monitor their patients' prescription history. When the PDMP database is not complete, it is less useful to control against overprescribing and doctor shopping. For example, approximately 2.4 million of the 5.5 million prescriptions (44 percent) that pharmacies submitted late were opioid prescriptions. If a prescriber checked the PDMP database prior to prescribing an opioid prescription, but the database is not up-to-date with all current controlled substance prescriptions, it could appear that the patient has not received an opioid recently when they may have received prescriptions that are not in the PDMP database. Furthermore, when the PDMP database is not complete, a prescriber who checks it could provide a patient a controlled substance that may be a dangerous combination with the existing prescription. For example, a prescriber might prescribe an opioid when the patient already has a benzodiazepine prescription. According to the CDC, prescribers should avoid prescribing concurrent opioids and benzodiazepines whenever possible because of the increased risk of a potentially fatal overdose [CDC, 2016].

RECOMMENDATION 4

The Department of Regulatory Agencies should work with the State Board of Pharmacy to ensure that pharmacies comply with rules to submit all dispensed controlled substance prescriptions to the Prescription Drug Monitoring Program database timely, by:

A Requiring zero reports from all pharmacies when they do not dispense controlled substances during that business day, using the reports to identify pharmacies that are noncompliant with rules for submitting data, and following-up to ensure the pharmacies submit prescription data timely.

B Establishing a process to ensure pharmacies correct data containing errors timely, and resubmit that data in line with rule.

C Developing and implementing enforcement mechanisms, such as penalties, for pharmacies that are consistently noncompliant with rules for submitting data.

RESPONSE

DEPARTMENT OF REGULATORY AGENCIES

A AGREE. IMPLEMENTATION DATE: MAY 2022.

The Department will work with the Board of Pharmacy to require zero reports from all pharmacies that do not dispense controlled substances during a business day and perform appropriate follow-up with non-compliant pharmacies consistent with data submittal rules. These changes will enhance the Department's ability to identify noncompliance and support enforcement to ensure pharmacies submit prescription data timely, subject to resource constraints for enforcement. This implementation could be further

enhanced, however extended, by the pending PDMP RFP as noted in Response 2B.

B AGREE. IMPLEMENTATION DATE: SEPTEMBER 2022.

The Department will work with the Board of Pharmacy to develop a process that would ensure pharmacies would correct errors in a timely manner and resubmit the data in accordance with requirements. The Department will work to consider solutions that take into account certain limitations that exist in verifying actual inaccuracies in submitted data compared to actual prescriptions versus how a prescription was written and dispensed, subject to enforcement resource constraints. This implementation could be further enhanced as noted in Response 4A.

C AGREE. IMPLEMENTATION DATE: SEPTEMBER 2022.

The Department will work with the Board of Pharmacy to develop and implement enforcement mechanisms, as allowable by statute, for pharmacies that are consistently noncompliant with rules for submitted data. This may include rulemaking or updating current policies related to pharmacies that fail to submit required data. For example, the Board may update current Policy 30-8, which provides guidance for varying levels of enforcement and depending on the frequency of noncompliance by the pharmacy. This implementation could be further enhanced as noted in Response 4A.

CONTRACT MONITORING

Since April 2017, the Department has contracted with Appriss to develop, collect, and maintain prescription data for the PDMP. Appriss designs prescription drug monitoring databases and makes them available to states. Currently, Appriss contracts with 37 other states to provide PDMP databases. For Colorado, Appriss collects controlled substance prescription data from pharmacies in the State; manages the electronic database, including cleaning, matching, and validating the prescription data it receives; and stores the validated data for access by registered users. The Pharmacy Board's statutory duty is to create a method and a format for pharmacies to report controlled substances to the PDMP [Section 12-280-404, C.R.S.], and the Department's primary role with the PDMP, as the Pharmacy Board's designee, is to manage the PDMP database contract and monitor its contractor. In Fiscal Years 2017 through 2020, the Department paid Appriss a total of $1.3 million through the contract.

WHAT AUDIT WORK WAS PERFORMED, WHAT WAS THE PURPOSE, AND HOW WERE THE RESULTS MEASURED?

We reviewed the Department's current contract with Appriss, effective 2017 through August 2020, including all amendments. We also analyzed the 15.6 million prescription records that pharmacies submitted to Appriss for inclusion in Colorado's PDMP database in Calendar Years 2018 and 2019. The purpose of our audit work was to evaluate the Department's contract management and monitoring of Appriss, based on the following requirements:

THE DEPARTMENT'S CONTRACT REQUIRES APPRISS TO MAKE THE DATA AVAILABLE TO DATABASE USERS. To help ensure that the PDMP database is accurate and complete, and that the prescribers and pharmacists have access to the prescription data when needed, the contract requires Appriss to:

- Clean and validate the prescription data it receives and notify pharmacies within 24 hours if there are problems with the data [Contract Section 4.2.1]. Once the data has been cleaned and validated, Appriss should load the data into the PDMP database within 24 hours of the time the data was received from the pharmacy so that the data is available for user access [Contract Section 4.3.1].

- Ensure the PDMP database is available 99.5 percent of time during the prime hours, 6:00 a.m. to 6:00 p.m. Mountain Time, Monday through Friday, and 97.5 percent of time during non-prime hours, inclusive of scheduled maintenance [Contract Section 4.7.1]. The hours listed in the contract for when the PDMP database must be available to users are called uptime hours; the hours when the PDMP database is not available are called downtime hours.

THE STATE OWNS THE PDMP DATA. The Department's contract with Appriss specifies that the State has the right to access and retrieve the prescription information stored on Appriss' computers at the State's sole discretion, and that the State has all rights to PDMP database data, state information, and related data and content [Contract Section 10(L)]. There are no contract provisions that give Appriss rights to the PDMP data that it stores in its IT systems.

STATE CONTRACTS SHOULD INCLUDE CLEAR DELIVERABLES. All state departments must follow the State Controller's policy on mandatory provisions for state contracts that requires contracts to include a clear description of each deliverable that the contractor is required to provide.

WHAT PROBLEMS DID THE AUDIT WORK IDENTIFY AND WHY DO THESE PROBLEMS MATTER?

We found that the Department is not ensuring that Appriss complies with some contract terms. Specifically:

APPRISS DOES NOT APPEAR TO LOAD ALL DATA INTO THE PDMP DATABASE WITHIN 24 HOURS. Of the 15.6 million prescription records we reviewed from the PDMP database, we identified 158,100 prescription records (1 percent) that Appriss did not appear to load within 24 hours, as required by the contract. Appriss was more than 30 days late in loading about 11 percent of these prescription records, as shown in EXHIBIT 2.12.

EXHIBIT 2.12. SUMMARY OF PRESCRIPTIONS NOT LOADED BY APPRISS WITHIN 24 HOURS CALENDAR YEARS 2018 AND 2019

NUMBER OF BUSINESS DAYS TAKEN TO LOAD	NUMBER OF PRESCRIPTION RECORDS LOADED LATE	PERCENTAGE OF PRESCRIPTION RECORDS LOADED LATE
2 to 5 days	117,440	74.3%
6 to 30 days	23,768	15.0%
31 to 180 days	16,402	10.4%
181 to 360+ days	478	0.3%
TOTAL	**158,088**	**100%**

SOURCE: Office of the State Auditor analysis of PDMP data.

Appriss reviewed a sample of 79,500 prescriptions that we identified as being loaded untimely and told us that it believes that the untimeliness may have happened if pharmacies modified the prescription records after the initial load date, which would show a new load date in the database. Appriss also believed that about 57,200 of the prescription records appeared late because the load dates were likely changed when Appriss reprocessed and corrected records that had data entry errors. However, Appriss could not provide documentation or other evidence to support that it had initially loaded the prescriptions within 24 hours, as required.

Without complete information, the PDMP database may not be an effective tool to help prevent prescription drug misuse and abuse. It is important that the Department monitor and enforce its contract with Appriss to ensure that the information in the PDMP database is accurate and complete.

Lack of evidence that Appriss complies with PDMP database uptime and downtime requirements. The Department could not provide any documentation showing that Appriss has complied with the contract requirements of 99.5 percent uptime during prime hours and 97.5 percent uptime during nonprime hours.

When the Department does not know whether Appriss complies with uptime and downtime requirements in the contract, it is possible that the PDMP database has not been available to prescribers and pharmacists when needed. For example, prescribers are statutorily required to query the PDMP database before giving a second opioid prescription. However, they cannot conduct a query if the PDMP database is down for maintenance or technical problems. If a prescriber cannot check the PDMP database, they may not know of their patients' other opioid prescriptions from other prescribers.

The State cannot access its data without paying a fee. We found that the Department paid Appriss $3,000, in addition to the amount the Department pays for its contract, to obtain PDMP data for the audit and the Department told us that it pays for the PDMP data whenever Appriss staff extract it for the State's use. The Department reported that the cost for the data depends on the amount of work that Appriss has to conduct in addition to what it already provides by contract. For example, the Department sometimes asks Appriss to extract and anonymize the PDMP data for researchers. For this audit, Appriss provided the Department raw data that was not prepared for the Department's or our use, and not anonymized by Appriss. The Department anonymized the PDMP data before providing it to us. Further, the contract has no provision requiring the Department to pay fees when it requests data from its PDMP database.

When the Department has to pay Appriss for the State's data, it is not a prudent use of state funds because it is more costly to implement the PDMP as statute intended to identify prescribers who may be prescribing more opioids than recommended or individuals who may be doctor shopping. Additionally, when the Department must pay to access the State's data, the Department cannot readily access and use the data to monitor PDMP operations or the effectiveness of its contractor.

INAPPLICABLE CONTRACT PROVISION. We found that the Department's contract with Appriss has one provision that is not applicable. The contract requires Appriss to deactivate PDMP database user accounts for prescribers who do not have active licenses. However, the PDMP database does not interface with the Department's electronic licensing system so Department staff have deactivated PDMP database user accounts manually for the duration of the Appriss contract. Additionally, the Department has not reduced the contract payment to Appriss for not carrying out this deliverable that is in the contract.

The provision for Appriss to deactivate user accounts was put into the contract with the goal of having Appriss begin providing this service. When Appriss tried to link the PDMP database to the Department's licensure system, it discovered it was not feasible because the Department's licensure system lacks the functionality needed to link to the database. When the contractor does not provide all deliverables specified in the contract, the State does not receive the full value for the $1.3 million the State has paid Appriss for the contract from 2017 to 2020.

WHY DID THESE PROBLEMS OCCUR?

LACK OF DEPARTMENT CONTRACT MONITORING TO ENSURE PRESCRIPTION LOADING. Department staff do not have a process to check that Appriss loads data into the PDMP database within 24 hours, as required. The Department told us that because it does not know which prescriptions pharmacies have dispensed at any given time, it does not know which prescriptions should be loaded into the PDMP

database, and therefore, has not developed a method to check if Appriss complies with this contract provision. However, the Department has also not asked Appriss to report metrics for this contract provision. For example, the Department has not asked Appriss to report on the average time it takes to upload prescriptions or report how many and which prescriptions it has not loaded timely, and explain why. Furthermore, the Department could require Appriss to maintain documentation or data to support that it loads prescription records into the PDMP database in line with the contract. Alternately, the Department could analyze prescription data, as the audit team did, to identify prescriptions that are not uploaded to the PDMP database timely, and require Appriss to explain delayed uploads and correct the issues causing the delays.

Colorado regulations require the Department to monitor its contracts to ensure compliance with terms [1 CCR 101-1, Section 10.2]. Specifically, regulations require each state agency to monitor its contracts for satisfactory performance and completion of the state contract's scope of work. By not monitoring Appriss' prescription uploading timeliness, the Department is not meeting the State's contract monitoring standards. The contract allows the Department to withhold or deny payment, or terminate the contract, if Appriss does not comply with contract terms.

Inadequate monitoring of up and down time percentages. The Department told us that it has verbal conversations with Appriss about the percentages of uptime and downtime for the PDMP database, and Department staff said that they believe Appriss has consistently met the percentages. However, Department staff have not documented the conversations and could provide no other support that Appriss complies with these contract requirements.

Statute requires each state agency to institute and maintain systems of internal accounting and administrative control [Section 24-17-102(1), C.R.S.]. In 2016, the Office of the State Controller directed all state agencies to begin following the Standards for Internal Control in the Federal Government (Green Book), which specify:

- Managers should establish monitoring activities through ongoing monitoring and evaluations to evaluate the effectiveness of a program [Principles 16.01 and 16.04].

- Ongoing monitoring and evaluations of the effectiveness of internal controls test their operating effectiveness for the purpose of identifying and addressing internal control issues [Principle 16.09].

THE CONTRACT IS UNCLEAR ON WHETHER APPRISS CAN CHARGE THE DEPARTMENT TO ACCESS THE STATE'S DATA. The Department's contract with Appriss does not specifically state that Appriss can charge the Department or the State for PDMP data. The contract only states that Appriss can charge the Department when it requests, "to modify the (PDMP database) application, either through customization, core program changes, or through additional report writing" [Contract Section 6.3]. The contract contains no provisions regarding the cost if the Department or another State agency requests that Appriss provide aggregate or de-identified data. The contract states that Appriss would charge a non-state researcher if the Pharmacy Board approved for the researcher to receive requested de-identified PDMP data, but states, "the State shall make no payment to Contractor (Appriss) for these requests" [Contract Section 4.7.4].

The Department reports that it does not generally have operational reasons to extract aggregate data from the PDMP database, so Appriss requested payment to cover its time sending the data to the Department for our audit. However, our audit includes recommendations for the Department to use the PDMP data for monitoring and enforcement, so the Department would need to clarify the contract regarding payment for the State's data so that access to the data, in aggregate or customized parts of the data, is not limited in the future.

We interviewed representatives in three other states that contract with Appriss to administer their PDMP databases—Connecticut, Oregon, and Louisiana—and that recently had audits of their PDMP databases. All three states used large datasets from Appriss to conduct their analysis, and none had to pay for the data they received. For example,

in Connecticut, auditors requested that Appriss develop and provide certain data analyses. The representatives from the three states told us that their states do not have any provisions in their contracts that require payment for PDMP data. According to the Department, other states may not have to pay to access their data because their laws and policies may differ.

No process to update inapplicable contract provision. During the contract term 2017 to 2020, the Department has not modified the Appriss contract to remove the inapplicable provision requiring Appriss to deactivate accounts, nor has the Department addressed the inability of the PDMP database to interface with its licensure system. Department staff told us that they did not modify the contract payment to Appriss when it did not deactivate PDMP database accounts because there is not incremental funding in the contract for that specific purpose. The Department reports that it is re-bidding the PDMP database contract and plans to ensure that the contract provisions are accurate and complete, and that the new licensure system can interface with the PDMP database by the summer of 2022.

RECOMMENDATION 5

The Department of Regulatory Agencies should improve its contract management practices to ensure that the contractor for the Prescription Drug Monitoring Program (PDMP) database complies with the Department's contract by:

A Improving contract monitoring to ensure timeliness of prescription uploads into the PDMP database, and compliance with uptime and downtime requirements. This could include, but should not be limited to, requiring the contractor to report on its upload times and uptime and downtime percentages; identifying contract noncompliance; following up with the contractor to require it to correct problems identified; and employing contract remedies for ongoing noncompliance, such as withholding payment until problems are addressed.

B Working with Appriss to amend the current contract to clarify that the State, including the Department, has access to PDMP data without payment. If the current contractor is not amenable to amending the contract, the Department should ensure future contracts with a PDMP contractor confirm that the State has data access without payment.

C Revising the current Appriss contract to remove the provision related to account deactivation, which is no longer applicable; change the contract payment amount, as applicable; and clarify contractor responsibilities. The Department should also ensure future contracts with a PDMP contractor do not contain the account deactivation provision.

RESPONSE

DEPARTMENT OF REGULATORY AGENCIES

A AGREE. IMPLEMENTATION DATE: JUNE 2022.

The Department will work to improve contract monitoring with the vendor. The Department has already begun monitoring system downtimes, and the next step will be to require the vendor to report uptime and downtime percentages. The Department will work with the vendor to develop reporting that provides transparency on time-frames for prescription uploads. For any contract issues, the Department will work with the vendor to identify the problem and resolve the issue and employ contract remedies in the event of ongoing noncompliance.

B AGREE. IMPLEMENTATION DATE: JUNE 2022.

The current vendor has not historically charged the Department or State for raw PDMP data, from which the Department or State can create certain reports; however, the Department will work with the vendor, and future requirements in the pending RFP, to amend the contract to clarify language regarding State and Department access to PDMP data without payment. Generally, when the Department receives a PDMP data request that requires additional specific parameters beyond the raw data available, the current vendor fulfills these requests at a cost pursuant to current contract provisions. The Department will work with the current vendor to amend the current contract to minimize costs associated with fulfilling the more complex requests for the State and will also work with the vendor to amend the contract [so] that State and Department requests for raw and aggregated data come at no cost. Implementation may be extended if the implementation of this recommendation is necessarily part of the requirements of the pending RFP as noted in Response 2B.

C AGREE. IMPLEMENTATION DATE: JUNE 2022.

The Department will work with the vendor to amend the contract to remove the provision related to account deactivation, including payment amount, if applicable. The Department will also add the recommendation to the requirements for the upcoming PDMP RFP as noted in Response 2B.