



TO: Patty Salazar, Executive Director, Colorado Department of Regulatory Agencies
Members of the Colorado General Assembly

FROM: Colorado Consortium for Prescription Drug Abuse Prevention

DATE: July 1, 2022

RE: 2022 Prescription Drug Monitoring Program Task Force Report

The Colorado Consortium for Prescription Drug Abuse Prevention (Consortium) submits the enclosed report on behalf of the Prescription Drug Monitoring Program (PDMP) Task Force pursuant to 12-280-409(2), C.R.S. This report details the Consortium's work on 1) evaluating the effectiveness of unsolicited reporting to licensing boards of licensees' prescribing activity; and 2) evaluating the effects of allowing law enforcement access to PDMP data without requiring a subpoena or court order; and 3) evaluating and making recommendations, after engaging in a stakeholder process, regarding balancing the program as a health-care tool with the enforcement of the program under Colorado Revised Statutes Title 12, Article 280.

Respectfully,

Colorado Consortium for Prescription Drug Abuse Prevention



COLORADO ELECTRONIC
PRESCRIPTION DRUG MONITORING PROGRAM

2021-2022 TASK FORCE REPORT

July 1, 2022

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COLORADO ELECTRONIC PRESCRIPTION DRUG MONITORING PROGRAM

2021-2022 TASK FORCE REPORT

Introduction:

Pursuant to Section 12-280-409(1), Colorado Revised Statutes (C.R.S.), the Executive Director of the Department of Regulatory Agencies (DORA) is required to create a Prescription Drug Monitoring Program (PDMP) Task Force or consult with and request assistance from the Colorado Consortium for Prescription Drug Abuse Prevention (Consortium) to:

- 1. Examine issues, opportunities, and weaknesses of the program, including how personal information is secured in the program and whether inclusion of personal identifying information in the program and access to that information is necessary;*
- 2. Make recommendations to the executive director on ways to make the program a more effective tool for prescribers and pharmacists in order to reduce prescription drug abuse in Colorado; and*
- 3. Effective May 27, 2022, pursuant to Colorado Senate Bill 22-027 (SB 22-027) evaluate and make recommendations to the executive director, after engaging in a stakeholder process, regarding balancing the program as a health-care tool with the enforcement of Colorado Revised Statutes, Title 12, Article 280, .*

Should the Executive Director convene a Task Force, it shall submit an annual report to the Executive Director and the General Assembly detailing its findings and recommendations, per 12-280-409(2) C.R.S.

This report provides the recommendations of the Task Force to the Executive Director in response to the items assigned to the Task Force by the DORA Executive Director as detailed below. In addition, SB 22-027, which was recently signed by the Governor, requires an evaluation regarding balancing the program as a health-care tool with the enforcement of the requirements of the program, which includes a stakeholder process. These requirements were met this year through the items that were assigned to the Task Force and the stakeholder process that was used to obtain input about those items.

Requests for 2022 Task Force Report

Following the issuance of the 2021 PDMP Task Force Annual Report and in response to the recommendations in the Colorado Office of the State Auditor's 2021 PDMP Performance Audit¹, DORA's Executive Director requested the Task Force to evaluate the following:

Task #1: Evaluate Effectiveness of Unsolicited Reporting to Licensing Boards of Licensees' Prescribing Activity

12-280-404(3)(i), C.R.S. authorizes access to Colorado PDMP data to state regulatory boards and programs within the Division of Professions and Occupations only if the information is specific to an individual practitioner and is part of a bona fide investigation, and the request for information is accompanied by an official court order or subpoena. While some states authorize their PDMPs to provide unsolicited reports to state licensing boards regarding prescribers who meet certain criteria determined by their respective licensing boards, the Colorado PDMP is not authorized by current law to provide such unsolicited reports. The Task Force was asked to evaluate the benefits and risks of such unsolicited reporting to licensing boards in reducing prescription drug abuse and problematic prescribing and was asked to detail how these licensing boards use such information in practitioner education and academic detailing or disciplinary action against practitioners.

Task #2: Evaluate the Effects of Allowing Law Enforcement Access to PDMP Data without Requiring a Subpoena or Court Order

Section 12-280-404(3)(g), C.R.S. allows law enforcement to access Colorado PDMP data so long as the information released is specific to an individual patient, pharmacy, or practitioner and is part of a bona fide investigation, and the request for information is accompanied by an official court order or subpoena. Some states allow law enforcement to access PDMP data without such restrictions. The Task Force was asked to evaluate the effects of allowing law enforcement to access PDMP data results with respect to reducing prescription drug abuse, law enforcement actions against practitioners, pharmacies, and patients and to assess how such access affects patient privacy and other potential unintended consequences.

The Executive Director's requests can be found in Appendix A.

This report also meets the requirements of SB 22-027, which was recently signed into law and requires the Task Force to evaluate and make recommendations to the Executive Director, after engaging in a stakeholder process, regarding balancing the program as a health-care tool with the enforcement of Colorado Revised Statutes Title 12, Article 280.

These two tasks are closely related as they both relate to the role of regulatory oversight with respect to the PDMP. This report therefore evaluates both tasks in tandem and provides individual recommendations regarding each task on page 25.

¹ Colorado Office of the State Auditor. (2021). Prescription Drug Monitoring Program Performance Audit, March 2021. <https://leg.colorado.gov/audits/colorado-prescription-drug-monitoring-program>

Task Force Review and Responses to DORA Executive Director’s Request for Assistance

The Executive Director’s requests were submitted to the PDMP Work Group at the Colorado Consortium for Prescription Drug Abuse Prevention (Consortium), which was designated as the PDMP Task Force by the Executive Director. Established in 2013, the Consortium is a coordinated, statewide, inter-university/inter-agency network. It now supports 11 different work groups with more than 1000 participants, including providers, professionals, laypersons and other stakeholders. The participants and work groups study, recommend and implement ways to reduce prescription drug abuse in Colorado. The PDMP Work Group focuses on issues relating to the use and improvement of the state’s PDMP.

The PDMP Work Group at the Consortium is composed of representatives with medical, legal, or health information technology expertise, interested patients and family members, members of the Colorado legislature, as well as representatives from various state and federal agencies. A full list of the PDMP Work Group members and their corresponding organizations may be found in Appendix B.

OSA Performance Audit Recommendations

Consistent with the recommendations made in the 2021 Performance Audit of the Colorado PDMP by the Office of the State Auditor (OSA)² and the directive in SB 22-027, this year’s report evaluates whether the General Assembly should amend Colorado’s PDMP statute (Section 12-280-404, C.R.S.) to authorize the PDMP to share PDMP information on an unsolicited basis to the prescribing boards that license and regulate DEA-licensed practitioners and to law enforcement.

Specifically, recommendation 1 of the OSA Audit states:

The Department of Regulatory Agencies (Department) should work with the General Assembly to improve the effectiveness of Colorado’s [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.

The OSA report stated that “Colorado has not designed its PDMP as an effective tool to address doctor shopping, opioid misuse, dangerous combinations of opioid and benzodiazepine

² Ibid. <https://leg.colorado.gov/audits/colorado-prescription-drug-monitoring-program>

prescriptions, or overprescribing of opioids, nor does it aid regulatory boards and law enforcement in addressing these problems” (p. 28). The report also states:

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. (p. 28-29).

Recommendation 1(A) was addressed in House Bill 21-1276 (HB 21-1276) and was clarified in House Bill 22-1115 (HB 22-1115) and SB 22-027 which requires practitioners to query the PDMP before writing opioid and benzodiazepine prescriptions. Certain pre-existing exceptions remain such as not needing to check it for patients in hospice or palliative care, patients diagnosed with cancer, and patients who are receiving a single dose in connection with a test or procedure. However, a violation of these query requirements “does not create a private right of action or serve as the basis of a cause of action” (12-30-109(3), C.R.S. and 12-280-404(4)(d), C.R.S.) and “failure to comply with section 12-280-404(4) constitutes unprofessional conduct or grounds for discipline... only if the prescriber repeatedly fails to comply” (12-30-109(1)(b), C.R.S.).

Regarding Recommendation 1(B), the Department agreed to work with the General Assembly 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.

Regarding Recommendation 1(C), the Department agreed to work with the General Assembly to provide the Board of Pharmacy authority to develop criteria to identify prescribers who fall significantly outside 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.

Based on the request by the Executive Director, SB 22-027, and the agreement to comply with the recommendations in the OSA Audit, this report evaluates whether Colorado law should enable PDMP data to be leveraged for more proactive regulatory enforcement through reporting prescribers and patients to regulatory boards and/or law enforcement and whether the subpoena or court order requirement for PDMP access by these entities should be amended. To that end, this report:

- describes the history of Colorado PDMP statute regarding licensing board and law enforcement access to PDMP information and unsolicited reporting;
- assesses laws and procedures in other states concerning these topics;
- analyzes academic research and media reports concerning the impacts on patients and prescribers with respect to regulatory oversight of controlled substance prescribing and PDMPs including the unintended consequences of such laws and initiatives;
- summarizes the results of a survey sent to other state PDMPs regarding their use of unsolicited reports and their laws regarding law enforcement and regulatory agency access;

- details the results of stakeholder feedback received through outreach to various Colorado stakeholders;
- describes the history and current state of the opioid and drug overdose epidemic, and
- identifies other evidence-based initiatives that may warrant further evaluation which may help improve PDMP effectiveness.

History of the Opioid Crisis and Overdose Trends

In order to fully address the OSA recommendations as well as the questions posed in this year’s report, it is necessary to highlight some of the history of the opioid crisis, the trends that have occurred and the various reactions to address the crisis. More details about all of these topics can be found in the appendices to this report. Since 1999, over 500,000 Americans died from an overdose involving any opioid, including prescription and illicit opioids. This rise in opioid overdose deaths occurred in three distinct waves. The first wave began with increased prescribing of opioids in the 1990s, with overdose deaths involving prescription opioids increasing since at least 1999. The second wave began in 2010 with rapid increases in overdose deaths involving heroin. The third wave began in 2013 with marked increases in overdose deaths involving fully synthetic opioids, primarily illicitly manufactured fentanyl. The market for illicitly manufactured fentanyl continues to change, and it is now frequently found in combination with heroin, counterfeit pills, and cocaine.³

Most PDMPs were established in the early-to-mid 2000s in response to the first wave of the opioid crisis⁴ where loosening regulations regarding opioid prescribing led many well-meaning prescribers to significantly increase their opioid prescribing and where a lack of oversight allowed some practitioners, driven by profit motives, to establish “pill mills” where practitioners wrote large volumes of opioid prescriptions to patients without properly assessing patients or treating within established standards of care. Investigations and prosecutions of pill mills and the implementation of PDMPs has resulted in significant decreases in pill mills across the United States by closing the regulatory gaps that unethical practitioners and drug seekers exploited. Consistent with trends across the United States, multiple-provider visits suggesting possible “doctor shopping” has decreased by 92% in Colorado since 2014.

Appendix C includes additional information regarding overdose trends both nationally and in Colorado as well as recent prescribing trends in Colorado.

Statutory History and Considerations

There are long-established state and federal laws related to the possession and distribution of controlled substances. New attention was focused on these laws as it became apparent that opioid prescribing dramatically accelerated in the late 1990s and early 2000s. Clinically related efforts were taken to reduce over-prescribing. Questions were also raised about law enforcement’s role in addressing this epidemic.⁵ In addition, many states created or expanded

³ Ibid.

⁴ Centers for Disease Control and Prevention. (2021). History of the Opioid Crisis. <https://www.cdc.gov/drugoverdose/epidemic/index.html>

⁵ See, for example:

Boustead, A. E. (2021). Privacy protections and law enforcement use of prescription drug monitoring databases. *Law & policy*, 43(3), 229-261. <https://doi.org/10.1111/lapo.12174>

PDMPs to monitor opioid prescriptions. One of the oft-stated goals was to help reduce dangerous activity by both providers and patients. Nearly all states have implemented a PDMP, though there is wide variation between states in the management and accessibility of the PDMP.⁶ The statutory history of the Colorado PDMP and major milestones of the program are detailed in Appendix D.

Law enforcement access is one such area where access varies between states. Some states stipulate that law enforcement can only obtain PDMP data under a search warrant, subpoena or court order establishing probable cause, while other states such as Colorado allow law enforcement access to PDMP data upon issuance of a subpoena or court order without explicitly requiring probable cause. Other states only require law enforcement to demonstrate the request is related to an active criminal investigation, often by providing a case number with a PDMP data request. Other states do not set forth explicit standards that law enforcement must meet⁷ or leave this determination up to the discretion of PDMP officials, such as in Texas.⁸

Current Colorado law authorizes the PDMP to provide confidential unsolicited reports to prescribing practitioners and dispensing pharmacies for purposes of education and intervention to prevent and reduce occurrences of controlled substance misuse, abuse and diversion using criteria developed by the Board of Pharmacy in consultation with the six Colorado Boards that license prescribers. Licensing boards and the Director of the Division can only access Colorado PDMP data through a subpoena for a specific practitioner as part of a bona fide investigation. Law enforcement officials can only access Colorado PDMP data through a subpoena or court order for an individual patient, pharmacy or practitioner as part of a bona fide investigation.

This current Colorado law regarding the PDMP is the product of several pieces of legislation concerning the PDMP. As outlined above, the laws regarding law enforcement and licensing board access to PDMP data and the use of unsolicited reporting have evolved over time. In 2005, House Bill 05-1130 (HB 05-1130) first authorized the creation of the Colorado PDMP. In that bill, PDMP data could be released to law enforcement so long as it was “specific to an individual,” was part of a bona fide investigation, and was accompanied by an official court order or subpoena. That bill did not authorize PDMP data to be released to state regulatory boards and did not authorize unsolicited reporting from the PDMP.⁹ Senate Bill 11-192 (SB 11-192) updated law enforcement access to PDMP information, allowing for information to be released so long as it was “specific to an individual patient or prescriber” and was accompanied by a subpoena or court order. SB 11-192 also authorized PDMP data to be released to state regulatory boards so long as the information released was “specific to an individual prescriber” and was accompanied by a court order or subpoena.¹⁰ House Bill 14-1283 (HB 14-1283) expanded law

Knopf, A. (2015). Should law enforcement be required to obtain search warrants for PDMP data? *Alcoholism & drug abuse weekly* 27(11), 1-3. <https://doi.org/10.1002/adaw.30110>

Knox, Ryan. (2020). Fourth Amendment Protections of Prescription Drug Monitoring Programs: Patient Privacy in the Opioid Crisis. *American Journal of Law*, 46(4), <https://doi.org/10.1177/0098858820975531>

Oliva, Jennifer. (2019). Prescription-Drug Policing: The Right to Health Information Privacy Pre- and Post-Carpenter. *Duke L.J.*, 69:775-853. <https://scholarship.law.duke.edu/dlj/vol69/iss4/1>

⁶ Prescription Drug Monitoring Program Training and Technical Assistance Center. (2021). State PDMP Profiles and Contacts. <https://www.pdmpassist.org/State>

⁷ Boustead, Anne E. (2021). “Privacy protections and law enforcement use of prescription drug monitoring databases Texas Health & Safety Code 2018 §481.076(a)(3).” *Law & Policy*, 43(3):229-261. <https://doi.org/10.1111/lapo.12174>

⁸ Texas Health & Safety Code 2018 §481.076(a)(3). <https://statutes.capitol.texas.gov/docs/HS/htm/HS.481.htm>

⁹ https://leg.colorado.gov/sites/default/files/images/olls/2005a_sl_272.pdf

¹⁰ https://leg.colorado.gov/sites/default/files/documents/2022A/bills/2022a_192_eng.pdf

enforcement access by allowing for information to be released so long as it was “specific to an individual patient, pharmacy or practitioner” and was accompanied by a court order or subpoena. HB 14-1283 also authorized the Board of Pharmacy to develop, in consultation with Colorado’s prescribing boards, criteria for indicators of misuse, abuse and diversion of controlled substances, and based on those criteria, provide unsolicited reports to prescribing practitioners and dispensing pharmacies for the purposes of education and intervention to reduce occurrences of controlled substance misuse, abuse and diversion.¹¹ Senate Bill 18-022 (SB 18-022) clarified that unsolicited reports generated by the PDMP are not public records under the “Colorado Open Records Act,” are not discoverable in any criminal or administrative proceeding against a prescribing practitioner, and are not admissible in any civil, criminal, or administrative proceeding against a prescribing practitioner.¹² In each iteration of the PDMP statute, law enforcement and regulatory boards have been granted relatively narrow authority to access PDMP information. Additionally, unsolicited reports from the PDMP have been narrowly authorized to be sent to practitioners and pharmacies using criteria developed by their respective licensing boards while strictly protecting the confidentiality of such unsolicited reports.

When considering the historical context of the Colorado PDMP and comparing how PDMP data can be shared in law enforcement, regulatory oversight or public health contexts in Colorado versus other states’ PDMP statutes and regulations, the Colorado PDMP can best be characterized as a clinical decision support tool more so than a regulatory or law enforcement surveillance tool. And while some states allow for more use by those bodies, there is a trend away from that use. Patrick Knue, director of the national Training and Technical Assistance Center for Prescription Drug Monitoring Programs (PDMP TTAC), told the Deseret News following a 2015 state law change regarding law enforcement access in Utah that there has been a national shift away from these state databases being used as law enforcement tools to them being used primarily as health care tools. “Originally, monitoring programs were all established for the benefit of law enforcement investigating crimes. As the focus has shifted, law enforcement access has been restricted in a number of states.”¹³ That trend has continued since 2015.

Law Enforcement PDMP Access and Privacy Concerns

The Supreme Court has ruled that states are not violating patient confidentiality by simply collecting prescription histories in the PDMP⁶, but they have not yet addressed the legality of law enforcement use of the PDMP under the Fourth Amendment. However, there is some precedent for consideration in this area. Courts have ruled that because prescription drugs are tightly regulated by multiple government entities, individuals have a lower expectation of privacy in highly regulated activities (*DEA v Utah Department of Commerce*, 2016).¹⁴ The Supreme Court recently held that the third-party doctrine does not apply to historical cell phone records because there are strong privacy interests associated with those records and sharing of that information cannot be considered voluntary (*Carpenter v United States*, 2018,

¹¹ <http://www.corxconsortium.org/wp-content/uploads/HB14-1283-as-signed-into-law-052114.pdf>

¹² <https://leg.colorado.gov/bills/sb18-022>

¹³ Evans, Erica. (2017, Dec. 8). How a 2015 law change affected law enforcement’s fight against the opioid crisis. *The Deseret News*. <https://www.deseret.com/2017/12/8/20636896/how-a-2015-law-change-affected-law-enforcement-s-fight-against-the-opioid-crisis>

¹⁴ https://www.govinfo.gov/app/details/USCOURTS-utd-2_16-cv-00611

p 16-17),¹⁵ which some scholars have argued could mean that PDMP protected health information is also entitled to Fourth Amendment warrant protection.^{16,17}

Several lower federal and state courts have considered the issue of whether the Fourth Amendment or state laws protect PDMP information and specifically whether the DEA can access the data. For example, in *Oregon Prescription Drug Monitoring Program v DEA* (2017),¹⁸ the Ninth Circuit held that Oregon's warrant requirement for accessing PDMP information was preempted by the Controlled Substances Act, under which the DEA can obtain evidence to investigate controlled substance-related crimes through an administrative subpoena, overruling a district court opinion that Fourth Amendment protections apply to PDMP information on standing grounds.¹⁹

While the DEA's authority to access PDMP records through an administrative subpoena has been confirmed in several federal courts, legal requirements for PDMP access by local and state law enforcement jurisdictions is largely governed by state statutes. These laws vary with respect to the methods and evidentiary requirements for local and state law enforcement access; thus the legal decisions regarding authority will vary state to state.

Unsolicited Reporting to Law Enforcement and Licensing Boards in Other States

Nearly all states allow for unsolicited reporting from PDMPs, though there is wide variation in the criteria used, the entities eligible to receive unsolicited reports, and the intent of unsolicited reports. Citing the PDMP Policies and Capabilities: Results from 2020 State Assessment by PDMP TTAC,²⁰ (PDMP TTAC) the OSA reported that 37 states allow unsolicited reporting to regulators and 22 states allow unsolicited reporting to law enforcement.²¹

However, our analysis shows that the numbers may be less. A supplementary table in the report referenced by OSA that summarizes PDMP solicited and unsolicited reports to law enforcement indicates that 27 PDMPs reported having the statutory authority to send unsolicited reports to law enforcement, but only 16 PDMPs were engaged in sending such unsolicited reports.²² Analysis of the PDMP TTAC table summarizing PDMP solicited and unsolicited reports to

¹⁵ https://www.supremecourt.gov/opinions/17pdf/16-402_h315.pdf

¹⁶ Oliva, Jennifer. (2019). Prescription-Drug Policing: The Right to Health Information Privacy Pre- and Post-Carpenter. *Duke L.J.*, 69:775-853. <https://scholarship.law.duke.edu/dlj/vol69/iss4/1>

¹⁷ Knox, Ryan. (2020). Fourth Amendment Protections of Prescription Drug Monitoring Programs: Patient Privacy in the Opioid Crisis. *American Journal of Law*, 46(4), <https://doi.org/10.1177/0098858820975531>

¹⁸ <http://cdn.ca9.uscourts.gov/datastore/opinions/2017/06/26/14-35402.pdf>

¹⁹ Boustead, A. E. (2021). Privacy protections and law enforcement use of prescription drug monitoring databases. *Law & policy*, 43(3), 229-261. <https://doi.org/10.1111/lapo.12174>

²⁰ Prescription Drug Monitoring Program Training and Technical Assistance Center, Bureau of Justice Assistance. (2021). PDMP Policies and Capabilities: Results from the 2020 State Assessment. https://www.pdmpassist.org/pdf/PDMP%20Policies%20and%20Capabilities%202020%20Assessment%20Results_20210111.pdf

²¹ Colorado Office of the State Auditor. (March 2021). Department of Regulatory Agencies, Colorado Prescription Drug Monitoring Program Performance Audit. p.31. http://leg.colorado.gov/sites/default/files/documents/audits/1933p_colorado_prescription_drug_monitoring_program.pdf

²² PDMPs Authorized and Engaged in Sending Solicited and Unsolicited Reports to Law Enforcement Entities. https://www.pdmpassist.org/pdf/Law_Enforcement_Entity_Table.pdf

regulators²³ indicates that 36 PDMPs reported having authorization to send unsolicited reports to regulators, but only 19 PDMPs were engaged in sending such unsolicited reports. The lower number actually engaged in sending reports suggests that such unsolicited reporting may have recently ceased or was never implemented in several states. The Task Force was challenged in ascertaining why some states were not engaged in sending unsolicited reports because the specific thresholds, the number of unsolicited reports generated, and the results or impacts of unsolicited reporting are often not publicly reported due to the sensitive nature of such information.

In addition, the 2020 PDMP TTAC State Assessment indicated that states were last asked about unsolicited reporting to law enforcement and licensing/regulatory boards in 2016. The Task Force reviewed other data sources and disseminated a survey to other PDMP administrators to verify the information in the TTAC State Assessment and to gain additional clarity regarding how other states utilize unsolicited reports to law enforcement and licensing boards. The PDMP Task Force survey was disseminated to all other state PDMP administrators and requested additional information regarding law enforcement and regulatory boards access, whether the PDMP sent unsolicited reports to these entities, the criteria used for generating unsolicited reports, and whether any evaluations had been performed on such activities. Eighteen PDMPs (AL, CT, FL, IA, ID, KS, MD, MA, MN, MI, MT, NV, PA, UT, VA, WA, Puerto Rico and Northern Marianas Islands) responded to the survey. See Appendix E for the survey questions. The survey results sometimes conflicted with the information listed on the TTAC Assessment.

Discrepancies between the TTAC Assessment and the Task Force Survey include:

- The TTAC Assessment stated that the Colorado PDMP has the statutory authority to send unsolicited reports to law enforcement and licensing boards, but the Colorado PDMP does not.
- The TTAC Assessment stated that Idaho and Mississippi send unsolicited reports to licensing or regulatory boards. Idaho and Mississippi reported in the Task Force Survey that licensing boards have unrestricted access to PDMP data, but the PDMP does not send unsolicited reports to licensing boards.
- The TTAC Assessment stated that Alabama was engaged in unsolicited reports to licensing boards but did not indicate that Alabama had the authority to do so. Alabama reported in the Task Force Survey that they do not send unsolicited reports to licensing boards.
- Florida and Nevada were listed as not sending unsolicited reports in the TTAC Assessment but reported in the Task Force survey that they send unsolicited reports to licensing boards.
- The TTAC Assessment stated that Connecticut, Massachusetts, Mississippi and Utah send unsolicited reports to law enforcement, but indicated in the Task Force survey that their PDMPs do not send unsolicited reports to law enforcement.
- The TTAC Assessment stated that Nevada does not send unsolicited reports to law enforcement but indicated in the Task Force survey that the PDMP sends unsolicited reports to local and state law enforcement.

Another limiting factor in obtaining accurate information is that the thresholds for disseminating unsolicited reports to law enforcement or licensing boards are not always public.

²³ PDMPs Authorized and Engaged in Sending Solicited and Unsolicited Reports to Regulatory Agencies
https://www.pdmpassist.org/pdf/Regulatory_Entity_Table.pdf

In most states that send unsolicited reports to licensing boards or law enforcement, suspicious activity is often internally reviewed by authorities or committees before sending unsolicited reports. Additionally, the frequency or results of unsolicited reporting are rarely publicly reported. It is therefore difficult to fully understand how such reports are leveraged in other states and even more difficult to assess their effectiveness. However, it appears that unsolicited reports are generally sent to law enforcement or regulatory boards in other states only when there is a high likelihood of illegal or improper behavior after review by individuals or groups with expertise on this topic. Based on published reports and state responses to the Task Force Survey, states which send unsolicited reports to licensing boards or law enforcement require review by experts because PDMP outliers may be due to a practitioner's unique patient population.

Law Enforcement Access to PDMP Data in Other States

The Task Force also evaluated 2016 reports from the National Association for Model State Drug Laws (NAMSDL) summarizing law enforcement access to PDMP data in each state. Neither NAMSDL nor any other organization have published more current summaries of such access, so some states' laws may have changed since the report was published. Maine, Nebraska and Vermont were the only states that did not have a specific provision in their laws for access by law enforcement or judicial authorities. In this 2016 summary, Nebraska was the only state that specifically prohibited law enforcement access. In Maine, information could be released to criminal justice authorities only in response to a grand jury subpoena. Vermont did not allow law enforcement to access PDMP data either directly or upon request, though law enforcement in Vermont could receive reports from health regulatory or licensing agencies when such agencies suspected fraudulent or illegal activity by a dispenser or prescriber.²⁴

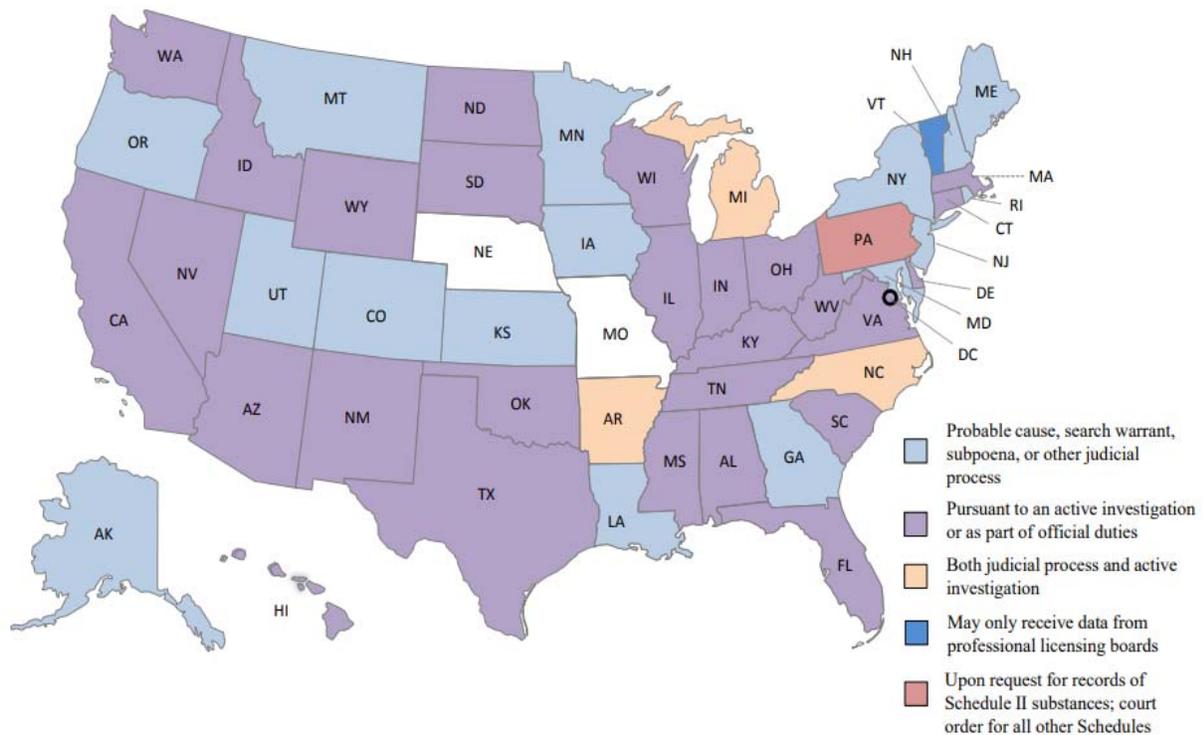
Figure 5 was taken from the 2016 NAMSDL report and displays the status of each state as of 2016:

Figure 5: PDMP Law Enforcement Access Requirements²⁵

²⁴ National Alliance for Model State Drug Laws. (2016, May). Types of Authorized Recipients - Law Enforcement and Judicial Officials. <https://namsdl.org/wp-content/uploads/Law-Enforcement-and-Judicial-Officials.pdf>

²⁵ Ibid.

Types of Authorized Recipients – Law Enforcement Officials



© 2016 The National Alliance for Model State Drug Laws (NAMSDL). Headquarters Office: 100 ½ E. Main Street, Suite C, Manchester, Iowa 52057.

PDMP Task Force Survey Responses Concerning Law Enforcement Access

The PDMP Task Force Survey requested states to detail their requirements and restrictions concerning law enforcement access to PDMP data. All responding states reported allowing law enforcement to access the PDMP, though requirements and the process for accessing the data varies by state as listed below.

Table 4: PDMP Task Force Survey Responses Concerning Law Enforcement Access

State/Territory	Law Enforcement Access Requirements	Restrictions for Access to an Individual Practitioner, Pharmacy or Patient?
Alabama	Probable Cause certification, case number required	Yes
Connecticut	Active Investigation	No
Florida	Active Investigation, case number required	Yes
Idaho	Active Investigation, case number required	Yes
Iowa	Warrant or Court Order	Yes

Kansas	Subpoena	Yes
Maryland	Subpoena	Yes
Massachusetts	Warrant or Court Order	Yes
Minnesota	Required Search Warrant signed by Minnesota Judge	(No response)
Mississippi	Active Investigation, case number required. The Director of the MS Bureau of Narcotics is permitted direct access for criminal prescription investigations.	Yes
Montana	Subpoena	Yes
Nevada	Active Investigation	Yes
Northern Mariana Islands	Subpoena	Yes
Pennsylvania	Open access to schedule II; schedule III-V require a court order	No
Puerto Rico	Law enforcement have access to run pharmacy and prescriber reports. Patient reports require a subpoena.	Yes
Utah	Warrant or Court Order	Yes
Virginia	Active Investigation, case number required	Yes
Washington	In-state law enforcement agencies can access the PDMP for an active investigation. Out of state law enforcement agencies must have subpoena or court order.	Yes

The PDMP Task Force Survey also requested states to detail whether unsolicited reports were sent to law enforcement, which entities receive reports, and what criteria are used. Of the respondents, only Florida, Nevada and Virginia reported sending unsolicited reports to law enforcement. Details regarding these unsolicited reports are listed below:

Table 5: PDMP Task Force Survey Responses Concerning Unsolicited Reporting to Law Enforcement

State	Entities Receiving Unsolicited Reports	Criteria	Information Included
Florida	Local and State Law Enforcement	Multiple provider information	Information concerning individual, prescriber or pharmacy
Nevada	Local and State Law Enforcement	Confidential	Confidential
Virginia	State Law Enforcement	Patients with 6 or more prescribers AND 6 or more pharmacies within 60 days	Previous year of prescription history for the patient to the Virginia State Police Drug Diversion Unit

Licensing Board Access to PDMP Data in Other States

A 2016 NAMSDL report also found that all states except Nebraska, Hawaii and Missouri allowed licensing boards to access PDMP information in connection with an active investigation concerning a licensee or registrant.²⁶ While Colorado requires a subpoena or court order for licensing board access to PDMP data, the subpoena requirement for licensing board access is not substantively different from other states' laws that limit board access to information related to an active investigation against a licensee. Colorado's licensing boards have subpoena authority and therefore, the subpoena requirement for licensing board access in Colorado should be viewed as a method of validating an active investigation into a licensee. A review of a 2016 NAMSDL summary found that over 30 other states' statutes stipulated that licensing boards may request PDMP data in connection with an active investigation concerning a licensee, with some stipulating that a subpoena is required. Sixteen states did not have language in their statutes specifying that licensing board access to PDMP data must be related to a licensee associated with an active investigation in the 2016 report.²⁷

Assessing whether PDMP information is used by licensing boards for purposes other than license discipline was challenging because such uses are rarely mentioned in statute or rule. Only California, Pennsylvania and Washington statutes referenced the use of PDMP data for provider education or practice improvement purposes. Assessing unsolicited reporting of PDMP information to licensing boards through public documents was also challenging because the thresholds and information regarding the number of unsolicited reports sent to licensing boards are often confidential or are not publicly reported. Therefore, the Task Force disseminated a survey to other states' PDMP administrators requesting more information on these topics.

PDMP Task Force Survey Responses Concerning Licensing Board Unsolicited Reporting

The PDMP Task Force Survey also requested states to advise whether unsolicited reports were sent to licensing boards, what criteria were used for such reports, and how that information is used by licensing boards. Six of the 18 states that responded to the PDMP Task Force survey reported sending unsolicited reports to licensing boards. The criteria for generating these reports and how the information is used is listed below:

Table 6: PDMP Task Force Survey Responses Concerning Unsolicited Reporting to Licensing Boards

State	Criteria for Unsolicited Reporting to Licensing or Regulatory Board	How Information is Used
Florida	Multiple provider thresholds	Open investigations into licensees
Iowa	Multiple provider and multiple pharmacy thresholds	Open investigations into licensees, provide informational notices regarding best practices
Massachusetts	Confidential	Open investigations into licensees
Nevada	Top prescribers, prescribers who do not query PDMP before prescribing	Open investigations into licensees

²⁶ National Alliance for Model State Drug Laws. (2016, May). Types of Authorized Recipients - Professional Licensing or Regulatory Boards. <https://namsdl.org/wp-content/uploads/Professional-Licensing-or-Regulatory-Boards.pdf>

²⁷ National Alliance for Model State Drug Laws. (2016, May). Types of Authorized Recipients - Professional Licensing or Regulatory Boards. <https://namsdl.org/wp-content/uploads/Professional-Licensing-or-Regulatory-Boards.pdf>

Pennsylvania	Confidential	Boards do not share details on how the information is used
Virginia	Highest ranked prescribers of opioids and all controlled substances, opioid prescribers with minimal PDMP use, prescribers with patients on high dosages of opioids, dispensers of opioids with high ratio of Schedule II vs Schedule II-V, dispensers with high distances to patients and prescribers	Open investigations into licensees

States with Different Levels of Access for Law Enforcement and Regulatory Boards

The Task Force also reviewed publicly available reports from other states regarding law enforcement and regulatory board access to gather additional information. Notable examples of law enforcement and regulatory access or where such access differs within a state are listed below:

- Oregon requires a valid court order based on probable cause for law enforcement access but provides access to licensing boards in connection with active investigations related to licensure, renewal or disciplinary action involving an applicant, licensee or registrant.²⁸
- Maryland may disclose PDMP data to local, state, or federal law enforcement agencies, certain Maryland health professional licensing boards, and four agencies within the Department of Health to further existing bona fide individual investigations. PDMP data is also disclosed to fatality review teams to further existing case review.²⁹
- New Hampshire requires a valid court order based on probable cause for law enforcement access but allows health care regulatory boards to request PDMP information in an active investigation related to licensure, renewal or disciplinary action involving an applicant, licensee or registrant.³⁰
- Tennessee allows law enforcement to access its Controlled Substance Monitoring Database (CSMD) by submitting a request with a case number corresponding to a criminal investigation. The Tennessee Department of Health and the CSMD Committee, comprising of members of each respective licensing board and the board of pharmacy, monitor the database to detect unusual patterns of prescribing and dispensing of controlled substances. The CSMD Committee may refer this information to licensing boards or law enforcement.
- Louisiana requires a subpoena for law enforcement access but authorizes licensing boards to access PDMP information to enforce PDMP mandates.³¹

²⁸ Oregon Health Authority, Public Health Division. (2020, Jul. - 2021, Sept.). Prescription Drug Monitoring Program Quarterly Reports.

<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SAFELIVING/PDMP/Pages/reports.aspx>

²⁹ Maryland Department of Health. (2019, Jan.). Annual Prescription Drug Monitoring Program Report. <https://health.maryland.gov/pdmp/Documents/HG%2021-2A-05%28f%29%283%29%20-%202018%20PDMP%20Annual%20Report.pdf>

³⁰ New Hampshire Controlled Prescription Health and Safety Program. RSA 318-B 31-38. Annual Report July 1, 2017 - June 30, 2019. <https://www.oplc.nh.gov/sites/g/files/ehbemt441/files/inline-documents/sonh/pdmp-annual-report-2018.pdf>

³¹ Louisiana Board of Pharmacy. (2022). Prescription Monitoring Program Annual Report. FY 2020-2021. https://www.pharmacy.la.gov/assets/docs/PMP/PMP_AnnRpt_2021_Pkg.pdf

- Vermont allows the Department of Health to provide PDMP reports to licensing board investigators pursuant to a bona fide specific investigation, and to a licensee’s occupational licensing or certification authority if the Commissioner of Health reasonably suspects fraudulent or illegal activity by a healthcare provider. The licensing or certification authority may report data that are evidence for the suspected fraudulent or illegal activity to a drug diversion investigator. Drug diversion investigators are not allowed access to PDMP data except for the information provided by the licensing or certification authority.³²
- California’s PDMP is operated by the California Department of Justice and allows law enforcement access in connection with an investigation or prosecution of a violation or possible violation of law related to controlled substances and requires law enforcement to provide a case number and violation code or crime code to obtain a prescriber or dispenser’s information but must also provide a search warrant, court order or subpoena to obtain a patient’s information. Regulatory agency officials may access the database to investigate or evaluate compliance by a licensee with respect to any controlled substance-related requirements and laws including licensees’ PDMP utilization mandates.³³
- With the largest PDMP staff in the nation at 31 full-time equivalent employees, Kentucky allows the Cabinet for Health and Family Services (CHFS), Office of Inspector General (Kentucky OIG), and the Office of Health Data and Analytics (OHDA) to perform data analytics related to opioid prescribing. Kentucky’s Department for Medicaid Services’ Division of Program Integrity (DPI) also uses the information to recover Medicaid overpayments and to educate providers. The Kentucky OIG is required to review PDMP data quarterly to identify trends on inappropriate prescribing or dispensing. The Kentucky OIG Drug Enforcement and Professional Practices Branch (DEPPB) has five staff pharmacist consultants who review prescribing and dispensing PDMP data to identify potential inappropriate or illegal prescribing. DEPPB also receives referrals from the Medicaid/Welfare Fraud Hotline, professional licensure boards, and law enforcement concerning potential overprescribing practitioners or patients who may be “doctor shopping” or diverting controlled substances. Additionally, any evidence of Medicaid fraud is referred to the Kentucky OIG for a preliminary investigation. Depending on the results of its investigation and KASPER query, OIG will either close the case; refer to the appropriate licensure board(s); or refer to Federal, State, or local law enforcement for resolution.

2014 PDMP Center of Excellence Report Regarding Unsolicited PDMP Reporting

The Task Force also reviewed a 2014 report from the PDMP Center of Excellence (the previous name for PDMP TTAC) detailing how certain states sent unsolicited reports to law enforcement and/or licensing boards.³⁴ This report discussed scenarios in which PDMPs sent unsolicited reports to law enforcement or licensing boards regarding suspicious patient or practitioner activity. Responses from twelve states are detailed below.

Unsolicited Reporting Concerning Patients

³² Vermont § 18-84A-4284. <https://legislature.vermont.gov/statutes/fullchapter/18/084A>

³³ California § 825.4. Restrictions on Accessing CURES or Data from CURES. <https://oag.ca.gov/sites/all/files/agweb/pdfs/jdis/cures-sect100-toar-020221.pdf?>

³⁴ PDMP Center of Excellence at Brandeis University. (2014, Jan.). Guidance on PDMP Best Practices: Options for Unsolicited Reporting. <https://www.ojp.gov/pdffiles1/bja/247135.pdf>

North Carolina reported that its law required “unusual patterns” of patient behavior be reported to the Attorney General. The PDMP flagged patients who met a threshold of prescribers and pharmacies suggestive of doctor shopping and controlled substance diversion. The information was carefully reviewed to rule out explanations other than doctor shopping and to find recent indications of behavior change, such as receiving treatment for substance use disorder. At the time of the report, approximately 100 reports had been forwarded to the Attorney General in the previous three years.

In Kansas, a PDMP Advisory Committee, created in 2012, was empowered to “identify patterns and activity of concern” using PDMP data. A volunteer Peer Review Committee of six prescribers and pharmacists reviewed patient reports suggestive of possible doctor shopping and determined whether further action was warranted. If the Committee unanimously determined that further action was warranted, reports were sent to medical providers or law enforcement depending on the level of prescription activity. At the time of the report, the committee sent unsolicited reports to law enforcement on four individuals in the previous year. The Committee judged the level of activity for the four individuals was indicative of organized diversion for which criminal investigation was considered to be appropriate. The Kansas PDMP administration reported to the Task Force that the Peer Review Committee was disbanded on December 31, 2016 and the PDMP is not currently sending unsolicited patient reports to law enforcement.

The Wyoming PDMP advised that they sometimes notified law enforcement officials about individuals who exhibited suspicious behavior such as traveling out of state to obtain prescriptions while simultaneously using local providers. These individuals may not always meet the standard threshold for unsolicited reporting to medical providers and the decision to report to law enforcement was based upon the discretion of PDMP staff in deciding which prescription histories indicate likely instances of abuse or diversion that merit criminal investigations as opposed to instances of possible addiction or abuse best brought to the attention of medical providers.

The Texas PDMP, housed in the Texas Department of Public Safety (DPS), reported routinely conducting data analyses using automated algorithms to identify possible doctor shoppers for law enforcement investigation. Staff would review the data and decide whether to refer the case to investigators within DPS or to another law enforcement agency. Texas reported that an average of 20-25 prescription drug cases were produced for law enforcement investigation at the time of the 2014 report, making it one of the most active PDMPs for this type of reporting.

Unsolicited Reporting Concerning Practitioners

The 2014 report noted that “unsolicited reports on providers are only preliminary, possible indicators of a problem. Determining whether a problem exists, and any further investigation is appropriate, is a matter for further consideration by the body receiving the report.”³⁵

Kentucky reported sending unsolicited reports concerning prescribers to the Drug Enforcement and Professional Practices branch of the Office of the Inspector General (OIG). OIG investigators were registered pharmacists and certified peace officers in Kentucky who reviewed prescription history reports on the top two percent of prescribers in certain categories along with several other factors including their type of practice and prior record of disciplinary action. If the review indicated the likelihood of problematic prescribing, the information was forwarded to

³⁵ Ibid. p 12.

the appropriate licensing board for further review. Kentucky reported that from July 2012 to the time of the 2014 report, unsolicited reports from the Kentucky PDMP triggered over 80 licensing board investigations of prescribers.

Tennessee reported that they provided data to licensing board investigators on the highest-volume prescribers for both the number of prescriptions and total dosage units of certain controlled substances. Tennessee did not provide data regarding outcomes of unsolicited reporting of prescribers to licensing boards.

In addition to notifying law enforcement of suspected doctor-shopping, the Texas PDMP also reported prescribers to their licensing boards or to law enforcement, using PDMP staff's judgment to determine whether to refer medical providers to their licensing boards or to law enforcement agencies.

The New Jersey PDMP reported performing quarterly analysis of PDMP data to identify concerning patterns of prescribing and dispensing. If suspicious departures from normal prescribing were detected, the appropriate law enforcement agency or licensing board was notified, depending on the type and level of suspicious activity.

Finally, the Louisiana PDMP reported that in addition to sending unsolicited reporting of doctor shoppers to practitioners, the PDMP occasionally notified law enforcement about prescribers engaged in suspected diversionary prescribing such as operating pill mills.

Evaluations of Unsolicited Reporting

While unsolicited reports to prescribers and dispensers have been shown to reduce potentially dangerous prescribing and multiple provider episodes by scholars,^{36,37} very little research has been performed to specifically evaluate the effectiveness of PDMP unsolicited reporting to regulatory agencies and law enforcement. Evaluations are challenging due to the complexity of investigations and lack of public information regarding the role of such information in investigations.

A single qualitative study consisting of interviews with stakeholders regarding the effects of implementation and enforcement differences in Connecticut, Kentucky and Wisconsin was found through an extensive search of peer-reviewed papers published in academic journals. This study discussed unsolicited reporting to licensure boards in Kentucky. A perceived consequence of this activity according to interviews was that because of increased scrutiny based on patient histories, some physicians may engage in "patient dumping" which is not just discontinuing opioid prescriptions, but in many cases may lead to a refusal to treat a patient

³⁶ Young L, Kreiner P, Panas L. (2017). Unsolicited Reporting to Prescribers of Opioid Analgesics by a State Prescription Drug Monitoring Program: An Observational Study with Matched Comparison Group. *American Academy of Pain Medicine*, 19:1396-1407. [10.1093/pm/pnx044](https://doi.org/10.1093/pm/pnx044)

³⁷ McDonald D, Carlson K, Jalbert S. (2019). An Experimental Test of the Effectiveness of Unsolicited Reporting by a Prescription Drug Monitoring Program in Reducing Inappropriate Acquisition of Opioids. *Pain Medicine*, 20(5):944-954. <https://pubmed.ncbi.nlm.nih.gov/29868715/>

altogether.³⁸ Consequently, without proper pain management tapering of addictive substances, such as opioids, patients may go into withdrawals that pose a medical danger to themselves. Some of these patients may seek pain medication through illicit means, while others seek similar medication outcomes through heroin and other street drugs since finding another pain management doctor may be a challenging process on short notice.

Very little quantitative data was found to support or dissuade implementation of the questions evaluated in this year's report, and unsolicited reporting was often evaluated in concert with other PDMP activities in the few studies where it was examined. A 2013 study found that states which provided unsolicited reports appeared to be more effective in reducing the per capita supply of Schedule II drugs compared with states that lacked such proactive programs. While opioid prescribing increased over time in the states with monitoring programs, the rate of increase would have been 10 percent higher without proactive programs.³⁹ However, that study only evaluated whether states were engaged in unsolicited reports. It did not specifically assess unsolicited reporting to law enforcement or licensing boards. Another study found that compared to states with no or weak PDMPs, states with proactive PDMPs were associated with fewer deaths attributed to natural/semi-synthetic opioids. Proactive PDMPs were considered those that had a high probability of permitting/requiring unsolicited reporting of outlying patterns to law enforcement, licensing bodies and prescribers/dispensers, a high probability of providing access to PDMP data to law enforcement without requiring a warrant, subpoena, or active investigation, and a high probability of requiring dispensers to report data to the PDMP on a more frequent basis.⁴⁰

Patient outcomes related to law enforcement utilization of PDMP data is markedly absent from the literature. This could be a sign that law enforcement operations are more focused on identifying and punishing illegal behavior rather than focusing on the treatment needs of individuals involved. Accessing patient medical records to assess outcomes after law enforcement intervention with providers or patients can be difficult due to privacy concerns. Accessing data on admissions to substance use treatment for these patients is even more difficult due to limitations from 42 CFR part 2,⁴¹ which includes strict patient privacy requirements regarding any information that would identify an individual as having a substance use disorder. These data limitations are likely at least in part to be responsible for the lack of research on the topic.

Little is known about the full impact of law enforcement access and use of the PDMP, which warrants caution in enacting changes.⁴² Due to the difficulty of tracking patient-specific health and treatment outcomes, further research on prescribing behavior could be warranted as a proxy to understanding the need and impact of law enforcement oversight on opioid prescribing

³⁸ Dickson-Gomez J, Christenson E, Weeks M, et al. (2021, Mar. 25). Effects of Implementation and Enforcement Differences in Prescription Drug Monitoring Programs in 3 States: Connecticut, Kentucky, and Wisconsin. *Substance Abuse: Research and Treatment*, 15:1178221821992349. <https://pubmed.ncbi.nlm.nih.gov/33854323>

³⁹ Deyo RA, Irvine JM, Millet LM, et al. (2013). Measures such as interstate cooperation would improve the efficacy of programs to track controlled drug prescriptions. *Health Affairs*, Mar 2013;32(3):603-13. <https://www.healthaffairs.org/doi/10.1377/hlthaff.2012.0945>

⁴⁰ Cerdá M, Ponicki WR, Smith N, et al. (2020). Measuring Relationships Between Proactive Reporting State-level Prescription Drug Monitoring Programs and County-level Fatal Prescription Opioid Overdoses. *Epidemiology* 31(1):32-42. <https://pubmed.ncbi.nlm.nih.gov/31596794>

⁴¹ 42 U.S.C, Chapter 1, Subchapter A, Part 2 - Confidentiality of Substance Use Disorder Patient Records. (2010, Oct. 1). <https://www.ecfr.gov/current/title-42/chapter-1/subchapter-A/part-2>

⁴² Knopf, A. (2015). Should law enforcement be required to obtain search warrants for PDMP data? *Alcoholism & drug abuse weekly* 27(11), 1-3. <https://doi.org/10.1002/adaw.30110>

while minimizing risks to patients. Without extensive data assessing the effectiveness of such unsolicited reporting on patient outcomes, it is not possible to make evidence-based recommendations regarding unsolicited reports to law enforcement or regulatory boards.

Implications of Lower Requirements for Law Enforcement Access

An examination of the frequency of law enforcement utilization of PDMP based on the level of information needed by law enforcement found that the number of requests made for PDMP data decreases as more evidence is needed to obtain that data. The exception to this trend is when states require training before law enforcement can access PDMP data, which increases the utilization of the PDMP. In states that require probable cause, the rate of PDMP data requests by law enforcement were approximately 6 percent of the rate in states that have no restrictions. States that required a subpoena had an access rate that is approximately 34 percent of the rate in states that place no requirements on law enforcement requests for PDMP data.⁴³ Easier access to PDMP data by law enforcement officers generally indicates PDMP data will be sought more often, even if the data is not beneficial to the case. This can create greater risk of privacy violations and officer misconduct associated with this law enforcement activity.

Privacy breaches have occurred in some states with lower requirements for access. Utah revised its legislation surrounding PDMP access in 2015 after allegations of police abuse.⁴⁴ In 2011, a Utah police officer pled guilty to unlawful use of Utah PDMP information. The officer accessed the prescription history of a couple and then stole opioid medications from the couple during visits to their home that coincided with times they refilled their prescriptions.⁴⁵ In 2013, a Utah detective accessed the PDMP records of 480 firefighters in response to controlled substances disappearing from ambulances.⁴⁶ Utah now requires law enforcement officers to obtain a warrant before accessing PDMP records. The Utah Office of Legislative Auditor General found that in the year prior to the law change, the Utah PDMP was searched 2,851 times by 391 different law enforcement officers. In the six months following the change, only 71 warrants were obtained for access by 45 different officers. The audit also found that under the previous law, which was enacted in 1995, no additional policy guidance was provided to law enforcement and law enforcement interpreted their authority broadly.⁴⁷ Privacy advocates argued this decrease demonstrated that police were using the database recklessly and without reason prior to the change. Police contended that the numbers did not indicate a lack of need, but of the difficulty in obtaining a search warrant.⁴⁸ The audit reported that police previously used PDMP reports to build probable cause for an arrest, but the new law required probable cause to obtain PDMP reports. The DEA successfully sued Utah and won back its rights to use the database

⁴³ Boustead, A. E. (2021). Privacy protections and law enforcement use of prescription drug monitoring databases. *Law & policy*, 43(3), 229-261. <https://doi.org/10.1111/lapo.12174>

⁴⁴ Utah Senate Bill 119. (2015). Prescription Database Revisions. <https://le.utah.gov/~2015/bills/static/SB0119.html>

⁴⁵ Liesik, Geoff. (2013, Feb. 21). Ex-detective sentenced to probation for accessing drug database. <https://www.ksl.com/article/24160826/ex-detective-sentenced-to-probation-for-accessing-drug-database>

⁴⁶ Rombo, Dennis. (2015, Apr. 24). Unwarranted drug database search prompts new Utah law, lawsuits. *The Deseret News*. <https://www.deseret.com/2015/4/24/20563342/unwarranted-drug-database-search-prompts-new-utah-law-lawsuits>

⁴⁷ Office of Legislative Auditor General, State of Utah. (2015, Dec. 15). A Review of the Use of the Controlled Substance Database by Law Enforcement. Report Number ILR 2015-E. https://le.utah.gov/audit/15_eilr.pdf

⁴⁸ Evans, Erica. (2017, Dec. 8). How a 2015 law change affected law enforcement's fight against the opioid crisis. *The Deseret News*. <https://www.deseret.com/2017/12/8/20636896/how-a-2015-law-change-affected-law-enforcement-s-fight-against-the-opioid-crisis>

through administrative subpoena (*DEA v Utah Department of Commerce*, 2016), but local and state police still must obtain a warrant to access the PDMP.

In 2013, a Florida state attorney released the records of more than 3,300 individuals to attorneys of defendants accused of prescription fraud. This breach of privacy caused the Florida State Legislature to propose changes to PDMP regulations to improve privacy.⁴⁹

Implications of Law Enforcement and Regulatory Scrutiny for Practitioners and Patients

Legal scholars, academic studies and national media reports indicate that the increased regulatory and law enforcement scrutiny of controlled substance prescribing is resulting in some practitioners refusing to treat patients on long-term opioid therapy or on high doses of opioids for fear of regulatory action or prosecution, resulting in chronic pain patients struggling to find care. While only a few hundred doctors had been incarcerated in prosecutions related to over-prescribing between 1999 and 2015, over 3,000 physicians have surrendered their license to the DEA between 2011 to 2015, according to figures obtained by the Pittsburgh Post-Gazette in 2016.⁵⁰ Prosecutions of practitioners under the Controlled Substances Act of 1970 are also being scrutinized. The Supreme Court is also currently considering petitions by two practitioners (*Ruan v. United States*) prosecuted for violations of the Controlled Substances Act of 1970 which requires that prescriptions “must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” The Court will consider whether physician intent - namely, whether they prescribed in good faith - is relevant to that standard.⁵¹ The Court’s decision could have profound impacts on prosecutions of practitioners for violations of the Controlled Substances Act.

Concerns about the unintended consequences of the increasing scrutiny on prescribers have also been widely reported in national media and major newspapers. Numerous articles cite perceptions from practitioners, patients and other stakeholders which suggest that federal investigations and state laws aimed at addressing the opioid epidemic have created unintended consequences, with practitioners fearing prosecution for their prescribing behavior, which has made finding appropriate care for those with chronic pain increasingly difficult.⁵² In addition,

⁴⁹ Kam, D. (2013, Aug. 27). Proposed changes to Florida prescription drug database under fire. *Palm Beach Post*. <https://www.palmbeachpost.com/story/news/state/2013/08/27/proposed-changes-to-florida-prescription/7163220007/>

⁵⁰ Lord, Rich and Silber, Maia. (2016, Aug. 12). Feds have taken thousands of prescribing licenses. *Pittsburgh Post-Gazette*. <https://www.post-gazette.com/news/overdosed/2016/08/12/Feds-have-taken-thousands-of-prescribing-licenses/stories/201608120095>

⁵¹ Gluck, Abbe. (2022). Amid overdose crisis, court will weigh physician intent in "pill mill" prosecutions and more under the Controlled Substances Act. *Scotus Blog*. <https://www.scotusblog.com/2022/02/amid-overdose-crisis-court-will-weigh-physician-intent-in-pill-mill-prosecutions-and-more-under-the-controlled-substances-act/>

⁵² See, for example:

Hoffman, Jan. Were These Doctors Treating Pain or Dealing Drugs? (2022, Feb. 28). *New York Times*. <https://www.nytimes.com/2022/02/28/health/doctors-painkillers-supreme-court.html>

Stone, Will. (2022, Apr. 9). CDC weighs new opioid prescribing guidelines amid controversy over old ones. *National Public Radio*. <https://www.npr.org/sections/health-shots/2022/04/09/1091689867/opioid-prescribing-guidelines-pain>

Stone, Will. (2018, Jul. 7). Patients With Chronic Pain Feel Caught In An Opioid Prescribing Debate. *National Public Radio*. <https://www.npr.org/sections/health-shots/2018/07/08/622729300/patients-with-chronic-pain-feel-caught-in-an-opioid-prescribing-debate>

Krans, Brian. (2016, May 19). More ‘Pill Mill’ Doctors Prosecuted Amid Opioid Epidemic. *Healthline*. <https://www.healthline.com/health-news/pill-mill-doctors-prosecuted-amid-opioid-epidemic-fb?c=576727996312#1>

it has been suggested in one legal journal article that as pill mills become less prevalent, the factors used to identify pill mills are capturing other providers who are not engaged in such activities.⁵³

These perceptions have also been cited in peer-reviewed academic reports and articles in medical journals. For example, one article involved a focus group study with PDMP staff, law enforcement officials and administrative agency employees in Florida, Kentucky, New Jersey and Ohio reported that officials in multiple states had concerns about compromised access to pain medications for patients due to providers using PDMP data to “fire” patients without ensuring they were transferred to a pain management or addiction specialist. Officials were also concerned that patients forced to taper or experiencing interruptions in their opioid medications might resort to illicit opioids.⁵⁴ Another study consisted of in-depth interviews with key informants in Connecticut, Kentucky and Wisconsin from a variety of backgrounds who had experience with PDMPs. Informants reported that unintended consequences of state PDMPs included under-prescribing for pain and ‘dumping’ patients who were long term users of opioids or who had developed opioid use disorders, which may explain the increase in illicit heroin or opioid use.⁵⁵ A 2017 American Journal of Medicine article addresses physicians’ concerns about liability risks related to opioid prescribing, and provides recommendations on how to avoid liability by following established guidelines and best practices.⁵⁶ Other researchers found that law enforcement’s involvement in prosecuting physicians and uncertainty regarding how a patient’s prescription history would be interpreted by law enforcement resulted in physicians disciplining patients to shield themselves from liability. Such disciplinary measures include pain management quasi-legal “contracts” that are otherwise uncommon in the practice of medicine.⁵⁷ Such contracts often require strict patient compliance and violations of these contracts can result in the patient being released by the practitioner. When patients abruptly

Satel, Sally. (2019, Aug. 4). The Truth About Painkiller Addiction. *The Atlantic*.

<https://www.theatlantic.com/ideas/archive/2019/08/what-america-got-wrong-about-opioid-crisis/595090/>

Llorente, Elizabeth. (2018, Dec. 10). As doctors taper or end opioid prescriptions, many patients driven to despair, suicide. *Fox News*. <https://www.foxnews.com/health/as-opioids-become-taboo-doctors-taper-down-or-abandon-pain-patients-driving-many-to-suicide>

Silverglate, Harvey. (2015, Jun. 12). When Treating Pain Brings a Criminal Indictment. *The Wall Street Journal*.

<https://www.wsj.com/articles/when-treating-pain-brings-a-criminal-indictment-1434148923>

Nedelman, Michael. (2017, Jul 31). "Doctors Increasingly Face Charges for Patient Overdoses." *CNN*.

<https://www.cnn.com/2017/07/31/health/opioid-doctors-responsible-overdose/index.html>

Hadley, Megan. (2018, Dec. 12). Are Pain Doctors Wrongly Taking the Blame for the Opioid Crisis? *The Crime Report*. Center on Media Crime and Justice at John Jay College. <https://thecrimereport.org/2018/12/12/are-pain-doctors-wrongly-taking-the-blame-for-the-opioid-crisis/>

⁵³ London, Cathleen. (2022). DOJ Overcriminalization: Prosecuting Physicians.

<http://dx.doi.org/10.2139/ssrn.4050914>

⁵⁴ Yuanhong Lai, Alden et al. (2019) Perceived Unintended Consequences of Prescription Drug Monitoring Programs, *Substance Use & Misuse*, 54(2): 345-349. <https://pubmed.ncbi.nlm.nih.gov/30463465>

⁵⁵ Dickson-Gomez, Julia et al. (2021). Effects of Implementation and Enforcement Differences in Prescription Drug Monitoring Programs in 3 States: Connecticut, Kentucky, and Wisconsin. *Substance Abuse: Research and Treatment*, Vol. 15:1-13. <https://pubmed.ncbi.nlm.nih.gov/33854323>

⁵⁶ Yang et al. (2017). Managing Increasing Liability Risks Related to Opioid Prescribing. *American Journal of Medicine*, 130(3): 249-250. <https://doi.org/10.1016/j.amjmed.2016.08.041>

⁵⁷ Hussain, Mustaffa and Bowker, Geoffrey. (2021). Phenotyping as disciplinary practice: Data infrastructure and the interprofessional conflict over drug use in California. *Big Data & Society*, July-December: 1-5.

<https://doi.org/10.1177/20539517211031258>

lose access to care, they are put at increased risk of resorting to illicit substances to mitigate withdrawal symptoms, which may lead to accidental overdose and suicide.⁵⁸

Two additional studies document the challenges experienced by chronic pain patients when needing to find a new provider. In 2021, 28 pain management clinics abruptly closed in California, leaving approximately 20,000 patients without pain management. Those who were on long-term opioid therapy were given 30 days of medication and were instructed to contact their primary care clinicians or find a new pain management provider. Many patients quickly found that their primary care clinicians were unwilling to prescribe opioids. Patients without a current primary care provider learned that almost no prospective new providers would prescribe opioids to new patients, and some would not prescribe opioids at all. Referrals to pain-management specialists took as long as 6 months, leaving them without care for extended periods. Many of these patients went from emergency department to emergency department trying to obtain medications to avert opioid withdrawal.⁵⁹ In the second study, researchers called 452 primary care clinics in nine states as simulated chronic pain patients under two scenarios for needing a new provider: their previous physician had either 1) retired or 2) stopped prescribing opioids for unspecified reasons. Of the clinics that responded to both scenarios, 43% said their providers would not prescribe opioids in either scenario, 32% said their providers might prescribe in both, and 25% responded differently to each scenario, with clinics being less likely to be willing to prescribe when the previous doctor stopped prescribing for unspecified reasons.⁶⁰

Research is only beginning to explore patient outcomes associated with prescribing restrictions and heightened regulatory oversight on prescribing behavior. Even less is known about the impact of criminal justice utilization of PDMP data on patients. Information has not been collected on patient outcomes related to law enforcement use of the PDMP to identify and disrupt illegal practices of opioid prescribing. If Colorado law expands PDMP access to law enforcement or licensing boards, prescribers may perceive that they are at increased risk of criminal or board investigation for prescribing to patients with complex conditions or on long-term and/or high dose opioid therapy, which could make finding care a challenge for certain patients.

Unintended Consequences in Implementing Clinical Guidelines and Prescribing Limitations

The unintended consequences of misapplying the CDC's 2016 Opioid Guideline for Prescribing Opioids for Chronic Pain (CDC Opioid Guidelines)⁶¹ to pursue or enact strict limitations on opioid prescribing could be enlightening for review of the two tasks in this report. In 2019, the authors of the CDC Opioid Guidelines acknowledged that some practitioners, government agencies, and

⁵⁸ Rosenberg, Jack, MD et al. (2017). Opioid Therapy for Chronic Pain: Overview of the 2017 US Department of Veterans Affairs and US Department of Defense Clinical Practice Guideline, *Pain Medicine* 19(5): 928-921. <https://doi.org/10.1093/pm/pnx203>

⁵⁹ Coffin, Phillip, M.D. and Barrevel, Antje, M.D. (2022, Feb. 17). Inherited Patients Taking Opioids for Chronic Pain - Considerations for Primary Care. *New England Journal of Medicine*, 386:611-613. <https://www.nejm.org/doi/full/10.1056/NEJMp2115244>

⁶⁰ Lagisetty, Pooja; et al. (2021). Assessing reasons for decreased primary care access for individuals on prescribed opioids: an audit study, *PAIN*, 162(5): 1379-1386. <https://pubmed.ncbi.nlm.nih.gov/33230009>

⁶¹ Dowell, Deborah, M.D., M.P.H., Haegerich, Tamara, Ph.D., and Chou, Roger, M.D. (2016). CDC Guideline for Prescribing Opioid for Chronic Pain. - United States, 2016. *Morbidity and Mortality Weekly Recommended Report*; 65(No. RR-1):1-49. <http://dx.doi.org/10.15585/mmwr.rr6501e1>

state governments were misapplying the guidelines in several ways.^{62,63} In response to challenges in implementation and misapplication of the 2016 Guidelines, the CDC submitted an updated Clinical Practice Guideline for Prescribing Opioids draft for public comment in 2022.⁶⁴ These draft updated guidelines no longer include specific limits on the dose and duration of an opioid and emphasize that clinicians should use their own judgment in deciding what will be a safe and effective dose for each patient and reiterate that the Guidelines are not “intended to be applied as inflexible standards of care” or as “law, regulation or policy that dictates clinical practice.” The final Guidelines are expected to be released in late 2022. Additional information regarding the unintended consequences and misapplication of these guidelines and an example of how Arizona may have misapplied these guidelines to enact strict limits on opioid prescribing dosages and durations can be found in Appendix F.

Unlike other states that seemingly misapplied the CDC Guidelines as justification for implementing limits on opioid prescribing, Colorado adopted the Guidelines for the Safe Prescribing and Dispensing of Opioids.⁶⁵ This document “provides guidelines and represents the Boards’ current thinking on this topic. It does not set a standard of care for prescribers or dispensers. Practitioners may use an alternative approach provided the approach satisfies the requirements of the applicable statutes, regulations, and standard of care.” The Colorado Guidelines were first adopted in October 2014 and were revised in March 2018 and again in March 2019. The Colorado Guidelines include recommendations that practitioners perform additional assessments when prescribing a dosage above 50 MME per day, to reassess pain and function within 30 days of initiating opioid therapy to ensure a clear benefit, and if an opioid treatment exceeds 90 days for chronic, non-cancer pain to: 1) ensure the patient continues to show clinical improvement with opioid therapy; 2) ensure the benefits of continued opioid therapy outweighs the risk; and 3) ensure additional risk mitigation strategies are in place. The Colorado Guidelines reflect Colorado’s approach to addressing the opioid epidemic in which practitioners are empowered to make prescribing decisions using their professional judgment, supported by evidence-based guidelines and where the PDMP is considered a clinical decision support tool providing practitioners with information to help them decide what is best for each patient, rather than imposing hard limits on prescribers and their patients.

Stakeholder Outreach and Feedback

Cognizant of the controversial nature of law enforcement and regulatory access to PDMP information and the unintended consequences of increasing scrutiny and regulation of practitioners and opioid prescribing, the Task Force sought feedback from Colorado stakeholders regarding the two tasks evaluated in this report through a virtual stakeholder meeting on April 28, 2022. Stakeholders were also given the opportunity to submit written

⁶² Dowell, Deborah, M.D., M.P.H., Haegerich, Tamara, Ph.D., and Chou, Roger, M.D. (2019). No Shortcuts to Safer Opioid Prescribing. *New England Journal of Medicine*, 380: 2285-2287. <https://www.nejm.org/doi/full/10.1056/NEJMp1904190>

⁶³ Centers for Disease Control and Prevention. (2019). Media Release. CDC Advises Against Misapplication of the *Guideline for Prescribing Opioids for Chronic Pain*. <https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html>

⁶⁴ Centers for Disease Control and Prevention. Federal Register Notice: CDC’s updated Clinical Practice Guideline for Prescribing Opioids is now open for public comment. <https://www.cdc.gov/media/releases/2022/s0210-prescribing-opioids.html>

⁶⁵ Colorado Department of Regulatory Agencies, Division of Professions and Occupations. (Revised 2019, May 14). Guidelines for the Safe Prescribing and Dispensing of Opioids. <https://drive.google.com/file/d/19xrPqsCbaHHA9nTD1F13NeCn5kwK60zR/view>

comments. The Division sent invitations to all Colorado-licensed prescribers and pharmacists as well as key stakeholders that previously participated in stakeholder meetings on topics affecting prescribers and pharmacists. The Division also coordinated with the Consortium to share the invitation with members of other Consortium working groups, Consortium members and patient advocates. Members of law enforcement were also invited, including the DEA Diversion Denver Field office. Over 190 individuals registered for the virtual meeting and approximately 80 attended. Thirteen individuals provided oral commentary concerning these items during the meeting and another eight submitted comments through the meeting chat. Another eight individuals or organizations submitted written comments. Ten of the thirteen individuals who provided comments during the stakeholder meeting were current or former DEA-licensed practitioners while the other three were the Executive Director of the Colorado Center for Prescription Drug Abuse Prevention at the University of Colorado, a Senior Program Manager for the Colorado Consortium for Prescription Drug Abuse Prevention, and the Senior Director of Policy at the Colorado Medical Society. Written comments were submitted by five individual DEA-licensed practitioners including one Physician Assistant, an addiction medicine physician in Western Colorado, an emergency physician, an optometrist, a psychiatric nurse practitioner, as well as the Colorado Society of Addiction Medicine (COSAM), the Colorado Psychiatric Society and the DEA Diversion Program Manager of the DEA Denver Field Division.

Stakeholder Feedback Regarding Law Enforcement Access

Except for the DEA, commenters were overwhelmingly against the prospect of ending the subpoena or court order requirement for law enforcement access to PDMP data and were opposed to unsolicited reporting to law enforcement. Commenters cited concerns including possible impacts on patient privacy and that the perceived loss of patient privacy could discourage individuals from seeking care and may instead turn to illicit substances. Concerns about law enforcement lacking the training or expertise to interpret prescription records arose, as well as reduced accountability for law enforcement if a subpoena or court order was not required. Several stakeholders reported that they had been involved with the PDMP since its inception and stressed that the PDMP was always intended to be a clinical decision support tool in Colorado, and that these questions regarding law enforcement and board access were raised when previous PDMP bills were considered and adopted and consistently it was decided to not allow this. A comprehensive summary of stakeholder feedback regarding law enforcement access can be found in Appendix G.

Stakeholder Feedback Regarding Licensing Board Access and Unsolicited Reporting

Stakeholders had fewer comments regarding licensing board access or unsolicited reporting to licensing boards. Several stakeholders were opposed to sending unsolicited reports to licensing boards. Multiple commenters advised that unsolicited reporting to licensing boards may be appropriate for significant or extreme outliers but recommended that the specific parameters be determined by licensing boards and/or otherwise clearly stated for transparency. Several expressed concern that the increased scrutiny of prescribers by their licensing boards could deter some prescribers from treating patients with complex or chronic pain, those currently on high doses of opioids, or those with substance use disorders.

If the General Assembly chooses to grant licensing boards additional PDMP access or the authority to receive unsolicited reports, stakeholders felt that such reporting should be used with caution. In addition, the parameters of such reports should only identify extreme outliers and should be scrutinized by experts to account for other potential explanations before sharing

with licensing boards and to ensure transparency and accountability. A comprehensive summary of stakeholder feedback regarding licensing board access can be found in Appendix H.

Limitations and Risks of Unsolicited Reporting

The OSA audit identified unsolicited reporting to law enforcement and licensing boards as a best practice based on a 2020 PDMP TTAC report of PDMP policies and capabilities⁶⁶ when recommending that licensing boards and law enforcement should be granted additional access to PDMP information including the statutory authority to receive unsolicited reports from the PDMP due to the continued danger of opioids to Coloradans. In citing justification for these recommendations, OSA reported that in 2018 and 2019, of the 1.4 million Coloradans who received an opioid prescription, nearly 8,700 patients received opioid prescriptions from 10 or more prescribers, and about 1,200 patients received opioid prescriptions from 15 or more prescribers. OSA also reported that after excluding prescribers in pain management, hospice and palliative care, oncology, and surgery specialties, 85 prescribers prescribed at least 26 times the number of opioids as the average for all other prescribers.

These outliers may represent patients who are doctor-shopping and practitioners who are practicing outside the accepted standards of their discipline, but as noted in a 2014 PDMP TTAC guidance document regarding unsolicited reporting, "unsolicited reports (and PDMP data in general) are themselves never conclusive evidence of aberrant behavior, but simply one piece of information ... in determining whether an investigation or intervention should be initiated."⁶⁷ PDMP data does not include information regarding the reason a prescription was written or the patient's medical condition, and it is not clear based on PDMP data whether a patient's multiple providers are working collaboratively with each other. Patients may meet multiple provider episode thresholds because they lack a primary health care provider and must rely on emergency departments or urgent care clinics or may have inadequately treated mental illness or substance use disorder or be experiencing other issues preventing them from receiving stable and consistent health care. The unsolicited reports currently sent in Colorado alert a patient's treating providers of multiple provider and multiple pharmacy episodes while advising that no conclusions or judgments are made based on the information. Instead, the unsolicited reports ask the patient's treating providers to review the patient's prescription history and take whatever action they deem appropriate to improve patient safety. Under this current structure, a patient's providers can determine whether a patient's prescription history is appropriate without fear that such unsolicited reports might be used as the basis for a board or criminal investigation. Additionally, while some states criminalize "doctor shopping," this is not a crime in Colorado. Reporting patients whose prescription history suggests possible diversion to law enforcement creates additional stigma against patients with substance use disorders and creates elevated risk that these individuals will avoid seeking treatment and will instead resort

⁶⁶ PDMP TTAC. (2021). PDMP Policies and Capabilities: Results from 2020 State Assessment. p. 6. https://www.pdmpassist.org/pdf/PDMP%20Policies%20and%20Capabilities%202020%20Assessment%20Results_20210111.pdf

⁶⁷ Prescription Drug Monitoring Program Center of Excellence. (2014, October; Updated 2016, May). Guidance on PDMP Best Practices: Options for Unsolicited Reporting (Waltham, MA: Brandeis University). <https://www.ojp.gov/pdffiles1/bja/247135.pdf>

to illicit drugs,⁶⁸ where the risk of accidental overdose is exceptionally high with the current illicit market saturation of fentanyl contaminating heroin, counterfeit prescription pills, and other illicit substances.

PDMP Task Force Recommendations

Based on the research and stakeholder input outlined above, the Task Force makes the following recommendations in furtherance of its stated objective to make the PDMP a more effective tool to improve medication safety and reduce prescription drug abuse and misuse in Colorado.

Recommendations Regarding Task #1: Evaluate Effectiveness of Unsolicited Reporting to Licensing Boards of Licensees' Prescribing Activity

The General Assembly should proceed with caution when considering changes to current law regarding licensing board access and unsolicited reporting from the PDMP. Such a change would be counter to the history of the use of the PDMP in Colorado as a clinical tool for prescribers. It would also be counter to national trends where PDMPs are increasingly leveraged as clinical decision support tool rather than a law enforcement and regulatory tool. Furthermore, the Task Force could not find evidence that unsolicited reporting of prescribing or dispensing activity to licensing boards has benefitted patient safety but found evidence that increasing regulatory and law enforcement scrutiny of prescribing has created unintended consequences for patients by discouraging practitioners from treating patients with chronic pain or on long-term opioid therapy. While the Task Force does not recommend authorizing unsolicited PDMP reporting to licensing boards, if the General Assembly determines that the PDMP should proactively notify licensing boards of practitioners who are outliers compared to others based on criteria such as high prescribing volume or who consistently have patients who meet multiple provider thresholds, a cautious first step would entail granting licensing boards the authority to determine the criteria, requiring transparency in what criteria are used to generate such reports and how the information could be used, and requiring that de-identified data be reviewed by an expert committee to ensure that alerts are only sent when there is a high likelihood of professional misconduct or criminal activity.

With the opioid crisis evolving from the first wave when overdoses were driven by excessive prescribing and dispensing of prescription opioids, to the second wave beginning around 2010 when heroin overdoses began increasing, to the third wave beginning around 2013 when illicit fentanyl emerged as a major cause of overdose deaths, PDMPs are most effective when utilized by practitioners as a patient safety and clinical decision support tool. Because patients' comprehensive medical history is not often accessible to their treating providers, PDMPs provide a data point in a patient's medical history that provides clinical value to practitioners by avoiding potentially dangerous combinations of prescription medications and identifying at-risk individuals and those with substance use disorders. Rather than enabling unsolicited reporting to licensing boards to improve PDMP effectiveness and address the opioid epidemic, other initiatives that strengthen the PDMP as a clinical decision support and public health tool may have greater impact.

⁶⁸ Kunkel, T. The Stigmatization of Justice-involved Individuals with Substance Use Disorders: Perspectives from Criminal Justice Practitioners and those with Lived Experience. Washington, DC: Legislative Analysis and Public Policy Association. 2021. <http://legislativeanalysis.org/wp-content/uploads/2022/03/The-Stigmatization-of-Justice-involved-Individuals-with-Substance-Use-Disorders.pdf>

Recommendations Regarding Task #2: Evaluate the Effects of Allowing Law Enforcement Access to PDMP data without Requiring a Subpoena or Court Order

The General Assembly should also proceed with caution when considering changes to current law regarding law enforcement access to PDMP data. The Task Force does not recommend changes to Colorado law regarding law enforcement access to PDMP data. Such a change would be counter to the history of the use of the PDMP in Colorado as a clinical tool for prescribers. In addition, the Task Force could not find evidence that lower barriers to law enforcement access are associated with beneficial outcomes to patients or decreased aberrant controlled substance prescribing by providers. Where evaluations of such activities have been performed, qualitative data suggests that such oversight can have a chilling effect on practitioners, creating downstream effects on patients. Patients on long-term opioid therapy, or those on high doses, report challenges in finding appropriate care, especially when attempting to find a new provider. These challenges appear to be due in part to practitioners increasingly fearing criminal, civil or regulatory investigations which places those patients at greater risk of resorting to illicit substances that carry a higher risk of overdose or suicide. Such unintended consequences have been reported following a variety of measures and laws to increase regulatory and law enforcement scrutiny of prescribing activity and appear to cause some practitioners to avoid treating new or existing patients and drive vulnerable patients to seek illegal and unsafe illicit drugs.

Though the Task Force found that some other states provide greater PDMP access to law enforcement and regulatory entities than in Colorado, we could not find evidence that such activities have had a positive effect on the health and safety of residents in those states. Such strategies reflect the approaches seen in the first wave of the opioid crisis, when prescription opioid abuse drove the opioid crisis. While PDMP data has an important role in investigating those who violate the Controlled Substances Act or perpetrate Medicaid or Medicare fraud, unsolicited reporting from the PDMP could create perceptions that practitioners in Colorado were increasingly scrutinized and at a higher risk of disciplinary action, criminal prosecution, or civil liability. The Task Force found evidence that such perceptions by practitioners have created challenges for some patients in finding appropriate care as some practitioners are reticent to treat patients with chronic pain, those who are on long-term opioid therapy, and those on high dosages of opioids.

While the Task Force does not recommend authorizing unsolicited PDMP reporting to law enforcement due to a lack of evidence regarding the benefits of such activity, if the General Assembly determines that the PDMP should proactively notify law enforcement of practitioners who are outliers compared to others based on criteria such as high prescribing volume, a cautious first step would entail granting licensing boards and/or an expert committee the authority to determine the criteria and review potentially problematic prescribing or dispensing before sharing the information with law enforcement to ensure that data is only released when there is a high likelihood of criminal activity.

Governmental responses to the opioid crisis and overdose epidemic have evolved in recent years. While those with SUDs are frequently involved in the criminal justice system, treatment-focused approaches are becoming more prevalent as comprehensive drug abuse treatment to criminal offenders reduces both substance abuse and recidivism including here in Colorado.¹¹ PDMPs have similarly evolved from a law enforcement tool to a patient safety and clinical decision support tool. In the initial phase of PDMP implementation, most states focused on the collection of prescription data to identify illegal activity by practitioners as well as

patients who obtained large quantities of prescriptions from multiple practitioners and diverted excess medications to the illicit market. PDMPs were effective in identifying the bad actors who fueled the first wave of the opioid crisis in this initial phase but utilization by practitioners was still a work in progress. Organized diversion through pill mills, complicit pharmacies, and patients obtaining substances in large quantities has become far less prevalent in recent years due in part to PDMPs as well as greater law enforcement and regulatory scrutiny of prescription opioids.

Rather than enabling greater law enforcement access to improve PDMP effectiveness and address the opioid epidemic, other initiatives that strengthen the PDMP as a clinical decision support and public health tool may have greater impact. To understand how the PDMP can help address the opioid crisis through a clinical decision support and public health lens, it is important to understand the role of controlled prescription drugs with respect to the development of substance use disorders and unintentional patient harm as discussed in Appendix F.

Future Evaluation Considerations

State-level responses to the opioid crisis over the past two decades have varied widely, and researchers' attempts to assess these laws' impacts have often struggled to differentiate the impact of these laws from other initiatives that were simultaneously implemented in response to the opioid overdose epidemic.^{69,70,71} A comprehensive analysis of CMS's State Drug Utilization Data including all outpatient prescriptions covered by Medicaid fee-for-service and managed care in all 50 states from 2011 through 2016 found that states with PDMP use mandates had an 8.9% reduction of opioid prescriptions, while states without comprehensive use mandates had no statistically significant reductions. Comprehensive use mandates requiring prescribers to query the PDMP before prescribing certain controlled substances were also associated with a 4.3% reduction in opioid-related inpatient hospital stays and a 17.8% reduction of opioid-related emergency department visits, while states without comprehensive use mandates had no statistically significant reductions.⁷² The authors also suggest that use mandates may help promote referrals to opioid use disorder treatment. This is consistent with others who found PDMPs to be effective only if practitioners are required to check a patient's PDMP history prior to prescribing,⁷³ and another that found the rate of opioid-related deaths declined in states in the year after PDMP implementation and states whose PDMPs had more robust features such as unsolicited reports to providers and PDMP use mandates requiring the PDMP be queried in

⁶⁹ Ayres, Ian and Jalal, Amen. (2018). The impact of prescription drug monitoring programs on U.S. opioid prescriptions. *The Journal of Law, Medicine & Ethics*, 46. 387-403. <https://pubmed.ncbi.nlm.nih.gov/30146997>

⁷⁰ Goldstick JE, et al. (2021). Changes in Initial Opioid Prescribing Practices After the 2016 Release of the CDC Guideline for Prescribing Opioids for Chronic Pain. *JAMA Netw Open*. 4(7). [10.1001/jamanetworkopen.2021.16860](https://doi.org/10.1001/jamanetworkopen.2021.16860)

⁷¹ Dickson-Gomez, Julia et al. (2021). Effects of Implementation and Enforcement Differences in Prescription Drug Monitoring Programs in 3 States: Connecticut, Kentucky, and Wisconsin. *Substance Abuse: Research and Treatment*, 15: 1-13. [10.1177/1178221821992349](https://doi.org/10.1177/1178221821992349)

⁷² Ayres, Ian and Jalal, Amen. (2018). *The Journal of Law, Medicine & Ethics*, 46:387-403. [10.1177/1073110518782948](https://doi.org/10.1177/1073110518782948)

⁷³ McDonald D, Carlson K, Jalbert S. (2019, May 1). An Experimental Test of the Effectiveness of Unsolicited Reporting by a Prescription Drug Monitoring Program in Reducing Inappropriate Acquisition of Opioids. *Pain Medicine*, 20(5):944-954. [10.1093/pm/pny095](https://doi.org/10.1093/pm/pny095)

certain circumstances experienced greater reductions in deaths than those with less robust features.⁷⁴

Conversely, a 2022 study analyzing the effect of PDMP statutes suggests that declines in opioid prescribing have not been driven by state opioid prescribing laws and may be driven more by shifting clinical guidance, changing professional norms, or other factors.⁷⁵ Others argue that more robust state PDMPs are associated with higher rates of heroin-related deaths, potentially due to decreases in opioid availability,^{76,77} while a 2018 National Institute on Drug Abuse publication states:

It is not clear whether the increased availability of heroin is causing the upsurge in use or if the increased accessibility of heroin has been caused by increased demand. A number of studies have suggested that people transitioning from abuse of prescription opioids to heroin cite that heroin is cheaper, more available, and provides a better high. Notably, the street price of heroin has been much lower in recent years than in past decades... In a recent survey of people in treatment for opioid addiction, almost all—94 percent—said they chose to use heroin because prescription opioids were "far more expensive and harder to obtain."⁷⁸

PDMPs have been strengthened as clinical decision support tools in recent years, resulting in broader utilization by practitioners due to use mandates and the expansion of PDMP integration with electronic health records, health information exchanges and electronic prescribing software. These initiatives are only one part of the comprehensive approach toward addressing the opioid and overdose epidemics. For example, the CDC's Overdose Data to Action (OD2A) grant is a four-year cooperative agreement launched in September 2019 with 66 jurisdictions comprising state, territorial, county, and city health departments focused on understanding and tracking the complex and changing nature of the drug overdose epidemic and highlights the need for an interdisciplinary, comprehensive, and cohesive public health approach with seamless integration of data into prevention strategies.⁷⁹ OD2A provides funding to PDMPs to advance their development and expansion as public health surveillance and clinical decision-making tools.⁸⁰ These efforts to enhance PDMPs' utility as clinical decision support tools reflect the evolving understanding of the opioid epidemic, with resources being directed toward public

⁷⁴ Patrick SW, Fry CE, Jones TF, Buntin MB. Implementation Of Prescription Drug Monitoring Programs Associated With Reductions In Opioid-Related Death Rates. *Health Affairs*, 35(7):1324-32. [10.1377/hlthaff.2015.1496](https://doi.org/10.1377/hlthaff.2015.1496)

⁷⁵ McGinty, Emma et al. (2022, March 15). Effects of State Opioid Prescribing Laws on Use of Opioid and Other Pain Treatments Among Commercially Insured U.S. Adults. *Annals of Internal Medicine*. <https://doi.org/10.7326/M21-4363>

⁷⁶ Devon Meadowcroft & Brian Whitacre (2021). Do prescription drug monitoring programs encourage prescription - or illicit - opioid abuse?, *Substance Abuse*, 42:(1)65-75, <https://www.tandfonline.com/doi/abs/10.1080/08897077.2019.1695707>

⁷⁷ Mallatt, Justine. (2020). Policy-Induced Substitution to Illicit Drugs and Implications for Law Enforcement Activity. <https://dx.doi.org/10.2139/ssrn.3418615>

⁷⁸ National Institute on Drug Abuse. (2018). Prescription Opioids and Heroin Research Report. Revised January 2018. <https://nida.nih.gov/download/19774/prescription-opioids-heroin-research-report.pdf?v=fc86d9fdda38d0f275b23cd969da1a1f>

⁷⁹ Centers for Disease Control and Prevention. (2021). About OD2A. Last reviewed September 15, 2021. <https://www.cdc.gov/drugoverdose/od2a/about.html>

⁸⁰ Centers for Disease Control and Prevention. (2021, March). Leveraging Prescription Drug Monitoring Program (PDMP) Data in Overdose Prevention and Response. March 2021. <https://www.cdc.gov/drugoverdose/pdf/Leveraging-PDMPs-508.pdf>

health interventions and treatment rather than leveraging PDMP data for criminal justice or regulatory enforcement actions.

PDMP Integration to Promote Utilization

PDMPs are most effective in clinical decision support when they are used by prescribers and pharmacists. With HB 21-1276 expanding PDMP use mandates for prescribers and SB 22-027 and HB 22-1115 clarifying these use mandates where prescribers are now required to query the PDMP before prescribing opioids and benzodiazepines in many situations, Colorado could strengthen the PDMP by dedicating resources toward increasing PDMP utilization. Ensuring that practitioners have efficient access to PDMPs through their native health systems and electronic prescribing tools is key to utilization, though the wide variation in utilization rates for integrated PDMP users shows that this does not guarantee utilization. Over 13,000 Colorado practitioners accessed the PDMP through the integrated PMP Gateway connection in the first half of 2022 and RxCheck is now available as an alternative PDMP integration option in Colorado, but additional enhancements are necessary to maximize its utility. Regarding PDMP utilization, Colorado should continue to focus on expanding integrated access and should consider implementing a robust engagement strategy with practitioners and health care organizations to provide practitioners with training and resources to ensure they are knowledgeable about the system.

Practice Improvement Initiatives

Practice improvement initiatives leveraging PDMP data can help organizations and provider to implement safer prescribing practices. Colorado has worked to support multiple practice improvement initiatives, but PDMP data must be deidentified for such initiatives. CDPHE leverages its access to PDMP data to support practice improvement initiatives under the CDC OD2A grant. CDPHE contracts with the University of Colorado-Department of Family Medicine (UC-DFM) to improve the safety and effectiveness of chronic pain treatment in primary care settings by preventing substance use disorder and expanding behavioral health services for patients with chronic pain, as well as helping community health centers implement the evidence-based Six Building Blocks of Prescription Opioid Management (6BB).⁸¹ UC-DFM focuses on safety-net clinics and systems and federally qualified health clinics (FQHCs) or clinics that serve as the safety-net clinic in their area to train them in the 6BB and is currently engaged with 11 practices and 145 practice staff and clinicians. The prescription drug epidemiologist provides de-identified PDMP data concerning prescribers at participating community health centers so that UC-DFM can assess the effectiveness and uptake of the 6BB model and behavioral health integration into the clinics. UC-DFM provides a roster of clinics and their providers, and the prescription drug epidemiologist reports back the following metrics for each clinic using de-identified PDMP data:

1. Number of patients receiving chronic opioid treatment
2. Number of patients on high dose opioids
3. Number of patients with multiple types of opioids
4. Number of patients with opioid prescriptions from multiple prescribers
5. Number of patients co-prescribed benzodiazepines

⁸¹ Agency for Healthcare Research and Quality. (2019). AHRQ Six Building Blocks: A Team-Based Approach to Improving Opioid Management in Primary Care. <https://www.ahrq.gov/patient-safety/settings/ambulatory/improve/six-building-blocks.html>

The University of Colorado has also performed several grant-funded practice improvement initiatives demonstrating that embedded clinical decision support can increase PDMP use prior to prescribing opioids, decreases high risk opioid prescribing when PDMP is accessed and can be used screen PDMP data to identify high risk prescriptions resulting in an increase in PDMP review prior to prescribing. This electronic health record based clinical decision support goes beyond PDMP-integration and has demonstrated high acceptance by providers and change in practice.

Washington state embraced such practice improvement initiatives with legislation passed in 2017 that allows the state Department of Health to share identified PDMP information with healthcare organizations and provider groups that partner with the Department of Health for quality improvement initiatives, with the caveat that the information must only be used for individual prescriber quality improvement feedback purposes and the information is not used as the sole basis for any medical staff sanction or adverse employment action. The state hospital association and state medical associations are also authorized to access dispenser and prescriber data that includes indirect patient identifiers in connection with their coordinated quality improvement programs.⁸²

Pennsylvania law also allows for PDMP access by designated state personnel responsible for the development and evaluation of quality improvement strategies, program integrity initiatives or conducting internal compliance reviews and data reporting for the medical assistance program, Children’s Health Insurance Program, Pharmaceutical Assistance Contract for the Elderly, or the Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier.⁸³

Such practice improvement initiatives leverage evidence-based practices and appear to show promise in improving safe prescribing practices and providing more comprehensive treatment for those with SUDs. Further research could help determine whether providing identified or partially identified information concerning prescribers strengthens the effectiveness of such initiatives and improves the PDMPs effectiveness as a public health tool without compromising patient privacy.

Other initiatives such as collecting of non-fatal overdose information, authorizing PDMP data to be used in overdose fatality reviews, and sharing PDMP data with state Medicaid offices have been cited as best practices in some publications and may warrant further evaluation. Additional information on these topics can be found in Appendix I.

Conclusion

Though several states authorize greater access to PDMP data by law enforcement and licensing boards and a few send proactive unsolicited reports to these agencies, the Task Force could not find evidence demonstrating such access and activity improves patient safety. Very few studies have evaluated the impact of such access or unsolicited reporting, but numerous reports in national media suggest that extensive regulatory and law enforcement scrutiny of controlled substance or opioid prescribing likely created unintended consequences that were detrimental to certain patients’ ability to find care for chronic pain or substance use disorder. Stakeholders were overwhelmingly opposed to reducing the requirements for law enforcement access.

⁸² Washington State House Bill 1427. (2017). <https://lawfilesext.leg.wa.gov/biennium/2017-18/Pdf/Bills/House%20Passed%20Legislature/1427-S.PL.pdf?q=20220426103140>

⁸³ Pennsylvania 35 § 872.9(7). <https://codes.findlaw.com/pa/title-35-ps-health-and-safety/pa-st-sect-35-872-9.html>

Unsolicited reporting to licensing boards received mixed feedback from stakeholders and disparate approaches by other states. However, if Colorado enables unsolicited reporting to licensing boards, stakeholders recommended that such reports should be limited to those who appear to be practicing significantly outside common standards for their scope of practice, the thresholds or criteria for such reports should be transparent to ensure practitioners understand what activity may generate reports to their licensing boards. If unsolicited reports are authorized to be sent to licensing boards and/or law enforcement, Colorado should authorize an expert team or review committee to review deidentified summary information regarding the suspicious or potentially illegal behavior to reduce the possibility of unsolicited reports and subsequent board investigations being conducted when innocuous explanations are likely, similar to the groups established in Kentucky and Tennessee and which were previously used in Kansas to provide expert evaluation of potentially problematic or illegal prescribing before sharing such information with licensing boards.

Though some PDMPs were initially established in part to allow law enforcement and regulatory agencies a way to identify practitioners, pharmacies and patients who were over-prescribing, over-dispensing and diverting controlled substances, which were the major source of illicit opioids and overdoses in the first wave of the opioid crisis, PDMPs have increasingly become leveraged for their strengths as clinical decision support and patient safety tools in recent years as practitioners increasingly utilize the databases. Colorado's legislature considered such options when the PDMP was created and during subsequent legislative reviews and decided to not pursue those options. Now that the trend in other states is away from this sort of access, rather than updating Colorado's laws to provide greater access to law enforcement and licensing boards, Colorado should evaluate changes or enhancements that may improve the PDMP's utility as a clinical decision support and patient safety tool consistent with the policy approach for many years.

Appendix A: DORA Executive Director's Requests to the PDMP Task Force



March 3, 2022

Robert J. Valuck, PhD, RPh, FNAP | Professor
University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences
On behalf of the Colorado Consortium for Prescription Drug Abuse Prevention
12850 E. Montview Blvd, Mail Stop C238
Aurora, CO 80045

Dear Dr. Valuck,

On behalf of the Department of Regulatory Agencies (DORA or the Department), thank you and the Colorado Consortium for Prescription Drug Abuse Prevention (Consortium) for your continued support and advice concerning the Prescription Drug Monitoring Program (PDMP), including the Consortium's 2021 Task Force Report. The Consortium's support and expertise this past year was invaluable.

Section 12-280-409, C.R.S. requires the Executive Director of the Department to consult with and request assistance from the Consortium as the PDMP Task Force. To that end, on behalf of the Executive Director, I am requesting assistance from the Consortium to examine issues and opportunities regarding the PDMP and to make recommendations on ways to make the PDMP a more effective tool to reduce prescription drug abuse in Colorado. In doing so, please prepare and submit an annual report to the Executive Director and the Colorado General Assembly detailing the Consortium's findings and recommendations by July 1, 2022.

Task #1: Evaluate Effectiveness of Unsolicited Reporting to Licensing Boards of Licensees' Prescribing Activity

12-280-404(3)(i), C.R.S. authorizes access to Colorado PDMP data to State regulatory boards within the Division of Professions and Occupations and the Division Director only if the information is specific to an individual practitioner and is part of a bona fide investigation, and the request for information is accompanied by an official court order or subpoena. While some states authorize their PDMPs to provide unsolicited reports to state licensing boards

regarding prescribers who meet certain criteria of potentially problematic prescribing as determined by their respective licensing boards, the Colorado PDMP is not authorized by current law to provide such unsolicited reports. I request the Task Force to evaluate the benefits and risks of such unsolicited reporting in reducing prescription drug abuse and problematic prescribing. Please detail how these licensing boards use such information in practitioner education and academic detailing or disciplinary action against practitioners established by those states' licensing boards.

Task #2: Evaluate the Effects of Allowing Law Enforcement Access to PDMP data
without Requiring a Subpoena or Court Order

12-280-404(3)(g), C.R.S. allows law enforcement to access Colorado PDMP data so long as the information released is specific to an individual patient, pharmacy, or practitioner and is part of a bona fide investigation, and the request for information is accompanied by an official court order or subpoena. Some states allow law enforcement to access PDMP data without such restrictions. I request the Task Force to evaluate the benefits and risks of providing unsolicited reports to law enforcement with respect to reducing prescription drug abuse and law enforcement actions against practitioners, pharmacies and patients. Please also assess how such access affects patient privacy and other potential unintended consequences.

Sincerely,



Patty Salazar
Executive
Director
Colorado Department of Regulatory Agencies

CC: Jill Hunsaker Ryan, MPH | Executive Director, Colorado Department of Public Health and Environment (CDPHE)
Dr. Eric France, MD MBA | Chief Medical Officer, CDPHE

Appendix B: PDMP Work Group Members

PDMP Work Group Roster (current as of 3/14/22) Page 1 of 4		
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Appendix C: Prescribing and Overdose Death Trends

The Three Waves of the Opioid Crisis

Most PDMPs were established in the early-to-mid 2000s in response to the “first wave” of the opioid crisis⁸⁴ where loosening regulations regarding opioid prescribing led many well-meaning prescribers to significantly increase their opioid prescribing and where a lack of oversight allowed some practitioners, driven by profit motives, to establish “pill mills” where practitioners wrote large volumes of opioid prescriptions to patients without properly assessing patients or treating within established standards of care. Investigations and prosecutions of pill mills and the implementation of PDMPs has resulted in significant decreases in pill mills across the United States by closing the regulatory gaps that unethical practitioners and drug seekers exploited. Consistent with trends across the United States, multiple-provider visits suggesting possible “doctor shopping” has decreased by 92% in Colorado since 2014. Unsolicited reports to law enforcement or regulatory boards may have been effective during this first wave of the opioid crisis, when prescription opioids diverted to the illicit market were driving the opioid epidemic. More recently, the opioid crisis has evolved in recent years with heroin emerging as a major source of overdoses beginning around 2010, followed by fentanyl emerging as a major problem beginning in 2013 with overdoses from fentanyl rapidly accelerating in recent years.

Since 1999, over 500,000 Americans died from an overdose involving any opioid, including prescription and illicit opioids. This rise in opioid overdose deaths occurred in three distinct waves. The first wave began with increased prescribing of opioids in the 1990s, with overdose deaths involving prescription opioids increasing since at least 1999. The second wave began in 2010 with rapid increases in overdose deaths involving heroin. The third wave began in 2013 with marked increases in overdose deaths involving fully synthetic opioids, primarily illicitly manufactured fentanyl. The market for illicitly manufactured fentanyl continues to change, and it is now frequently found in combination with heroin, counterfeit pills, and cocaine.⁸⁵

According to provisional drug overdose deaths from May 2021 through April 2022, nearly 108,000 Americans died of overdoses, up nearly 30% from the prior year and more than double the overdose deaths in 2015.⁸⁶ Nearly 70,000 of these overdose deaths were from synthetic opioids including fentanyl. Nearly 33,000 overdose deaths were from psychostimulant drugs other than cocaine (primarily methamphetamine), which was up from approximately 25,000 in the previous year and represents a nearly five-fold increase from the 5,526 deaths reported from such stimulants in 2015.⁸⁷

CDPHE’s Office of Vital Statistics reported in 2022 that “since 2010, the overdose rate involving prescription opioids remained relatively constant, with an age-adjusted rate of 3.4 deaths per 100,000 population in 2010 increasing to 5.3 per 100,000 in 2020.” CDPHE also reported that the age-adjusted overdose death rate involving prescription opioids without the involvement of fully synthetic opioids such as fentanyl was 3.3 per 100,000 population in 2010, rising to just

⁸⁶ Ahmad FB, Rossen LM, Sutton P. (2022). Provisional drug overdose death counts. National Center for Health Statistics. Published May 11, 2022. <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

⁸⁷ National Institute on Drug Abuse. (2021). Methamphetamine-involved overdose deaths nearly tripled between 2015 to 2019, NIH study finds. <https://nida.nih.gov/news-events/news-releases/2021/09/methamphetamine-involved-overdose-deaths-nearly-tripled-between-2015-to-2019-nih-study-finds>

under 5.0 deaths per 100,000 in 2014 and 2015, and falling to 3.5 per 100,000 in 2020. Overdose deaths involving synthetic opioids such as fentanyl remained relatively constant around a rate of 1.2 deaths per 100,000 population from 2010 to 2016 but increased markedly to 10.0 per 100,000 in 2020. Overdose deaths involving psychostimulants such as methamphetamine have also steadily increased from 2010 (1.2 overdose deaths per 100,000) to 2020 (9.8 per 100,000).⁸⁸ With these shifts toward fentanyl and methamphetamine increasingly causing overdose deaths, the proportion of Colorado's overdose deaths attributed solely to prescription drugs has decreased from approximately 26% of Colorado's overdose deaths in 2010 to approximately 14% of Colorado's overdose deaths in 2020. These trends are consistent with the trends seen nationwide, which are further detailed below.

Overdose death reporting is also complicated by the fact that toxicology reports list the drug(s) in an individual's system at time of death, but do not indicate whether a patient who overdosed from a prescription opioid received the drug via prescription or obtained the drug illicitly. An analysis of veterans who died of opioid overdoses in 2012 and 2013 found that 54.4% of decedents had an active opioid prescription at the time of death and 62.2% had an active opioid prescription within 30 days of death. 20.4% did not have an opioid prescription within a year of death.⁸⁹ Tennessee found that only 36% of those who died of drug overdose in 2019 had received a controlled substance prescription within 60 days of death.⁹⁰ This is not to say that prescription opioids do not pose a danger to Coloradans; rather, illicit fentanyl and methamphetamine are currently driving the increase in opioid deaths and should be considered as equal dangers, if not greater ones.

The Denver DEA Field Division reported in the 2019 Drug Enforcement Administration National Drug Threat Assessment (NDTA) that controlled prescription drug availability was "moderate" which was lower than in 17 of the other 22 DEA Field Divisions in 2018. The report also stated:

[T]hrough a combination of increased law enforcement scrutiny, new prescribing guidelines, and lower quotas set by DEA, the amount of prescription opioids available on the legitimate market has declined each year since peaking in 2011. Although the number of prescription opioids available in 2018 remained significant, the amount of prescription opioids available dropped to their lowest level since at least 2006.⁹¹

The 2020 NDTA reported that national availability of controlled prescription drugs remained constant while abuse levels decreased from the previous year. Diversion of controlled prescription drugs continued to decrease across most categories and the number of opioid dosage units available on the retail market and opioid thefts and losses reached their lowest levels in nine years. Additionally, opioids sold to retail distributors had declined by roughly 15% each year since 2016. The DEA also found that 71% of the confiscated 30 mg oxycodone tablets were consistent with Mexican transnational criminal organizations' illicitly manufactured

⁸⁸ Demont, Christine, MPH; Yocum, Kylie, MPH; Bol, Kirk, MSPH. (2022). Drug Overdose Deaths in Colorado: 2010-2020. *HealthWatch* No. 118. January 2022. <https://drive.google.com/file/d/1VGOSUU15rxV-Zj37T5c9GW13w2D76uzm/view>

⁸⁹ Moyo, P., et al. (2019). Patterns of opioid prescriptions received prior to unintentional prescription opioid overdose death among Veterans. *Research in social & administrative pharmacy: RSAP*, 15(8), 1007-1013. <https://doi.org/10.1016/j.sapharm.2018.10.023>

⁹⁰ Controlled Substance Monitoring Database 2021 Report to the 112th Tennessee General Assembly. (2021, March 1). <https://www.tn.gov/content/dam/tn/health/healthprofboards/csmd/2021-CSMD-Annual-Report.pdf>

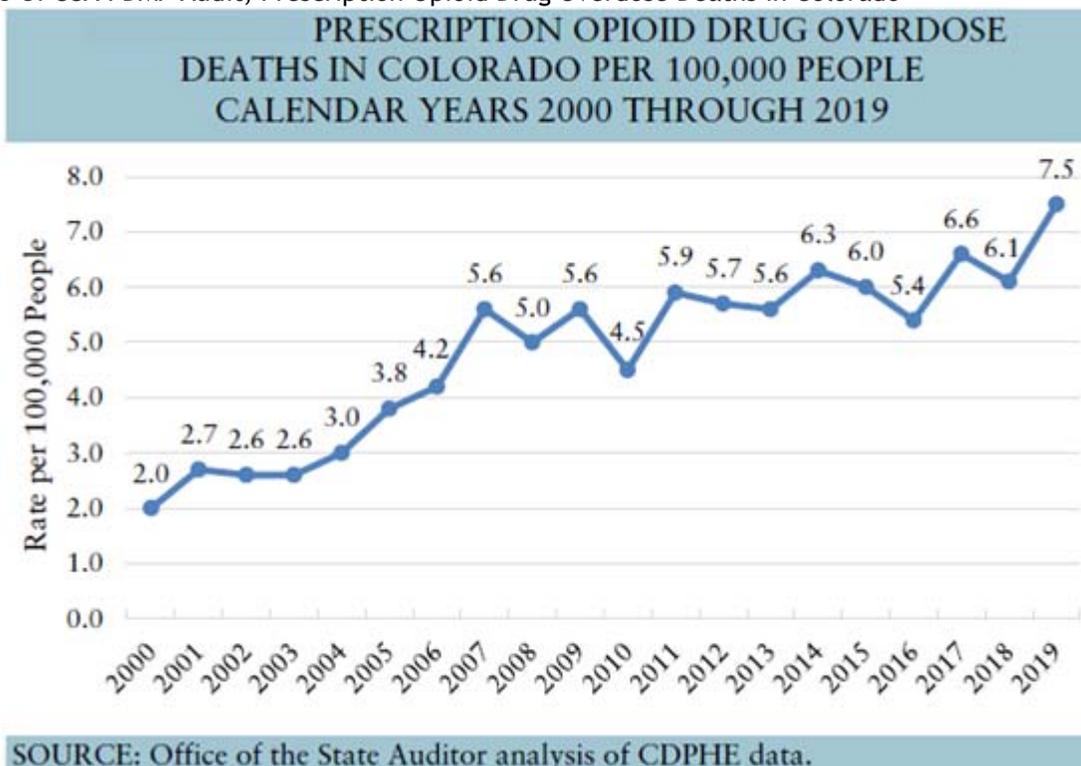
⁹¹ 2019 Drug Enforcement Administration National Drug Threat Assessment. (December 2019). US Department of Justice, Drug Enforcement Administration. https://www.dea.gov/sites/default/files/2020-01/2019-NDTA-final-01-14-2020_Low_Web-DIR-007-20_2019.pdf

fentanyl production techniques and 26% of analyzed illicit tablets containing fentanyl contained a potentially lethal dose of fentanyl in 2019, up from 14 percent in 2018 and 10 percent in 2017.⁹²

Recent Overdose Trends

The OSA audit states that PDMP access by licensing boards and law enforcement should be enabled because deaths from prescription opioids have steadily increased from 2000 (2.0 deaths per 100,000 people) to 2019 (7.5 deaths per 100,000 people) based on OSA’s analysis of overdose data from CDPHE.

Figure 6: OSA PDMP Audit, Prescription Opioid Drug Overdose Deaths in Colorado⁹³



CDPHE’s Office of Vital Statistics reported in 2022 that “since 2010, the overdose rate involving prescription opioids remained relatively constant, with an age-adjusted rate of 3.4 deaths per 100,000 population in 2010 increasing to 5.3 per 100,000 in 2020.” Overdose deaths involving heroin increased from an age-adjusted rate of 0.9 deaths per 100,000 population in 2010, peaking in 2016 at 4.1 per 100,000, and decreased slightly to 3.7 per 100,000 in 2020. Overdose deaths involving synthetic opioids such as fentanyl remained relatively constant around a rate of 1.2 deaths per 100,000 population from 2010 to 2016 but increased markedly to 10.0 per 100,000 in 2020. Additionally, the age-adjusted overdose death rate involving prescription opioids without the involvement of fully synthetic opioids such as fentanyl, the age-adjusted

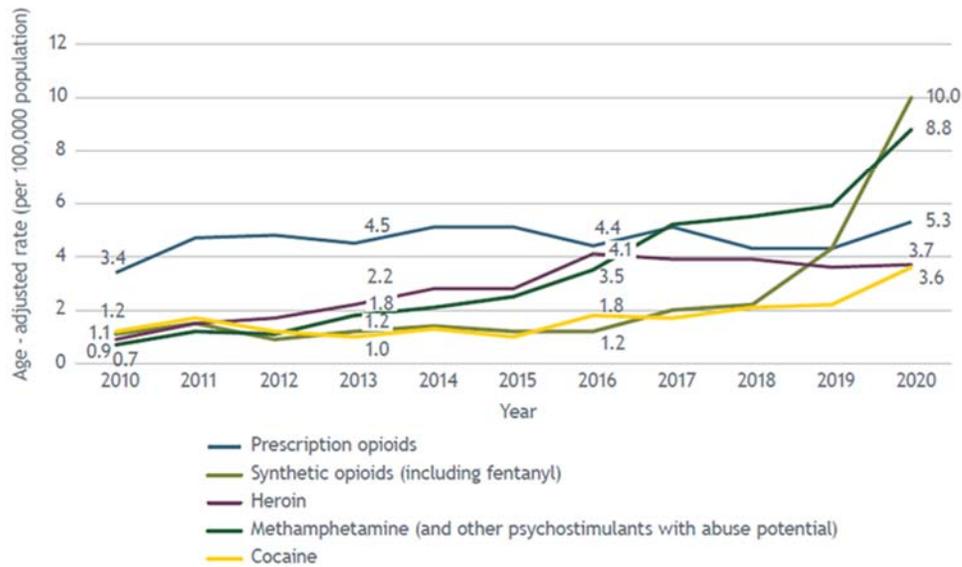
⁹² 2020 Drug Enforcement Administration National Drug Threat Assessment. (March 2021). US Department of Justice, Drug Enforcement. https://www.dea.gov/sites/default/files/2021-02/DIR-008-21%202020%20National%20Drug%20Threat%20Assessment_WEB.pdf

⁹³ Colorado Office of the State Auditor. (2021). Prescription Drug Monitoring Program Performance Audit, March 2021. <https://leg.colorado.gov/audits/colorado-prescription-drug-monitoring-program>

prescription opioid death rate was 3.3 per 100,000 population in 2010, rising to just under 5.0 deaths per 100,000 in 2014 and 2015, and falling to 3.5 per 100,000 in 2020. Overdose deaths involving psychostimulants such as methamphetamine have also steadily increased from 2010 (1.2 overdose deaths per 100,000) to 2020 (9.8 per 100,000).⁹⁴ With these shifts toward fentanyl and methamphetamine, the proportion of Colorado’s overdose deaths attributed solely to prescription drugs has decreased from approximately 26% of Colorado’s overdose deaths in 2010 to approximately 14% of Colorado’s overdose deaths in 2020.

Figure 7: Age-adjusted Drug Overdose Deaths Among Colorado Residents, 2010-2020.

Age-adjusted drug overdose death rates involving prescription opioids, heroin, cocaine, methamphetamine (and other psychostimulants with abuse potential) and synthetic opioids other than methadone: Colorado residents, 2010-2020.



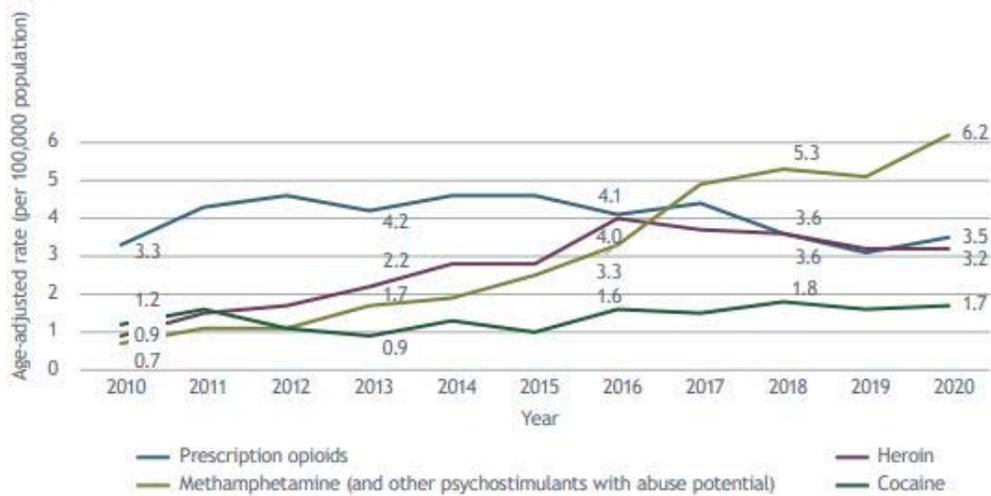
Source: Vital Statistics Program, Colorado Department of Public Health and Environment.

Note: Deaths involving more than one type of drug were included in the rates for each applicable category, therefore, the drug categories are not mutually exclusive.

⁹⁴ Demont, Christine, MPH; Yocum, Kylie, MPH; Bol, Kirk, MSPH. (2022). Drug Overdose Deaths in Colorado: 2010-2020. *HealthWatch* No. 118. <https://drive.google.com/file/d/1VGOSUU15rxV-Zj37T5c9GW13w2D76uzm/view>

Figure 8: Age-adjusted Drug Overdose Deaths Without Fully-Synthetic Opioids Among Colorado Residents, 2010-2020

Age-adjusted drug overdose death rates without involvement of fully-synthetic opioids: Colorado residents, 2010-2020.



Source: Vital Statistics Program, Colorado Department of Public Health and Environment.

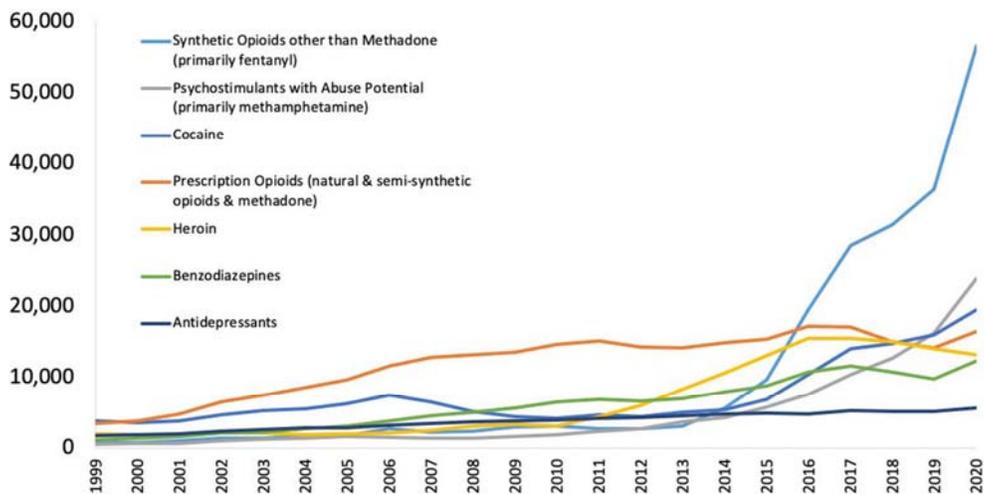
Note: Deaths involving more than one type of drug were included in the rates for each category, therefore, the drug categories are not mutually exclusive.

Colorado’s trends follow national overdose trends with fentanyl leading the current overdose crisis while methamphetamine overdose deaths also continue to increase. The below figures from the National Institute on Drug Abuse⁹⁵ further demonstrate that illicit fentanyl is driving the current overdose epidemic, though overdose deaths from psychostimulants such as methamphetamine have also been increasing in recent years.

⁹⁵ National Institute on Drug Abuse. Overdose Death Rates. January 20, 2022. <https://nida.nih.gov/drug-topics/trends-statistics/overdose-death-rates>

Figure 9: National Drug-Involved Overdose Deaths, 1999-2020.

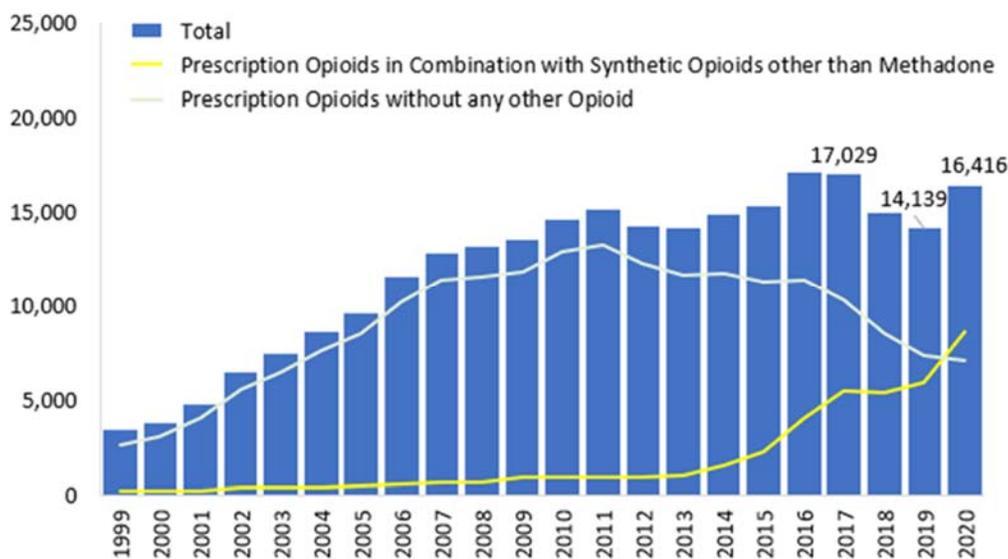
Figure 2. National Drug-Involved Overdose Deaths*, Number Among All Ages, 1999-2020



*Includes deaths with underlying causes of unintentional drug poisoning (X40–X44), suicide drug poisoning (X60–X64), homicide drug poisoning (X85), or drug poisoning of undetermined intent (Y10–Y14), as coded in the International Classification of Diseases, 10th Revision. Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2020 on CDC WONDER Online Database, released 12/2021.

Figure 10: National Overdose Deaths Involving Prescription Opioids, 1999-2020

National Overdose Deaths Involving Prescription Opioids*, Number Among All Ages, 1999-2020



*Among deaths with drug overdose as the underlying cause, the prescription opioid subcategory was determined by the following ICD-10 multiple cause-of-death codes: natural and semi-synthetic opioids (T40.2) or methadone (T40.3). Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2020 on CDC WONDER Online Database, released 12/2021.

Prescription Drug Monitoring Training and Technical Assistance Center, Prescription Behavior Surveillance System Measurements

The previous four PDMP Task Force Annual Reports to the General Assembly detailed characteristics of all controlled substance and opioid prescriptions in Colorado as well as high risk prescribing practices and patient behaviors. This data is updated in this year’s report in Tables 1-3 and Figures 1-3 below. As PDMP integration increases, it will be important to continue to review these metrics to understand if integration is associated with reduced high risk prescribing and patient behaviors.

Table 1: Characteristics of Controlled Substance Prescriptions Dispensed, Colorado, 2014-2021

Characteristics	2014	2015	2016	2017	2018	2019	2020	2021
Controlled Prescriptions Dispensed	8,499,973	8,739,789	8,554,976	8,053,171	7,497,618	7,163,385	6,888,118	7,005,490
Number of Distinct Patients	1,614,277	1,642,929	1,606,599	1,550,864	1,447,709	1,371,939	1,282,451	1,324,345
Number of Distinct Prescribers	39,226	38,750	46,177	45,564	43,996	43,488	43,858	45,648
Number of Distinct Pharmacies	1128	1028	1229	1298	1198	1235	1219	1238

Data Source: Colorado Prescription Drug Monitoring Program, DORA; Data Analysis by: CDPHE, 2022

Table 2: Characteristics of Opioid Prescriptions Dispensed, Colorado, 2014-2021

Characteristics	2014	2015	2016	2017	2018	2019	2020	2021
Opioid Prescriptions Dispensed	4,039,048	4,310,254	4,159,575	3,765,259	3,317,520	3,139,087	2,721,850	2,705,070
Number of Distinct Patients	1,085,551	1,131,781	1,102,297	1,027,685	931,427	867,038	776,847	801,964
Number of Distinct Prescribers	25,011	24,784	28,063	27,676	26,718	26,870	25,464	25,559
Number of Distinct Pharmacies	941	839	1039	1097	989	1016	980	973

Data Source: Colorado Prescription Drug Monitoring Program, DORA; Data Analysis by: CDPHE, 2022

Figure 1: Annual Controlled Substance and Opioid Prescription Totals, 2014-2021

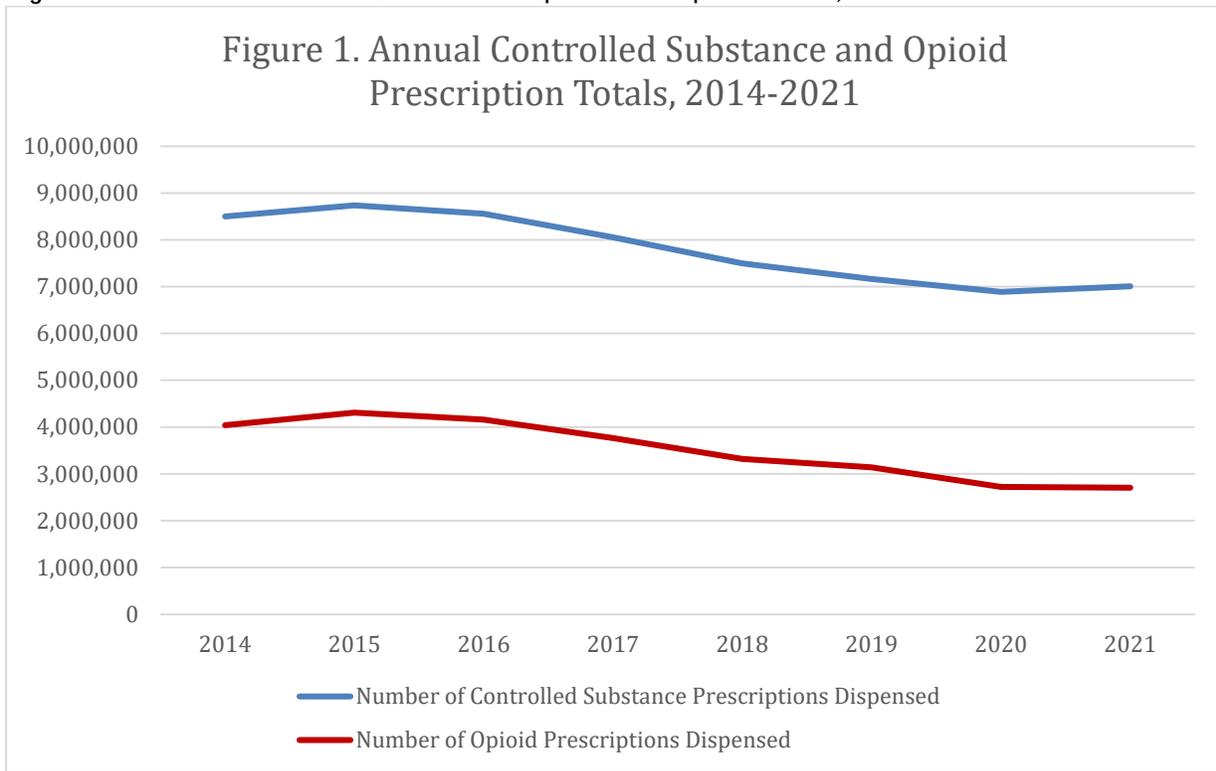
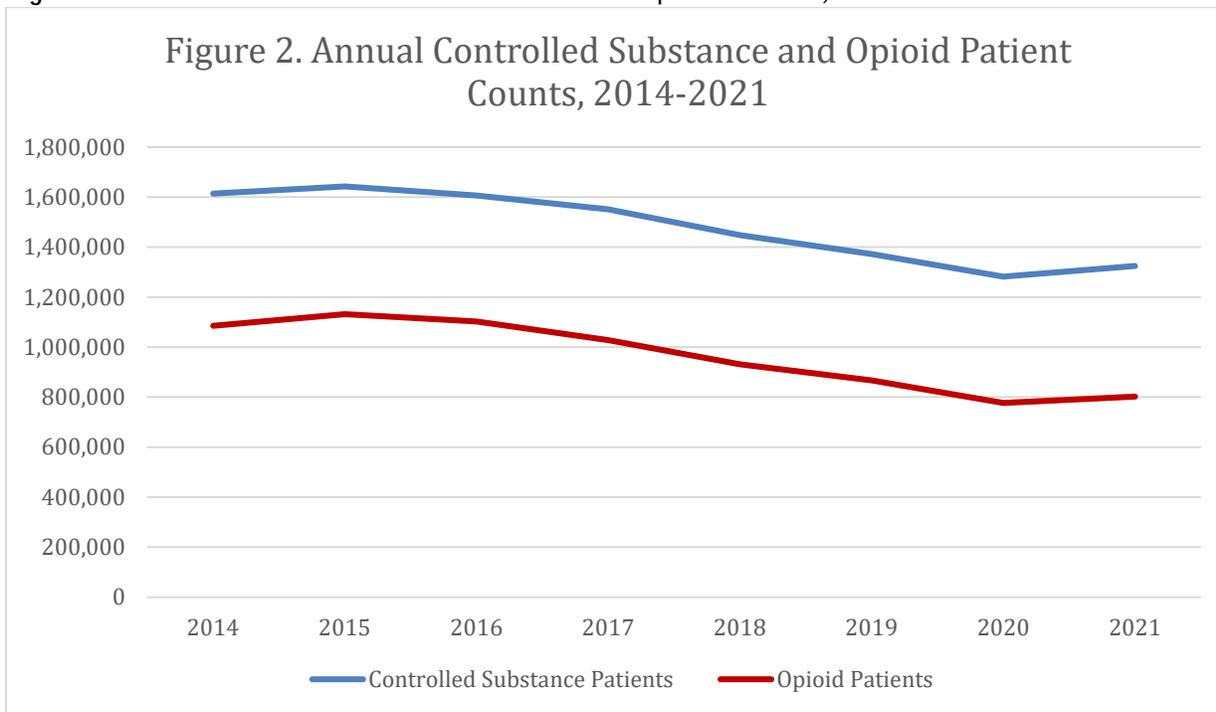


Figure 2: Annual Patients Controlled Substance and Opioid Patients, 2014-2021



As referenced in Tables 1 and 2 and Figures 1 and 2 above, total controlled substance prescriptions decreased by 19.0% from 2014 to 2020 but increased by 1.7% from 2020 to 2021.

Patients receiving at least one controlled substance prescription decreased by 20.6% from 2014 to 2020 but increased by 3.3% from 2020 to 2021. Total opioid prescriptions decreased by 33.0% from 2014 to 2021 and decreased by 0.6% from 2020 to 2021 after decreasing by 13.3% from 2019 to 2020. Patients receiving at least one opioid prescription decreased by 28.4% from 2014 to 2020 but increased by 3.3% from 2020 to 2021 after decreasing by 9.2% from 2019 to 2020.

High-Risk Prescribing Practices and Patient Behaviors

BJA’s PDMP Training and Technical Assistance Center’s Prescription Behavior Surveillance System (PBSS) uses several measurements and metrics to gauge the effectiveness of statewide PDMP systems. The definition of PBSS Measures⁹⁶ provides key metrics to monitoring and determining the success of PDMPs, which are developed in collaboration with the CDC to monitor trends in controlled substance prescribing and dispensing. The PBSS’ measurements include: overall usage within drug classes and for selected individual drugs; daily dosage; overlapping prescriptions within each drug class; across the opioid and benzodiazepine classes; across dosage forms of opioid analgesics (i.e., immediate vs. extended release); questionable activity within a class or classes; inappropriate prescribing measures; and pharmacy-based measures of possible inappropriate dispensing.⁹⁷

Table 3: High Risk Prescribing Practices, Colorado, 2014-2021

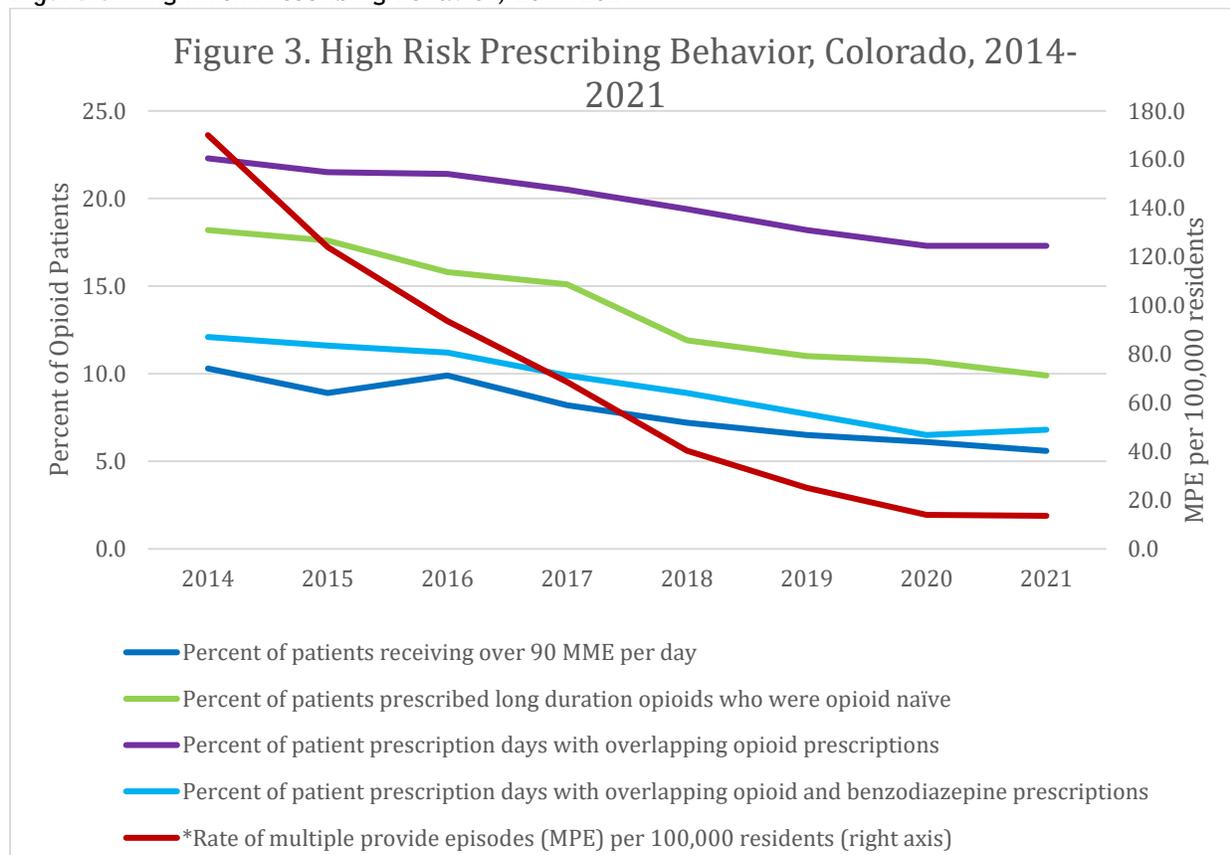
Characteristics	2014	2015	2016	2017	2018	2019	2020	2021
Percent of patients receiving over 90 MME per day	10.3%	8.9%	8.7%	8.2%	7.3%	6.5%	6.1%	5.6%
*Rate of multiple provider episodes per 100,000 residents	170.1	124.0	93.6	68.0	40.3	25.1	14.0	13.6
Percent of patients prescribed long duration opioids who were opioid-naïve	18.2%	17.6%	15.8%	15.1%	12.1%	11.0%	10.7%	9.9%
Percent of patient prescription days with overlapping opioid prescriptions	22.3%	21.5%	21.4%	20.5%	19.4%	18.2%	17.3%	17.3%
Percent of patient prescription days with overlapping opioid and benzodiazepine prescriptions	12.1%	11.6%	11.2%	9.9%	8.9%	7.7%	6.5%	6.8%

*2021 rates are calculated with 2020 population estimates as 2021 estimates are not yet available. Annual percentages are based on an average of quarterly percentages. Data source: Colorado Prescription Drug Monitoring Program, DORA: Data Analysis by CDPHE, 2022

⁹⁶ PDMP Training and Technical Assistance Center Prescription Behavior Surveillance System, Definitions of PBSS Measures, http://www.pdmpassist.org/pdf/COE_documents/Add_to_TTAC/Definitions%20of%20PBSS%20Measures.pdf

⁹⁷ PDMP Training and Technical Assistance Center, PBSS website, <http://www.pdmpassist.org/content/prescription-behavior-surveillance-system>

Figure 3: High Risk Prescribing Behavior, 2014-2021



As referenced in Table 3 and Figure 3 above, the percent of opioid patients receiving over 90 Morphine Milligram Equivalents (MME) decreased by 45.6% from 2014 to 2021 and decreased by 8.2% from 2020 to 2021. The rate of multiple provider episodes per 100,000 residents, defined as patients receiving controlled substance prescriptions from five or more providers and at five or more pharmacies within 90 days, decreased by 92.0% from 2014 to 2021 and decreased by 2.9% from 2020 to 2021. The percent of opioid-naïve patients prescribed long-duration opioids decreased by 45.6% from 2014 to 2021 and decreased by 7.5% from 2020 to 2021. The percent of patient prescription days with overlapping opioid prescriptions decreased 22.4% from 2014 to 2021 and remained the same from 2020 to 2021. The percent of patient prescription days with overlapping opioid and benzodiazepine prescriptions decreased 46.3% from 2014 to 2020 but increased 4.6% from 2020 to 2021.

Appendix D: PDMP Statutory History and Milestones

The progression of the Colorado PDMP includes the following milestones:

- In 2005, House Bill 05-1130 (HB 05-1130) authorized the creation of the Colorado PDMP. Pharmacies began submitting prescription data to the Colorado PDMP in 2007, and the Colorado PDMP web portal went live to users in 2008.
- In 2011, Senate Bill 11-192 (SB 11-192) reauthorized the Colorado PDMP through 2021.
- In 2013, Colorado began sharing PDMP data with other states through PMP InterConnect.
- In 2014, an administrative change increased controlled substance dispensing reporting from bi-weekly to daily, thereby providing up to date PDMP patient data for prescribers and pharmacists.
- In 2014, House Bill 14-1283 (HB 14-1283) made several updates to the PDMP, including:
 - The Colorado Department of Public Health and Environment (CDPHE) was authorized to collect PDMP data for population-level analysis, expanding Colorado's ability to study the effectiveness of the PDMP through statistical analysis, including CDPHE's Prescription Drug Data Profiles for each of Colorado's 64 counties.⁹⁸ This access also allows CDPHE to work with healthcare organizations to evaluate the effectiveness of PDMP integration and other organizational initiatives related to controlled substance prescribing and PDMP utilization, including CDPHE's PDMP integration pilot project evaluation and the University of Colorado's PDMP integration.
 - Prescribers and pharmacists were authorized to designate up to three delegates to access the PDMP on their behalf with proper authorization.
 - The Colorado PDMP was authorized to issue unsolicited reports (Push Notices) to prescribers and pharmacies that inform them of their patients being prescribed controlled substances by multiple prescribers, at multiple pharmacies, over set periods of time. These Push Notices reduce potential patient misuse, abuse, and diversion of controlled substances, while increasing patient safety.
- In 2014, the Colorado Dental Board, Colorado Medical Board, State Board of Nursing, State Board of Pharmacy and the Nurse-Physician Advisory Task Force for Colorado Healthcare collaborated to develop *The Policy for Prescribing and Dispensing Opioids* to provide meaningful guidance to prescribers and dispensers of opioids in Colorado. This Policy was subsequently adopted by the State Board of Optometry and the Colorado Podiatry Board and endorsed by the Colorado State Board of Veterinary Medicine. This policy was the first of its kind to be adopted across numerous healthcare boards and groups within the Division of Professions and Occupations ("the Division").
- In 2015, DORA was awarded a grant through the US Department of Justice Bureau of

⁹⁸ Colorado Department of Public Health and Environment. (2017). Prescription Drug Data Profiles. <https://www.colorado.gov/pacific/cdphe/prescription-drug-data-profiles>

Justice Assistance (BJA). DORA contracted with the University of Colorado as a grant subrecipient and researcher. Pursuant to the grant, funding was used to strengthen PDMP efforts to develop and test innovative strategies and to implement evidence-based approaches that demonstrate the impact of expanded use of PDMP data to support decision making.

- In 2017, Senate Bill 17-146 (SB 17-146) broadened access to the PDMP, allowing prescribers and pharmacists to check the PDMP for reasons apart from controlled substance prescription considerations, including drug-drug interactions, dangerous side-effects and possible abuse or diversion issues. Specifically, the Bill authorized:
 - Prescribers to query the PDMP to the extent the query relates to a current patient of the prescriber;
 - Pharmacists to query the PDMP when considering dispensing any prescription drug to a specific patient; and
 - Veterinarians to query the PDMP when they suspect a client (person responsible for the animal) is diverting the patient's (animal) controlled substance(s) or when they suspect a client is purposely abusing the animal to obtain a controlled substance.
- In 2018, the Colorado prescribing boards and State Board of Pharmacy published the *Guidelines for the Safe Prescribing and Dispensing of Opioids* ("Opioid Guidelines") after soliciting statewide stakeholder feedback, consulting with experts in the fields of pain management, addiction and mental health, and reviewing current literature, policy and guidelines related to the safe prescribing and dispensing of opioids for pain. These guidelines updated the 2014 *Policy for Prescribing and Dispensing Opioids* to both harmonize the guidelines with current policies and to provide Colorado prescribers and dispensers with current, evidence-based guidance with best practices including regularly checking the PDMP, risk assessment, assessing pain and function, considering opioid alternatives, patient education and treatment agreements, collaboration with members of a patient's healthcare team, establishing a strategy for reducing or discontinuing opioids, identifying aberrant drug-related behavior and referral for treatment of opioid use disorder.
- In 2018, the PDMP initiated Prescriber Scorecards. These individual scorecards are sent to eligible prescribers and provide information such as prescription volume data, PDMP usage, morphine milligram equivalent (MME) dosing information, and assessments comparing an individual's prescribing history to others within the same specialty to assist prescribers in making more informed prescribing decisions.
- In 2018, Senate Bill 18-022 (SB 18-022) began limiting a prescriber from prescribing more than a seven-day supply of an opioid to a patient who has not had an opioid prescription in the last twelve months by that prescriber, with exceptions for chronic pain, cancer pain, post-surgical pain, or transfer of care from another prescriber who had prescribed an opioid to the patient. The law also restricted a second fill to a seven-day limit with a requirement that prescribers query the PDMP prior to prescribing a second seven-day fill.
- In 2019, Senate Bill 19-228 (SB 19-228) expanded PDMP access to Colorado medical examiners and elected coroners for patients whose death occurred under unusual,

suspicious, or unnatural circumstances and are the subject of an autopsy, and mandated opioid prescribers to complete up to four credit hours of training per licensing cycle in order to demonstrate competency regarding: best practices for opioid prescribing, recognition of substance use disorders, referral of patients with substance use disorders for treatment, and the use of the PDMP.

- In 2019, CDPHE was awarded the CDC Overdose Data to Action (OD2A) grant. CDPHE and DORA entered into an inter-agency agreement with funding from the OD2A grant. This inter-agency agreement is funding a Program Analyst position at DORA for the PDMP as well as funding to make improvements to the Colorado PDMP. The three-year OD2A grant was extended for a fourth year in 2021, ensuring continued funding through August 2023.
- In 2019, DORA was awarded a second grant from BJA. DORA contracted with the University of Colorado as a grant subrecipient and researcher and is using the funding to systematically investigate the impact of mandated PDMP use, automated PDMP screening, and adding high risk clinical features to PDMP screening, measuring the effects of each modification in all care settings and hospitals used in the research.
- In 2019, the Office of eHealth Innovation (OeHI) formed a new strategic policy subgroup that reports to the Consortium PDMP Task Force (PDMP Task Force) to advance statewide PDMP integration planning and implementation and to ensure alignment between various state agencies. This subgroup, comprised of representatives of the Department of Health Care Policy and Financing (HCPF), CDPHE, Office of Information Technology (OIT), DORA and OeHI, was focused on formulating recommendations involving funding, policy, governance, data sharing, research, and the future state of the PDMP technical architecture to advance PDMP integrations statewide.
- In 2020, the Division and CDPHE reimbursed PDMP integration costs for healthcare organizations through the award of mini grants via a Request for Applications (RFA) procurement process leveraging Overdose Data to Action grant funding from the Centers for Disease Control and Prevention (CDC).
- In 2020, OeHI and HCPF received funding from The Centers for Medicare and Medicaid Services (CMS) to implement the requirements of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (SUPPORT Act)⁹⁹ to expand integrated PDMP access for Medicaid providers.
- In 2021, Senate Bill 21-098 (SB 21-098) reauthorized the Colorado PDMP until September 1, 2028. The bill authorized the Board of Pharmacy to adopt rules to require reporting of certain non-controlled drugs with the potential for abuse to the Colorado PDMP and to adopt rules for a retention schedule for PDMP data. The Colorado State Board of Pharmacy considered this authority and after thorough review, discussion and receipt of stakeholder feedback, decided it was not necessary or beneficial for the PDMP to collect this information.

⁹⁹ Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (SUPPORT Act), H.R.6, 115th Cong. (2018). <https://www.congress.gov/bill/115th-congress/house-bill/6>

- In 2021, House Bill 21-1276 (HB 21-1276) required the Division to enable the RxCheck data sharing hub for integrating the PDMP into the electronic medical records of practitioners and health systems within the state by December 1, 2021. This bill also allowed medical examiners and coroners to query the PDMP for individuals who are the subject of a death investigation. Also, within the PDMP statute, this bill required practitioners to query the PDMP before prescribing any opioid or benzodiazepine, subject to certain exceptions. However, this bill resulted in conflicts regarding the statutory requirement of when to query the PDMP in 12-30-109(1)(b), C.R.S. versus 12-280-404(4), C.R.S. leaving PDMP query requirements unclear.
- In 2021, DORA began work on building out the requirements for the next PDMP RFP as the current vendor's contract was nearing expiration. In tandem with this effort, the Division led a market research effort to collect feedback from various private and government stakeholders, through individual and large stakeholder meetings regarding the PDMP RFP requirements. In 2022, the Division selected Bamboo Health (previously named Appriss, Inc.) to continue as the PDMP vendor.
- In December 2021, the Division enabled RxCheck for in-state integrations. Work continues to improve the functionality of this system and to incorporate RxCheck utilization data into a unified audit trail within vendor-provided analytical tools.
- In 2022, Senate Bill 22-027 (SB 22-027) clarified that the statutory PDMP query requirement enacted in HB 21-1276 applies to any opioid or benzodiazepine prescription, subject to certain established exceptions. The bill also clarified that all DEA-licensed practitioners and all pharmacists licensed in Colorado are required to register and maintain a user account with the Colorado PDMP and requires the PDMP Task Force to evaluate and make recommendations to the DORA Executive Director, after engaging in a stakeholder process, regarding balancing the program as a health-care tool with the requirements of Title 12, Article 280, C.R.S.
- In 2022, House Bill 22-1115 (HB 22-1115) also clarified the statutory PDMP query requirement enacted in HB 21-1276 applies to any opioid or benzodiazepine prescription, subject to certain established exceptions. It also removed restrictions on the number of delegate users that a practitioner or pharmacist may authorize to query the PDMP on the supervising practitioner or pharmacist's behalf. The bill also required the Division to implement a process whereby practitioners and pharmacists may apply for and receive reimbursement from the Division for all or a portion of the costs of integrating the PDMP with electronic medical records.

Appendix E: PDMP Task Force Survey Questions

State information

- 1) What state do you represent?
- 2) What state entity oversees your state's PDMP?

Licensing Board Access Questions

- 3) What is required for access to PDMP data by licensing boards? (Please select all that apply)
 - Subpoena
 - Active Investigation
 - No Restrictions
 - Access is not allowed
 - Other (please explain if selecting Other)
- 4) What information is accessible to licensing boards? (Please select all that apply)
 - Information related to an individual practitioner or pharmacy under investigation
 - Direct access to all PDMP data
 - Data provided upon request from PDMP (prescribers with highest prescription volumes, high-risk prescribing, etc.)
 - Other (please explain if selecting Other)
- 5) Does your state PDMP send unsolicited reports to licensing boards? (Proactive notifications to licensing boards regarding information reported to the PDMP).
 - Yes/No
 - If yes, What criteria are used for sending unsolicited reports to licensing boards? If you can advise what general categories are used such as multiple provider/multiple pharmacy thresholds or top prescribers of certain drugs, please provide what information you can share. If specific thresholds are confidential, please note this.
 - If yes, what information is included in the unsolicited reports? (Full prescription history, only prescriber or pharmacy information, other summary information, etc.)
 - If yes, what actions do licensing boards take on the basis of unsolicited reports from the PDMP? (Please select all that apply)
 - Open investigations into practitioners for possible discipline
 - Require academic detailing or continuing education for practitioners
 - Provide informational notices regarding best practices
 - Referral to law enforcement

- Other (please explain if selecting Other)

6) Does your state allow the overseeing Division, Department or Agency Director to access PDMP records?

- Yes/No
 - If yes, what information is accessible to the Division/Department/Agency Director from the PDMP? (Please select all that apply)
 - Information related to an individual practitioner or pharmacy under investigation
 - Direct access to all PDMP data
 - PDMP data provided upon request for certain metrics (prescribers with highest prescription volumes, high-risk prescribing, etc.)
 - Other (Please explain if selecting Other)
 - If yes, What action(s) can the Director take on the basis of this information? (Please select all that apply)
 - Referral of the licensee to licensing boards
 - Referral to law enforcement
 - Other (Please explain if selecting Other)

Law Enforcement access questions

7) What is the MINIMUM required for law enforcement access to your state's PDMP records?

- Warrant or Court Order
- Subpoena
- Active Investigation
- Proper Need/Upon Request
- Other (Please explain if selecting Other)
- If a warrant, court order or subpoena is not required for law enforcement access, how does law enforcement access PDMP information? Please also advise how the requests are reviewed or approved by the PDMP, if applicable.

8) Is law enforcement restricted to accessing PDMP data specific to an individual practitioner, pharmacy or patient related to an active investigation?

- Yes/No
- If Law Enforcement is not restricted to accessing PDMP data specific to an individual practitioner, pharmacy or patient related to an active investigation, what can Law Enforcement access? (All prescriptions for a certain drug or drug combination, top X prescribers for a certain medication, etc.)

- 9) Does your state PDMP send unsolicited reports to law enforcement?
- Yes/No
 - If yes, please select which entities receive unsolicited reports
 - Local law enforcement
 - state law enforcement
 - state Attorney General's office
 - Drug Enforcement Administration
 - Department of Health and Human Services
 - other Federal agencies
 - If yes, what criteria or situations are used for sending unsolicited reports to law enforcement? (If this is confidential, please state "confidential")
 - What information is included in the unsolicited reports?
- 10) If your state has performed any evaluations or created any reports regarding law enforcement or licensing board access to PDMP data or unsolicited reports sent to these entities, please provide links or references to such information.
- 11) Is there anything else you want to tell us regarding how your state PDMP approaches these topics?

Appendix F: Unintended Consequences and Misapplication of CDC Guidelines

In 2019, the authors of the CDC’s Opioid Guideline for Prescribing Opioids for Chronic Pain acknowledged that some practitioners, government agencies, and state governments were misapplying the guidelines in several ways. Guidelines were sometimes misapplied to patients in active cancer treatment, patients experiencing acute sickle cell crises, or patients experiencing post-surgical pain rather than those with chronic pain. Misapplication of the guidelines also occurred with dosage recommendations resulting in hard limits on dosages or abrupt tapering, or even sudden discontinuation of opioids.^{100,101}

A consensus panel analyzing challenges in the implementation of the CDC Opioid Guidelines also found several areas of concern.¹⁰² For example, the Centers for Medicare and Medicaid Services (CMS) proposed a policy that would have capped opioid prescription coverage at 90 MME per day dosages with the stated goal of concordance with the guideline. CMS reported that:

- physician groups expressed concerns about the risks for patients of abrupt discontinuation or rapid taper of high doses,
- patients sent hundreds of letters describing fear of abrupt reduction or discontinuation of their long-time medication regimens “with sometimes extremely adverse outcomes, including depression, loss of function, quality of life, and suicide,”
- CMS plan sponsors and other organizations expressed support for CMS’s goal to aggressively address opioid overuse but requested to set their own MME thresholds.

The panel also stated that “any legislative, regulatory, or payer policies enacted should make provisions for appropriately selected and monitored patients who need and benefit from longer duration or higher dosage.”¹⁰³

Regarding abrupt discontinuation of opioids or forced tapering, the panel stated:

While the guideline does not support abrupt non-collaborative opioid taper or cessation in patients on a dose above a given target, certain panel members observed that some clinicians, policymakers, managed care administrators and pharmacy benefit managers have inferred an enforceable dose ceiling as a de facto mandate... In addition, in an atmosphere of heightened enforcement, clinicians and dispensing pharmacists may harbor professional concerns about potential sanctions connected to prescribing patterns.¹⁰⁴

¹⁰⁰ Deborah Dowell, M.D., M.P.H., Tamara Haegerich, Ph.D., and Roger Chou, M.D. (2019). No Shortcuts to Safer Opioid Prescribing. *New England Journal of Medicine*, 380: 2285-2287. <https://www.nejm.org/doi/full/10.1056/NEJMp1904190>

¹⁰¹ Centers for Disease Control and Prevention. (2019). Media Release. CDC Advises Against Misapplication of the *Guideline for Prescribing Opioids for Chronic Pain*. <https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html>

¹⁰² Kroenke K, Alford DP, Argoff C, et al. (2019). Challenges with implementing the Centers for Disease Control and Prevention opioid guideline: a Consensus Panel report. *Pain Medicine*, 20:724-735. <https://pubmed.ncbi.nlm.nih.gov/30690556>

¹⁰³ Ibid. p. 726.

¹⁰⁴ Ibid. pp. 726-727.

Regarding limits on prescription durations, “concern was raised by some panel members that if the seven-day duration limit were inflexibly applied as a hard limit, patients with severe pain persisting more than a week and not controlled by nonopioid therapies could lack access to needed analgesia.”¹⁰⁵ The panel also found that integrated comprehensive pain care models are neither widely available nor sufficiently reimbursed despite demonstrated long-term cost and health care utilization advantages. Additionally, the panel noted that clinicians who prescribe long-term opioid therapy should be required to demonstrate a basic knowledge of opioid use disorder diagnosis and treatment.

Arizona’s 2018 Opioid Epidemic Act (Senate Bill 1001)¹⁰⁶ is one example of a state law that may have misapplied the CDC’s Opioid Guidelines to implement limitations on opioid prescribing. Schatman and Shapiro (2019) criticized the 2018 Arizona Opioid Epidemic Act as being based on outdated information regarding opioid prescribing and incorrect interpretations of the 2016 CDC Guideline for Prescribing Opioid for Chronic Pain.¹⁰⁷ This bill prohibited practitioners from directly dispensing most opioids, limited opioid dosages for many patients to 90 MME and limited the days’ supply for acute pain to five days, and to 14 days following a surgical procedure, among other restrictions. Though state documents asserted that the law excepted chronic pain patients from these restrictions,¹⁰⁸ chronic pain was not listed as an exempt condition in the bill (see A.R.S. 29-32-3248.01(B)(3)), and the bill required a practitioner to consult with a board-certified pain specialist before authorizing dosages above 90 MME.¹⁰⁹ After passage of the law, criticisms of the law’s unintended consequences¹¹⁰ and reports of chronic pain patients struggling to find care and practitioners fearing prosecution and regulatory discipline emerged.^{111, 112} Dr. Julian Grove, who worked with the state on the prescribing rules of the law and is president of the Arizona Pain Society told the Arizona Daily Star,

Many people who are prescribing medications have moved to a much more conservative stance and unfortunately pain patients are being negatively affected. A lot of practitioners are reducing opioid medications, not from a clinical perspective, but more

¹⁰⁵ Ibid. p. 727-728.

¹⁰⁶ Arizona State Senate. (2018). Fact Sheet for S.B. 1001/H.B. 2001

https://www.azleg.gov/legtext/53leg/1S/summary/S.100_ASENACTED.pdf

¹⁰⁷ Schatman, M. E., & Shapiro, H. (2019). Damaging State Legislation Regarding Opioids: The Need To Scrutinize Sources Of Inaccurate Information Provided To Lawmakers. *Journal of pain research*, 12: 3049-3053.

<https://doi.org/10.2147/JPR.S235366>

¹⁰⁸ The Arizona Opioid Epidemic Act: Protecting Individuals with Chronic Pain.

https://azgovernor.gov/sites/default/files/related-docs/chronicpainweb_0.pdf

¹⁰⁹ <https://www.azleg.gov/legtext/53leg/1S/laws/0001.htm>

¹¹⁰ Arizona Republic Editorial Board. (2018, Jan. 29). Our View: Arizona's new opioid epidemic law could cause you pain. *Arizona Republic*. [https://www.azcentral.com/story/opinion/editorial/2018/01/29/our-view-opioid-](https://www.azcentral.com/story/opinion/editorial/2018/01/29/our-view-opioid-plan-may-cause-grandma-pain/1068641001/)

[plan-may-cause-grandma-pain/1068641001/](https://www.azcentral.com/story/opinion/editorial/2018/01/29/our-view-opioid-plan-may-cause-grandma-pain/1068641001/)

[https://www.azcentral.com/story/opinion/editorial/2018/01/29/our-view-opioid-plan-may-cause-grandma-](https://www.azcentral.com/story/opinion/editorial/2018/01/29/our-view-opioid-plan-may-cause-grandma-pain/1068641001/)

[pain/1068641001](https://www.azcentral.com/story/opinion/editorial/2018/01/29/our-view-opioid-plan-may-cause-grandma-pain/1068641001/)
¹¹¹ Stone, Will. (2018, Jul. 7). Patients With Chronic Pain Feel Caught In An Opioid Prescribing Debate. *National Public Radio*. <https://www.npr.org/sections/health-shots/2018/07/08/622729300/patients-with-chronic-pain-feel-caught-in-an-opioid-prescribing-debate>

¹¹² Fischer, Howard. (2022, Apr. 3). Arizona opioid prescription limits might be eased. *Arizona Daily Star*.

https://tucson.com/news/state-and-regional/govt-and-politics/arizona-opioid-prescription-limits-might-be-eased/article_0ffd3794-b1dc-11ec-b093-93683efd12b6.html

from a legal and regulatory perspective for fear of investigation. No practitioner wants to be the highest prescriber.¹¹³

In response to criticism regarding the unintended consequences for chronic pain patients and practitioners, in 2022 Arizona passed Senate Bill 1162¹¹⁴ which added “chronic intractable pain” to the list of exemptions to the 90 MME daily dosage limit, stating that the 90 MME limit “does not apply to a patient with chronic intractable pain once the patient has an established health professional-patient relationship and the patient has tried doses of less than ninety morphine milligram equivalents that have been ineffective at addressing the patient’s pain” (A.R.S. 29-32-3248.01(E)).

¹¹³ Stone, Will. (2018, Jul. 7). Patients With Chronic Pain Feel Caught In An Opioid Prescribing Debate. *National Public Radio*. <https://www.npr.org/sections/health-shots/2018/07/08/622729300/patients-with-chronic-pain-feel-caught-in-an-opioid-prescribing-debate>

¹¹⁴ <https://www.azleg.gov/legtext/53leg/1S/laws/0001.htm>

Appendix G: Stakeholder Feedback Concerning Law Enforcement Access and Unsolicited Reporting

The following comments were submitted to the Task Force through a Stakeholder Meeting held on April 28, 2022 and in written comments provided to the Task Force.

Dr. Michael Nerenberg, a retired emergency medicine physician and Co-Chair of the Harm Reduction Work Group at the Consortium, advised that changes to law enforcement access raised concerns about privacy and he did not believe that law enforcement was qualified to examine the data. He stated that in emergency departments they often saw the unintended consequences of well-intentioned ideas such as required reporting of domestic violence. Domestic violence victims often left the emergency department or avoided treatment because they knew that providers were required to report evidence of domestic violence to law enforcement.

Certified Nurse Midwife Theresa Frick also analogized the potential unintended consequences of expanding law enforcement access to PDMP data to the consequence on patient care in states that criminalize drug use during pregnancy. Such laws resulted in worse outcomes because pregnant women avoided seeking care or disclosure of their substance use because of what happened to people who did disclose their substance use or sought care. She was concerned that patients who aren't at particular risk would probably be fine, but those at risk could go other routes to obtain medications.

Emergency physician Dr. Patricia VanDevander had been involved with the PDMP for a long time through her participation in the Consortium and was strongly against changing the law regarding law enforcement access, stating that this was not the intent of the PDMP and never has been, as reflected in the language of the current statute and previous bills. She stated that the PDMP is a tool for practitioners and pharmacists for assessment and helping with clinical decision making. If law enforcement wants access, it should continue to be for a specific individual and accompanied by a subpoena or court order.

PDMP Work Group public member Marjorie Zimdars-Orthman expressed concerns regarding how PDMP data might be used by law enforcement if law enforcement received unsolicited reports from the PDMP or had lower requirements for requesting PDMP data. She questioned what investigations are impeded when law enforcement does not have unrestricted access to PDMP data and questioned what parameters or rules law enforcement would have in place. She expressed concern that patients could be at risk if law enforcement made assumptions regarding certain prescriptions and expressed concern about patient privacy rights if law enforcement had unrestricted access to patients' prescription history.

Amy Goodman, Senior Director of Policy at the Colorado Medical Society, raised serious concerns about unsolicited reports from the PDMP to law enforcement and regulatory boards. She reiterated that the PDMP was always intended to be a clinical decision support tool that improves patient care and was never intended to be a regulatory tool or law enforcement tool. She stated that these questions had been raised multiple times and had repeatedly been reaffirmed. PDMP data lacks the context found in a patient's medical record and can't solely determine the appropriateness of the prescription for the patient's condition and was concerned that specialists with patients on high doses of opioids would be targeted because of their patients' medical conditions. She also highlighted that prescribing trends have been

moving in the right direction and recent legislation mandating PDMP utilization and training on appropriate prescribing were appropriate statutory updates. “Physicians have made a lot of progress and it doesn’t make sense to waste resources on something with no evidence base which will unfairly target patients and affect responsible prescribers.”

The Colorado Psychiatric Society commented that allowing law enforcement access to PDMP data without a subpoena or court order violates confidentiality in healthcare, which is particularly sensitive with respect to psychiatric treatment. They cited the American Psychiatric Association’s Principles of Medical Ethics with Annotations Especially Applicable to Psychiatry which states:

Psychiatric records, including even the identification of a person as a patient, must be protected with extreme care. Confidentiality is essential to psychiatric treatment. This is based in part on the special nature of psychiatric therapy as well as on the traditional ethical relationship between physician and patient. Growing concern regarding the civil rights of patients and the possible adverse effects of computerization, duplication equipment, and data banks makes the dissemination of confidential information an increasing hazard. (Section 4, Article 1).

They further stated their concerns that patients who are concerned about the loss of confidentiality may decline to seek treatment or decline to be treated with any medications that would be reported to the PDMP which could interfere with the welfare of individual citizens and undermine the public’s perception that medical treatment, and particularly psychiatric treatment, is confidential.

Rachel Povilus, PA-C, MPAS, MPH, also expressed concerns regarding the effects on patient health outcomes and safety if law enforcement had greater access to PDMP data. She stated:

If patients feel that their health information can be accessed easily by law enforcement they may: stop seeking legal/safe treatment, deceive or otherwise obscure information from their healthcare providers, run from or avoid interactions with law enforcement, or switch from prescription medications to illegal substances (which would potentially lead to more overdose deaths from rampant fentanyl or increased blood-borne diseases from unsafe injection practices). ...

In a public health realm, I am concerned that this would (again, intentionally or not) further marginalize patients from communities of color, disabled patients, low income/low socio-economic status or LGBTQ+ patients through the mechanisms mentioned [above]. This would further set back and adversely affect these marginalized groups' health outcomes. ...

It is not the intention or place of law enforcement to access health data unless needed for a criminal/legal proceeding, and without the appropriate training and context, these individuals would not be able to appropriately interpret the data from the PDMP. Additionally, without appropriate HIPAA and confidentiality training, as it relates to medical conditions, they may inadvertently share this information with people who do not need to have access to it and may respond in a way which could harm the patient.

In summary, simply having access to prescription medication without the act of illegal behavior regarding that medication (i.e. sales, fraud, etc.) is not a crime and should not

be treated as such by removing the protection offered by a court order or subpoena when law enforcement accesses this information.

Emergency physician Mark Breen, MD, FACEP, also expressed concerns about patient privacy if law enforcement had greater access to PDMP data. He advised that trying to interpret PDMP data is a complex issue. One record that appears suspicious to law enforcement could be a patient with an inadequately treated condition or could reflect social detriments to the patient's ability to coordinate care with a multidisciplinary pain team or financial hurdles to receiving definitive care, resulting in a band-aid of pain medication, psychiatric hurdles with chronic pain and noncompliance with follow-up, or opioid misuse or abuse. He argued that law enforcement would not add clarity to these complex situations. Regarding the outliers identified in the auditor's report, he stated:

Identifying 85 providers in Colorado who prescribe more than 3000 opioid prescriptions per year [in the OSA report] doesn't quite convey if this is legitimate pain management or unethical prescriptive practice... Identifying 8700 patients in Colorado who use multiple providers [in the OSA report] does not completely capture an unequivocal story of abuse either, but certainly identifies patients at risk of harm and at risk of abuse. The health care community MUST come up with a way to help the patients who have opioid use disorder rather than just turn this into a criminal offense.

Robert Valuck, Ph.D., Director of the Colorado Center for Prescription Drug Abuse Prevention at the University of Colorado, reaffirmed others' comments that the legislative intent since the beginning was that the PDMP was intended as a clinical decision support tool for practitioners and pharmacists to do their jobs, and that these questions had been raised several times over the years and have constantly been reaffirmed that the PDMP is a clinical decision support tool. He stated:

[The PDMP] is a valuable and useful tool but opening this up is a serious problem and raises many questions. The Center's position is that these have not been studied enough relative to the risks, and we don't have evidence for benefits relative to the risks, so we should err on the side of caution. ... We shouldn't approach it as "we don't have evidence that this harms" - first do no harm, first protect privacy, first protect the data, first protect the patient-pharmacy and patient-provider relationship. These aren't good ideas, and we are very cautious about the use of the PDMP outside of its clinical use.

Jennifer Place, a Senior Program Manager at the Colorado Consortium for Prescription Drug Abuse Prevention and licensed addictions and professional counselor, advised that she has worked for 15 years in the substance use disorder space and has worked in peer assistance. She spoke of the possibility of unintended consequences for pain patients if law enforcement was given greater access to PDMP data. With heightened regulations and prescribing practices around opioids, she has seen that some providers have not wanted to prescribe opioids due to perceived risks and have cut off patients who were appropriately using pain medications for years. These changes could further stigmatize patients with chronic pain, resulting in those with pain not being treated appropriately and resorting to illicit substances which carry a high risk of overdose from fentanyl contamination or place them at a higher risk of suicide.

The Colorado Advanced Practice Psychiatric Nurses (CAPPN), a district of the Colorado Nurses Association, stated that giving law enforcement access without a subpoena would be an extreme violation of confidentiality. "Our patients deserve the protection of a subpoena to

access their highly personal health/prescription information. Otherwise, they are being treated as possible criminals for their health conditions.”

Dr. Ryan Jackman, MD, FASAM, an addiction medicine physician in Western Colorado, also expressed concerns that greater law enforcement access to the PDMP has potential for greater harm than benefit by law enforcement misinterpreting or overinterpreting the data in the PDMP. He also stated:

Individuals accessing the data will not have access to clinical notes or situations that paint the whole picture. Additionally, law enforcement will not have the clinical training to make the assumptions they are at risk of making. Then there are the potential violations of doctor patient confidentiality that would particularly undermine the care that I and my colleagues provide as addiction specialists. We are already combatting societal stigma and fear of the law to engage patients. If I also have to address patients who report being looked up on the PDMP by law enforcement, there is a risk to patient engagement and ultimately safety. If the legislature feels that this needs to occur, then I would emphasize the fact that the law enforcement needs to employ medical professionals to review and determine the appropriateness of this data and not non-medical individuals.

Kerry Hamilton, Diversion Program Manager for the DEA Denver Field Division submitted the following written statement to the Task Force:

Thank you for allowing me to participate in the recent PDMP Stakeholder Meeting on behalf of the Denver Division of the Drug Enforcement Administration (DEA). I believe it would be appropriate for me to begin by briefly describing the role of the DEA in healthcare. I feel this is necessary because several of the oral and written comments from other participants misstated our responsibilities in enforcing the Controlled Substances Act (CSA).

Broadly speaking, DEA has two important roles. One role is the investigation of individuals and organizations involved in the manufacture, transportation, and/or distribution of illegal substances. In this role, DEA is a traditional law enforcement agency whose goal is to identify and target ongoing criminal enterprises so that we may disrupt or dismantle their illicit activities. DEA partners with local, state, and Federal agencies to bring these cases forward in both the state and Federal judicial systems. DEA’s second role is that of a health oversight agency with important responsibilities overseeing and enforcing the CSA as it pertains to the delivery of healthcare in the United States. The closed system of distribution is designed to prevent or minimize the diversion of controlled substances from the time they are manufactured until they reach the end user.

Within our role as a health oversight agency, the Diversion Control Division of DEA exists to prevent, detect, and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels while ensuring an adequate and uninterrupted supply of pharmaceutical controlled substances and listed chemicals to meet legitimate medical, commercial, and scientific needs. We accomplish our mission not just through traditional law enforcement activities, but also through administrative and/or regulatory actions. In the performance of our work, DEA seeks to

augment and support state regulatory boards or commissions in their supervision and regulation of state licensed practitioners in instances where the CSA has been violated. In my 22 years as a DEA Diversion Investigator, I have frequently utilized PDMP data as part of my inquiries into the diversion of controlled substances. In conjunction with other analytical and fact-finding tools, DEA Diversion Investigators utilize PDMP data to assist us in assessing and determining whether action against a DEA registrant is appropriate. Our inquiries are routinely administrative or civil in nature, but certain violations of the CSA are appropriate for criminal prosecution. It is key to understand that PDMP data alone does not determine the action we take in our investigations. While PDMP data is an important aspect of our work and an important evidentiary component of our analyses that we use to ensure our inquiries are thorough and complete, we understand that the PDMP data does not tell the whole story.

Our focus is on registrants and individuals/organizations who are diverting controlled substances. A large part of our work in the Diversion Control Division has to do with conducting regulatory inspections of specific types of registrants. In addition to regulatory inspections, we follow up on leads regarding potential violations of the CSA along with tips from the public and registrant population. DEA often receives information from practitioners who have concerns about the prescribing practices of their colleagues. In recognition of our budgetary and personnel constraints, DEA must proceed by making the most efficient and effective use of our limited resources by honing our focus whenever possible. So that we may strengthen and amplify our efforts, unsolicited reports from the PDMP would unquestionably assist us by allowing us to focus our efforts on the most egregious non-compliant registrants, i.e., health care practitioners who are suspected of violating the CSA. Such information would be only one component of our inquiries, and we would continue to utilize our broad range of analytical tools to understand and develop any information we receive.

There also seemed to be a misunderstanding about our current use and security of PDMP data. Through several distinct judicial decisions in the Federal Courts, DEA has secured access to PDMP data through the service of administrative subpoenas. DEA has repeatedly shown that our administrative subpoenas are narrow in scope and constructed to obtain the information necessary for a particular investigation. To ensure appropriate oversight, administrative subpoenas are comprehensively reviewed and approved by DEA senior management. Moreover, Federal law makes it a crime to disclose sensitive or controlled information, or information contained within a database, e.g., 18 U.S.C. 1905, 18 USC 1030, and 18 USC 641. Federal law also imposes civil penalties for inappropriate disclosures under the Privacy Act 5 U.S.C. 552a. Our supervisory oversight of our personnel and our access to sensitive information would not change if Federal law enforcement was given direct access to the state's PDMP data. DEA would welcome and encourage features and enhancements to the PDMP database that would ensure security over the information if we were granted access, as well as limits on who would be granted access and mandatory training requirements for those granted PDMP access rights. As professional investigators, we routinely have access to databases that contain DEA registration information, criminal history records, and records of distributions and receipts of controlled substances. We are trained to protect that information and utilize it in a confidential and discreet manner as required to protect sensitive information.

Thank you for the opportunity to provide the information above. In these clearly unprecedented times with overdose deaths occurring at alarming and all-time high rates, it is essential that government agencies at all levels work in concert to address the present addiction issues facing our nation. We believe that collaboration on these positive steps forward will go far in achieving that goal.

Appendix H: Stakeholder Feedback Concerning Licensing Board Access and Unsolicited Reporting

The following comments were submitted to the Task Force through a Stakeholder Meeting held on April 28, 2022 and in written comments provided to the Task Force.

Laura Mehringer, a psychiatric clinical nurse specialist felt that it may be appropriate for licensing boards to receive some information regarding only the significant outliers with respect to prescribing activity, though the specific parameters or thresholds should be made explicit so prescribers have an understanding of the parameters and expectations. Other individuals who commented in the meeting chat echoed the need for licensing boards to determine explicit parameters for receiving unsolicited reports to be fair to prescribers.

Abraham Wick, a pharmacist, echoed that those who are significant outliers and prescribing well outside the norms could be considered for unsolicited reporting but advised that he believes most over-prescribing is unintentional. He also argued that the PDMP should focus on integration with health systems to promote and improve PDMP utilization by prescribers and pharmacists to make the PDMP more effective.

Dr. Michael Nerenberg, a retired emergency medicine physician and Co-Chair of the Harm Reduction Work Group at the Consortium, acknowledged that there may be a role for regulatory boards receiving unsolicited reports regarding a specific practitioner for defined reasons and that regulatory boards would be more appropriate parties to review such information as licensing boards may be more focused on understanding the issue than seeking discipline or criminal action.

Dr. Patricia VanDevander, an emergency physician, had concerns that there may be large differences within a specialty or practice due to their patient population that can result in large differences in the amount they are prescribing. If Colorado chose to send information regarding prescribers to their licensing boards, the bar must be very high, such as the highest one percent of prescribers or those doing high-risk prescribing.

PDMP Work Group public member Marjorie Zimdars-Orthman questioned what individuals or DORA staff would facilitate unsolicited reporting to licensing boards and recommended that licensing board should set parameters for reports that would be sent on an unsolicited basis to licensing boards. She also questioned what the penalty would be for actions that practitioners' respective licensing boards consider a violation. She advised that DORA should take into account additional information that may not be available in PDMP data sets, such as patients in palliative care, cancer treatment, post-surgical pain, and certain surgical procedures performed on those who are already long-term chronic pain patients. She further advised that a subject matter expert or experts should be involved if Colorado chooses to send PDMP reports to licensing boards on an unsolicited basis.

Dr. Curtis Hayes, an oral and maxillofacial surgeon and member of the Colorado Attorney General's Opiate Crisis Funds Advisory Committee, stated that the Advisory Committee has been working on ideas to identify problematic practitioners and they had concerns about how to get this information from one regulatory agency to another. He felt that regulatory boards should at least see some limited provider-level information to allow boards to identify practitioner outliers.

Dr. Marc Breen, MD FACEP, an emergency physician, was against any changes to the current law. He cautioned that “it is inadequate to say one physician prescribes more controlled substances than another without the context to support why this may reflect illegal or unethical practice. He further advised that many prescribers would benefit more from further education regarding alternatives to opioid therapy and safer prescribing rather than board inquiries. “Many prescribers need pointed education and rehabilitation from the ‘pain is the 5th vital sign’ and ‘customer service scoring is most important’ practices that were forced upon the medical community by the medical authorities of the time.”

Dr. Ryan Jackman, an addiction medicine physician, expressed concern regarding potential unintended consequences of unsolicited reporting to licensing boards. He advised that PDMP data does not provide the clinical information necessary to truly determine inappropriate prescribing patterns, and when providers know that they could be reported to their licensing board, there will be an increased number of prescribers who elect not to prescribe controlled substances. He stated:

In Western Colorado we have seen a significant increase in the number of providers who refuse to prescribe any controlled substances due to varied movements at the state and national level. The PDMP, and fear of report is one of these that have been voiced by my colleagues. Assuredly this has resulted in prescription opioids or other controlled substances not ending up in unnecessary hands, but it hasn't decreased use of substances or overdoses in our state or country. The bigger clinical issue is that numerous patients who would benefit from access to these medications no longer have access to them or have been cut off from them. Historically, this has increased the rates of use of illicit substances and continued the rates of substance use disorder in our community (not decreased them). Furthermore, it has resulted in a small number of providers in communities being left to care for these patients. This potentially will result in an unfair and unbalanced targeting of prescribers. Addiction providers are often left to evaluate patients with opioid pain prescriptions for opioid use disorder versus just dependence. As a result, we work to taper individuals from opioids, continue to treat pain, and manage opioid use disorder. If there are not a high number of addiction providers in an area to share these patients, you will see one provider taking on a high number of these patients and as a result would be flagged and sent to the board inappropriately.

Rachel Povilus, PA-C, MPAS, MPH, stated that while oversight is appropriate for safe and effective prescribing, unsolicited reporting to licensing boards is not the best solution. She was concerned that prescribers may change their prescribing habits in response to such changes in the law, which could negatively affect patient health and treatment.

The Colorado Psychiatric Society expressed strong opposition to unsolicited reporting to licensing boards, arguing this would create a threatening atmosphere which may inhibit prescribers from accepting patients who require treatment with narcotic pain medications, stimulants or benzodiazepines. They stated that it is unacceptable for licensing boards to receive information about a practitioner's prescribing behavior if no complaints were filed against the practitioner. Such reporting could lead to prescribers discontinuing care for patients who are on chronic or high doses of controlled substances and make it even more difficult for these patients to receive treatment and in turn obtain illicit substances which carry a higher possibility of fatal consequences.

Appendix I: Other Future Evaluation Considerations

Overdose Fatality Reviews and Incorporating Non-Fatal Overdose Information in PDMPs

The 2020 PDMP TTAC State Assessment indicated that 18 PDMPs received information regarding fatal overdoses and 14 PDMPs received information regarding non-fatal overdoses.¹¹⁵ A few states have reported how such information is received and leveraged in their PDMPs. West Virginia reported receiving non-fatal overdose data from the state Office of Emergency Medical Services to PDMP staff who worked with their PDMP vendor to add the record to the appropriate patient's profile in the PDMP. This is displayed in a patient's report when a provider queries that patient in the PDMP advising that the patient experienced a suspected non-fatal overdose within the previous month, and unsolicited reports are proactively sent to prescribers that issued a controlled substance prescription to the patient within 60 days of the suspected overdose.¹¹⁶

A 2020 Pew Research Center report discusses how some PDMPs receive non-fatal overdose information and recommends states consider requiring emergency medical personnel, health care professionals, and law enforcement to promptly report non-fatal overdose information to the state agency operating the PDMP to help ensure clinicians have access to such information in a timely fashion and recommend that unsolicited reports be proactively sent to an individual's treating providers informing them of the non-fatal overdose.¹¹⁷ They cite one study that found that 91% of patients who had overdosed filed another prescription for opioids afterward, and 70% continued to receive opioids from the same prescriber who treated them before the overdose.¹¹⁸ The Pew report notes that in Wisconsin, law enforcement officers who encounter an individual who is undergoing or has just experienced an overdose are required to report the name and date of birth of the individual to the law enforcement officer's agency, which in turn reports the information to the Wisconsin PDMP. In Utah, overdoses related to prescribed controlled substances are reported to the PDMP.¹¹⁹

Given that such initiatives may bolster the clinical decision support aspects of PDMPs, Colorado should further research the impact this data access has on both prescribing behavior and patient outcomes. Because patients with SUDs can experience stigma from providers, it is important that such information would be used to support comprehensive SUD treatment rather than prompting prescribers to discontinue treatment and placing these individuals at higher risk of fatal overdose or suicide.

¹¹⁵ PDMP TTAC. (2021). PDMP Policies and Capabilities: Results from 2020 State Assessment. p. 6.

https://www.pdmpassist.org/pdf/PDMP%20Policies%20and%20Capabilities%202020%20Assessment%20Results_20210111.pdf

¹¹⁶ Centers for Disease Control and Prevention. (2021) Leveraging Prescription Drug Monitoring Program (PDMP) Data in Overdose Prevention and Response. <https://www.cdc.gov/drugoverdose/pdf/Leveraging-PDMPs-508.pdf>

¹¹⁷ Pew Research Center. (2020, Apr. 23). Policy Changes Could Bolster Prescription Drug Monitoring Programs. <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2020/04/policy-changes-could-bolster-prescription-drug-monitoring-programs>

¹¹⁸ M.R. Larochelle et al. (2016). Opioid Prescribing After Nonfatal Overdose and Association With Repeated Overdose: A Cohort Study. *Annals of Internal Medicine* 164(1):1-9. <https://doi.org/10.7326/M15-0038>.

¹¹⁹ Pew Research Center. (2020, Apr. 23). Policy Changes Could Bolster Prescription Drug Monitoring Programs. <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2020/04/policy-changes-could-bolster-prescription-drug-monitoring-programs>

The Pew report also recommends that states implement overdose fatality reviews (OFR) to examine drug-related overdose deaths and search for missed opportunities for intervention including treatment and social services. As of August 2018, nine states had authorized such reviews but only some had authorized OFR teams to access PDMP records. Maryland OFR teams were authorized to access PDMP records and as of August 2018, they had submitted 689 requests for PDMP data in these reviews.¹²⁰ Colorado could also further research the usefulness of authorizing OFRs and the ways in which such a review could be implemented.

Medicaid Access to PDMP Data

Colorado should also further evaluate whether to allow its Medicaid agency access to PDMP data. The 2020 PDMP TTAC State Assessment found that 34 states authorize Medicaid Drug Utilization and Review teams to access PDMP information for Medicaid participants and 37 states authorize Medicaid Fraud and Abuse teams to access PDMP information for Medicaid participants.¹²¹ The SUPPORT Act of 2018¹²² also requires Medicaid agencies to report certain metrics beginning in Federal Fiscal Year 2023 regarding opioid prescribing, other controlled substance prescribing, and PDMP utilization by Medicaid providers to the Centers for Medicare and Medicaid Services. This is in accordance with the SUPPORT Act's requirement that Medicaid providers query the PDMP before prescribing Schedule II-IV controlled substances.

The Department of Health Care Policy and Financing (HCPF), Colorado's Medicaid agency, is challenged in providing such information to CMS because they are not currently authorized to access the Colorado PDMP under any circumstances. Medicaid access could also improve HCPF's ability to provide responsive care to its members. HCPF currently can only see what prescriptions are reimbursed by Medicaid which gives a potentially partial picture of a patient's controlled substance use if the patient is paying cash for additional prescriptions. HCPF has policies designed to ensure patients receive needed medications through proper utilization. Access to the PDMP may allow HCPF to better manage care through Medicaid providers. In addition, HCPF can assess its opioid policies to determine their effectiveness. HCPF has done such assessments using their claims data which is helpful but does not allow for assessment of the extent to which patients pay cash for their medications to avoid the Medicaid policy limits. Historically there has been a concern that if the Medicaid program is granted access to the PDMP, other insurance plans would also want access, which depending on the use of this information by the insurance companies, could raise patient privacy and continued patient care issues. Given there is a distinct difference in statutory and regulatory scope and mission between Medicaid and insurance plans, access could be limited to the Medicaid program or guardrails could be put in place to limit the scope of use of this information. Further research in this area could be beneficial.

¹²⁰ Ibid.

¹²¹ PDMP TTAC. (2021). PDMP Policies and Capabilities: Results from 2020 State Assessment. p. 6. https://www.pdmpassist.org/pdf/PDMP%20Policies%20and%20Capabilities%202020%20Assessment%20Results_2021_111.pdf

¹²² Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (SUPPORT Act), H.R.6, 115th Cong. (2018). <https://www.congress.gov/bill/115th-congress/house-bill/6>