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, 2024

RE: 2023-2024 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 in response to the DORA Executive Director's requests to the PDMP Task Force.

Respectfully,

Colorado Consortium for Prescription Drug Abuse Prevention

COLORADO ELECTRONIC PRESCRIPTION DRUG MONITORING PROGRAM

2023-2024 TASK FORCE REPORT

July 1, 2024

Table of Contents

COLORADO ELECTRONIC PRESCRIPTION DRUG MONITORING PROGRAM

2023-2024 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. *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.

This report is a product of the Colorado Consortium for Prescription Drug Abuse Prevention and Prescription Drug Monitoring Program (PDMP) Task Force pursuant to 12-280-409(2), C.R.S. This report and the recommendations herein do not represent the views of Colorado's Governor's Office, Office of State Planning and Budgeting, the Colorado Department of Regulatory Agencies, or other state agencies.

Requests for 2023-2024 PDMP Task Force Report

Following the issuance of the 2022-2023 PDMP Task Force Annual Report, DORA's Executive Director requested that the Task Force evaluate the following:

Task #1: Evaluate the Impact of PDMP Integration on Utilization

The 2019-2020 PDMP Task Force Annual Report noted that although PDMP integration is a key prerequisite to increased utilization by healthcare practitioners, integration alone does not guarantee utilization. I request that the Task Force evaluate the extent to which integration impacts PDMP utilization and evaluate factors or activities that could increase PDMP utilization by practitioners with integrated PDMP access who are not regularly utilizing the PDMP.

Task #2: Evaluate the Risks and Benefits of Requiring Controlled Substances Administered or Directly Dispensed by Practitioners to be Reported to the Colorado PDMP

Section 12-280-407(1), C.R.S. requires prescription drug outlets to submit completed controlled substance dispensing transactions to the Colorado PDMP. Current law does not require controlled substances that are directly dispensed by a practitioner to a patient to be submitted to the Colorado PDMP. According to the PDMP Training and Technical Assistance Center, 46 states, the District of Columbia, and three U.S. territories may require controlled substance dispensations made directly by a practitioner to be reported to their PDMP. Additionally, 18 states and the District of Columbia may require controlled substance dispensations made directly by veterinarians to be reported to their PDMP. I request that the Task Force evaluate the benefits and risks of requiring controlled substances administered or directly dispensed by practitioners and/or veterinarians to be reported to the Colorado PDMP.

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

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 1,000 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 General Assembly, as well as representatives from various state and federal agencies. A full list of the PDMP Work Group members and their corresponding organizations can be found in **Appendix B**.

Task #1: Evaluate the Impact of PDMP Integration on Utilization

Evaluate the extent to which integration impacts PDMP utilization and evaluate factors or activities that could increase PDMP utilization by practitioners with integrated PDMP access who are not regularly utilizing the PDMP.

Response to Task #1

PDMPs are one of several tools and initiatives implemented in response to the prescription opioid overdose epidemic in the early 2000s. Initially, PDMPs were not widely utilized by practitioners or pharmacists and were instead a regulatory and law enforcement tool to identify and prosecute "pill mills" that exploited gaps in oversight and negligently prescribed or dispensed prescription opioids without a legitimate medical need, which significantly contributed to the widespread diversion of prescription opioids to the illicit market. However, PDMPs have become increasingly accessible over the past decade, and practitioners and pharmacists are increasingly (but not universally) utilizing PDMPs, which has resulted in PDMPs evolving from a law enforcement and regulatory tool to a clinical decision support tool.[1]

It is difficult to determine the impact of PDMPs on the steady decrease in opioid prescribing over the past decade. Research on the effects of various state laws designed to curb opioid prescribing including mandatory PDMP enrollment laws, mandatory PDMP query laws, "pill mill"

[1] Evans, Erica, Dec. 8, 2017. How a 2015 law change affected law enforcement's fight against the opioid crisis. The Deseret News. www.deseret.com/2017/12/8/20636896/how-a-2015-law-change-affected-lawenforcement-s-fight-against-the-opioid-crisis.

laws requiring pain management clinics to register with the state and meet administrative and patient care requirements, and prescribing cap laws limiting the dosage and/or day's supply of opioid prescriptions have had mixed results. Research suggests, however, that PDMPs have had a greater impact on prescribing behavior in states with PDMP use mandates.[2,3,4,5] Many of these studies only evaluated changes in statewide prescribing rates following the implementation of PDMP-related legislation and were unable to disentangle the effects of multiple laws implemented around the same time.[6] Additionally, the lack of uniform enforcement of state laws regarding PDMP registration, PDMP use, and prescribing limits makes it even more difficult to determine the impact of PDMPs on prescribing trends. However, studies leveraging interviews or surveys with practitioners that asked how PDMP utilization affected their prescribing behavior found that PDMP utilization was associated with a reduction in the supply of controlled substances, refusal to prescribe or treat for patients exhibiting deceptive behavior, risk mitigation strategies, communication, education and counseling, referrals and care coordination.[7] Stronger evidence indicates PDMPs have had a role in decreasing multiple provider episodes (MPEs) following the enactment of PDMP-related laws. MPEs are typically defined as patients receiving opioids from five or more prescribers and five or more pharmacies within a 90 day period. MPEs are more closely associated with PDMPs, as nearly all states have long leveraged unsolicited reports to notify practitioners and pharmacies when patients meet MPE thresholds. These unsolicited reports were especially critical years ago when PDMPs were not widely utilized and "doctor shopping," or patients visiting multiple practitioners and pharmacies to obtain multiple concurrent prescriptions, often for purposes of diversion and/or misuse, was common. Doctor shopping has become increasingly rare in recent years. An analysis of MPE rates in five states found MPEs decreased in each state between 2010 and 2016 by the following:

- California: 79.5%
- Delaware: 75.5%
- Florida: 76.6%
- Kentucky: 81.7%

[2] Fink, D.S., Schleimer, J.P., Sarvet, A., et al., 2018. Association between prescription drug monitoring programs and nonfatal and fatal drug overdoses: a systematic review. Ann. Intern. Med. 168(11), 783–790. doi.org/10.7326/M17-3074.

[3] Bao, Y., Pan, Y., Taylor, A., et al., 2016. Prescription drug monitoring programs are associated with sustained reductions in opioid prescribing by physicians. Health Aff. 35(6), 1045–1051. doi.org/10.1377/hlthaff.2015.1673.

[4] Buchmueller, T.C., Carey, C., 2017. The effect of prescription drug monitoring programs on opioid utilization in medicare. Nat. Bur. Econ. Res. 10 (1), 77–112. doi.org/10.1257/pol.20160094.

[5] Grecu, A.M., Dave, D.M., Saffer, H., 2019. Mandatory access prescription drug monitoring programs and prescription drug abuse. J. Policy Anal. Manag. 38 (1), 181–209. doi.org/10.1002/pam.22098.

[6] McGinty, E.E., Stuart, E.A., Caleb Alexander, G. et al., 2018. Protocol: mixed-methods study to evaluate implementation, enforcement, and outcomes of U.S. state laws intended to curb high-risk opioid prescribing. Implementation Sci 13, 37. doi.org/10.1186/s13012-018-0719-8.

[7] Picco, Louisa; Lam, Tina; Haines, Sarah; Nielsen, Suzanne, 2021. How prescription drug monitoring programs influence clinical decision-making: A mixed methods systematic review and meta-analysis. Drug and Alcohol Dependence, Vol 228. doi.org/10.1016/j.drugalcdep.2021.109090.

- Ohio: 86.9%[8]

Similarly, Colorado has experienced a 94% decrease in MPEs from 2014 to 2021, with the rate remaining relatively stable at approximately 3 per 100,000 patients since 2021. These decreases provide stronger support for the assertion that, when utilized, PDMPs are effective in identifying and preventing doctor shopping and diversion of prescribed controlled substances.

Opioid prescribing has consistently decreased over the past decade while PDMP utilization has steadily increased, but both trends are the result of broader changes in prescribing due to a broad recognition that opioids had been over-prescribed, statutory changes to the Colorado PDMP, and advances in integrations between PDMPs and other health IT systems. Opioid prescriptions in Colorado decreased 41% from 2015 (~4.3 million) to 2023 (~2.7 million) while prescriber PDMP utilization has increased over 400% and pharmacist PDMP utilization has nearly tripled. This increased utilization has primarily been driven by integrated connections within practitioners' and pharmacists' native health information technology such as their electronic health records (EHR) and pharmacy management systems. These integrated connections now account for over 60% of prescribing practitioner PDMP queries and 85% of pharmacist PDMP queries. These trends coincide with several pieces of legislation mandating that practitioners and pharmacists register with the Colorado PDMP and the creation and subsequent expansion of PDMP use mandates. Colorado enacted a PDMP registration mandate for DEA-licensed practitioners and pharmacists effective January 1, 2015 with Colorado House Bill 14-1283.[9] Colorado Senate Bill 18-022 implemented a 7-day supply limit on initial opioid prescriptions for certain conditions along with a mandate that prescribers query the PDMP before authorizing a second opioid prescription in 2018.[10] The PDMP query mandate was significantly expanded in 2022 with House Bill 22-1115 and Senate Bill 22-027, which required prescribers to query the PDMP before authorizing an opioid or benzodiazepine prescription, with several exceptions.[11,12]

Despite the increases in PDMP integrations and the implementation of registration and use mandates, the PDMP is not consistently utilized by many prescribing practitioners, even when integrated PDMP access is available. Further measures are needed to promote PDMP utilization beyond reducing time and effort-related barriers to PDMP access. States have pursued a variety of strategies to promote PDMP utilization, including promoting PDMP integration, enacting PDMP query mandates that require prescribing practitioners to query the PDMP before prescribing certain controlled substances, developing continuing education courses and/or training materials for broad distribution, requiring specific training for practitioners at initial licensure or license renewal, and offering in-person academic detailing sessions. Some researchers, EHR systems, and healthcare organizations have developed clinical decision

[8] Strickler GK, Kreiner PW, Halpin JF, Doyle E, Paulozzi LJ, 2020. Opioid Prescribing Behaviors — Prescription Behavior Surveillance System, 11 States, 2010–2016. MMWR Surveill. Summ 69, 1–14. doi.org/10.15585/mmwr.ss6901a1.

[9] HB14-1283. leg.colorado.gov/sites/default/files/images/olls/2014a_sl_239.pdf.

[10] SB18-022. leg.colorado.gov/bills/sb18-022.

[11] HB22-1115. leg.colorado.gov/bills/hb22-1115.

[12] SB22-027. leg.colorado.gov/bills/sb22-027.

support tools that can be configured to prompt users to query the PDMP in certain situations or leverage PDMP data to identify high-risk patients or promote prescribing practices in alignment with CDC guidelines. The Task Force reviewed how PDMP integration, PDMP use mandates, clinical decision support tools, continuing education, academic detailing, and other training efforts can promote PDMP utilization, which are outlined in the next sections of the report.

PDMP Query Mandates to Increase Utilization

States have increasingly legislated PDMP query mandates that require prescribing practitioners or pharmacists to review a patient's PDMP report before prescribing or dispensing certain controlled substances. These mandates often include exceptions for certain conditions, or only mandate a query before an initial prescription or mandate further queries for patients with ongoing prescriptions on a particular schedule. These use mandates tend to increase PDMP utilization, but their effectiveness is highly dependent on whether the use mandates are proactively enforced, and whether practitioners can efficiently access the PDMP.

By 2019, 40 states had PDMP use mandates in advance of prescribing certain medications, though the breadth of these use mandates vary widely, with some states mandating PDMP use before all controlled substances while others mandate PDMP queries only in specific situations or on a periodic basis.[13] Sections 5041 and 5042 of the 2018 SUPPORT Act also require Medicaid providers to query the PDMP before prescribing a Schedule II-IV controlled substance to a covered individual.[14] While PDMP use mandates can improve utilization through the prospect of punitive action for those who fail to comply with requirements, use mandates do not guarantee that practitioners will always review the PDMP as mandated, as these use mandates are not uniformly enforced due to statutory restrictions on enforcement, the complexity of laws and exemptions, resource limitations, and challenges in coordination between regulatory bodies. With millions of prescriptions issued each year and the fact that PDMPs typically do not collect diagnostic information that would inform PDMP staff whether a prescription is subject to a PDMP use mandate, it is virtually impossible for even the most well-resourced state agency to thoroughly enforce PDMP use mandates. It is also difficult to expect practitioners to query the PDMP before each controlled substance prescription if the PDMP is not available directly in their clinical workflow.

An evaluation of how five other states (AK, NY, OK, PA, VA) implemented and enforced mandatory PDMP query laws found information dissemination to be the primary implementation strategy. This included building awareness of the law's existence and its requirements through proactive outreach to clinicians, professional associations and other stakeholders as well as training resources and continuing education courses. Four states reported active enforcement

[13] National Association of Model State Drug Laws. Prescriber Mandated Use of PDMP/PMPs. 2019. namsdl.org/wp-content/uploads/Prescriber-Mandated-Use-of-PDMPs-Map.pdf.

[14] H.R.6 – Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act or the SUPPORT For Patients and Communities Act of 2018. www.congress.gov/115/bills/hr6/BILLS-115hr6enr.pdf

of their PDMP query laws through prescription auditing, and all five states reported reactive complaint-based enforcement. Arkansas reported using report cards showing prescribers how their prescribing patterns compared to clinical guidelines and their peers, but did not use these report cards to identify non-compliant prescribers. Arkansas' Medical Licensure Board only investigated physicians' compliance with the mandatory PDMP query law if the board received a complaint from a patient or another clinician about the physician's opioid prescribing practices. Conversely, New York reported proactive audits of its PDMP system to determine whether users were querying the PDMP as required by law. The researchers found that practitioners' primary areas of concern were related to the exemptions to the mandatory PDMP query law. Interviewees also reported that insufficient IT infrastructure such as integration of PDMPs within EHRs were key barriers to successful implementation.[15]

Other evaluations of use mandate enforcement strategies in Kentucky, Connecticut and Wisconsin also found uneven enforcement. Kentucky has one of the most robust PDMPs in the nation with over 30 employees and a drug enforcement unit with six pharmacist consultants. Kentucky reported conducting regular proactive audits to enforce registration and use mandates, while Connecticut and Wisconsin reported that investigations concerning a practitioner's PDMP utilization were primarily initiated in response to complaints being submitted to their licensing boards. In Kentucky, licensing boards set parameters for audits of prescribers, such as the top five percent of prescribers who co-prescribe opioids and benzodiazepines. Wisconsin officials primarily investigated prescribing practitioners in response to complaints, but also worked with their Controlled Substances Board, which has the authority to review PDMP data to identify outliers or critically dangerous conduct, which is forwarded to licensing boards for investigation. In Connecticut, licensing boards did not have access to PDMP data except through a subpoena in connection with a bona fide investigation. The Connecticut PDMP wanted to avoid being perceived as a disciplinary body and instead focused on ensuring practitioners use the PDMP as a clinical tool and reported focusing their enforcement efforts on prescribers' PDMP registration requirements. PDMP staff from all three states also reported unintended consequences including: some practitioners under-prescribing for pain; practitioners misinterpreting patients' PDMP reports; refusal to treat new patients due to their prescription history; or discontinuing treatment for long-term opioid patients or those who had developed opioid user disorders, which could contribute to these patients transitioning to illicit opioid use.[16] As was reported in detail in the Task Force's 2022 Annual Report, increasing enforcement activity by state licensing boards and law enforcement can lead to a chilling effect on practitioners who may be reluctant to continue treating patients on long-term opioid therapy, those receiving high dosages, and those with substance use disorders. In summary, while use mandates can drive increased PDMP utilization, over-reliance on punitive measures to promote PDMP utilization and safer prescribing can lead to unintended consequences which can result in practitioners refusing to accept new patients on long-term opioid therapy, force

[15] Stone, Elizabeth et al., 2020. Implementation and enforcement of state opioid prescribing laws. Drug and Alcohol Dependence. Vol 213. doi.org/10.1016/j.drugalcdep.2020.108107.

[16] Dickson-Gomez J, Christenson E, Weeks M, 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. doi.org/10.1177/11782218219923349.

patients to taper their medication to lower doses, or abruptly discontinue treatment due to the practitioner's fear of consequences from licensing boards or law enforcement.

Another evaluation of Kentucky prescribers' compliance with its 2012 use mandate reviewed prescribers' PDMP utilization rates between 2010 and 2018 and found that between May and September 2012 (shortly before and after the PDMP use mandate took effect), the share of mandate-covered prescriptions with an associated PDMP query increased from 16 percent to 52 percent. However, the utilization rates decreased over time across all categories. Researchers also found uneven utilization among prescriber specialties and roles, with pain management practitioners querying the PDMP 72 percent of the time following the mandate, primary care practitioners querying 56 percent of the time, nurse practitioners querying 42 percent of the time, and surgical and emergency medicine practitioners querying 34 percent of the time.[17]

Considering the thousands of prescribers in Colorado and the millions of prescriptions issued annually, even if Colorado's licensing boards were granted authority to access Colorado PDMP data to proactively audit their licensees' PDMP records and either the PDMP or boards were granted significantly greater resources, the boards would not have the capacity to ensure complete compliance with PDMP use mandates as seen in the fact that even the most robust PDMPs struggle with achieving universal PDMP utilization. Like Arkansas, the Colorado PDMP lacks the authority to proactively notify licensing boards of a practitioner's information in the PDMP, such as their prescribing behavior or PDMP utilization. Additionally, a violation of the PDMP use mandate does not create a private right of action or serve as the basis of a cause of action.[18] Licensing boards can subpoena a practitioner's PDMP records in connection with a bona fide investigation, but the Colorado PDMP cannot be the source of the investigation, meaning proactive enforcement of the PDMP use mandate is not authorized by current law.

Communication, Continuing Education, and Informal Training

Colorado Senate Bill 19-228 required each licensing board regulating prescribers to promulgate rules that require opioid prescribers to complete training 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 Colorado PDMP as a condition of renewing, reactivating, or reinstating a license.[19] Colorado House Bill 21-1276 added the topics of the potential harm of inappropriately limiting prescriptions to chronic pain patients and best practices for prescribing benzodiazepines to the list of eligible training topics.[20] Though this required training is not limited to certified continuing education courses, the Colorado Consortium for Prescription Drug Abuse Prevention ("Consortium") developed free continuing education courses on several of these topics, but there is no official continuing

[17] Carey, Colleen M; Meille, Giacomo; Buchmueller, Thomas C., 2021. Provider Compliance with Kentucky's Prescription Drug Monitoring Program's Mandate To Query Patient Opioid History. Health Affairs, Vol 40, No. 3. doi.org/10.1377/hlthaff.2020.01316.

[18] §12-280-404(4)(d), C.R.S.

[19] SB19-228. Substance Use Disorders Prevention Measures. leg.colorado.gov/bills/sb19-228.

[20] HB21-1276. Prevention of Substance Use Disorders. leg.colorado.gov/bills/hb21-1276.

education course regarding use of the Colorado PDMP through the Consortium. However, the Colorado PDMP worked with the Colorado Veterinary Medical Association (CVMA) to provide content for a CVMA-created continuing education course to meet the Substance Use Prevention training requirements. This course is free for CVMA members.[21]

In August and September 2022, DPO hosted three PDMP legislative update and training webinars concerning the expanded PDMP use mandate pursuant to Colorado House Bill 22-1115 and Senate Bill 22-027, the PDMP registration mandate for Colorado-licensed pharmacists and DEA-licensed practitioners, authorized access to the PDMP, and supervising practitioners' and pharmacists' requirements for delegated user access. These live webinars were attended by over 1,000 total individuals, and a recording of this training available on DPO's PDMP Training website at dpo.colorado.gov/PDMP/Training has nearly 1,000 total views. Those who attended one of the three live webinars are eligible for one hour of credit toward the substance use prevention training required for Colorado opioid prescribers. DPO also has a number of other tutorial documents and webinars regarding registration and use of the Colorado PDMP web portal for practitioners and delegated users on this website. DPO also anticipates hosting additional training webinars in fall 2024.

The 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain is a robust set of guidelines to promote safe opioid prescribing which, among other guidelines, recommends practitioners utilize the PDMP before prescribing opioids.[22] Many Continuing Education courses, webinars, and seminars have been created to educate practitioners on the CDC's 2022 guidelines. Additionally, the Consolidated Appropriations Act of 2023 enacted a new, one-time eight-hour training requirement for all DEA-registered practitioners (except veterinarians) on the treatment and management of patients with opioid or other substance use disorders.[23] These federal efforts will also help ensure practitioners are educated on using the PDMP and PDMP use mandates.

Several studies have noted that some practitioners feel there is a lack of resources to help practitioners interpret, respond, and communicate PDMP-related information to patients.[24] Another study interviewed PDMP users in Massachusetts reported that some practitioners felt the PDMP was inadequate to guide clinical and prescribing decisions fully, and could lead to wrong conclusions on complex patients.[25] Colorado law does not dictate when a practitioner or

[21] Colorado Veterinary Medical Association, State-Required CE. www.colovma.org/requiredce.

[22] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R., 2022. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep, Vol 71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

[23] U.S. Drug Enforcement Administration. Medication Assisted Treatment. www.deadiversion.usdoj.gov/pubs/docs/MATE_training.html.

[24] Picco, Louisa; Lam, Tina; Haines, Sarah; Nielsen, Suzanne, 2021. How prescription drug monitoring programs influence clinical decision-making: A mixed methods systematic review and meta-analysis. Drug and Alcohol Dependence, Vol 228. doi.org/10.1016/j.drugalcdep.2021.109090.

[25] Hong, Mina, PharmD, MPH; et al., 2022. 'Nobody Knows How You're Supposed to Interpret It:' End-user Perspectives on Prescription Drug Monitoring Program in Massachusetts. Journal of Addiction Medicine. 16(3). doi.org/10.1097/ADM.0000000000000901.

pharmacist can or cannot prescribe or dispense a controlled substance except for limitations on initial opioid and benzodiazepine prescriptions in certain situations, and Colorado law prohibits practitioners from being disciplined solely based on a patient's opioid dosage.[26] Therefore, practitioners are expected to leverage PDMP information as one tool to support their clinical decision making while recognizing that each patient's situation is unique. It is therefore difficult to provide practitioners with detailed instructions or recommendations on what action a practitioner should take based on a patient's PDMP report beyond pointing toward existing guidelines. However, one item may warrant clarification or explanation. Though Colorado does not make Bamboo Health's NarxCare® platform the web portal or integration standard, some Colorado healthcare organizations and pharmacies use this software as part of their PDMP integration. In an integration using NarxCare® a Narx Score may be visible to the user within the link to the patient's full PDMP report. A Narx Score ranges from 000 to 999 and reflects past patient exposure to opioids, sedatives, and stimulants, with higher scores representing a relatively higher risk of overdose or potential misuse. Other factors used to calculate NarxScores include the number of prescribers and pharmacies, co-prescribed drugs, overlapping prescription days, and the quantity and doses of medication dispensed. The number in the third position (00X) represents the number of active prescriptions under that category.[27] Though users may glean information from these Narx Scores (such as a score of 000 meaning the patient has no controlled substance prescription history in the PDMP), the user is only credited with reviewing the patient's PDMP records if the user clicks on the PDMP shortcut link and views the patient's full report. Users may believe that viewing the patient's Narx Score sufficiently credits them for a PDMP query, but the Colorado PDMP has not issued guidance to users regarding the fact that users must view a patient's full report for the PDMP to credit them with a PDMP query. For example, the Texas PDMP's website advises practitioners that when a patient's PDMP record is accessed, some integrations show a patient risk score, but viewing this score is not considered compliant with Texas' PDMP query mandate and that users must review the full PDMP report to be credited for a PDMP query.[28] Users would likely benefit from guidance on this matter, which could be incorporated into PDMP training or continuing education materials.

To promote PDMP utilization, DPO should consider working with the Consortium and/or professional associations representing practitioners to develop formal continuing education courses to raise awareness of the expanded PDMP use mandate and the various ways practitioners can more efficiently comply with this mandate, either through integration with their native health IT system or through delegated access.

[26] §12-30-109, C.R.S.

[27] Bamboo Health, Press Releases, Oct 26, 2021. Peer-Reviewed Study Validates Bamboo Health's NarxCare as Effective Patient Screening Solution for Opioid Risk. bamboohealth.com/press-release/peer-reviewed-study-validates-bamboo-healths-narxcare-as-effective-patient-screening-solution-for-opioid-risk.

[28] Texas Prescription Monitoring Program. Mandated Use of the Texas PMP. txpmp.org/about.

Academic Detailing

Academic detailing is a resource-intensive form of prescriber education in which practitioners engage in individualized, one-on-one educational sessions between an academic detailer and practitioner. Academic detailers are typically practitioners, pharmacists, or others with an extensive healthcare background, and academic detailers typically identify practitioners to target for academic detailing leveraging the practitioner's prescribing and/or PDMP utilization information, which is not currently allowed under Colorado law. The 2023 PDMP TTAC Policies and Capabilities assessment indicates that 13 states were involved in academic detailing (CT, IL, IA, ME, MD, OK, PA, RI, SC, TX, UT, VT, VA).[29]

With the limited reach and resource intensiveness of academic detailing, the CDC has funded programs that support state health departments in employing academic detailing and other strategies to reduce morbidity and mortality from drug overdose, and the CDC developed a guide to assist health departments with implementing academic detailing programs.[30] Academic detailing has been found to result in increased PDMP utilization and safer opioid prescribing practices, but the resource-intensive nature of these programs means they have limited reach. For example, one evaluation focused on 87 physicians in South Carolina who received an office-based, individualized, educational intervention from a trained pharmacist who promoted three key messages about safer opioid prescribing. Physicians were registered for the state PDMP, guided through retrieving information from the PDMP, and given patient-centered materials. Of the 43 physicians who did not previously use the PDMP, 83% reported utilizing the PDMP following the academic detailing.[31]

In Illinois, a Peer Review Committee comprised of three physicians, three pharmacists, one dentist, one advanced practice nurse, one physician assistant and one optometrist meet twice per year to identify practitioners to target for academic detailing using a threshold of practitioners who co-prescribed opioids and benzodiazepines to 10 or more patients for three consecutive months over the previous six months and target 35 to 40 practitioners for academic detailing. These practitioners are sent a Request for Information letter asking them to explain their rationale for co-prescribing opioids and benzodiazepines, what risk mitigation strategies they employ, their board certifications in a specialty, how they currently utilize the PDMP, and request they confirm or correct their taxonomy information on their Illinois PDMP account. This committee sends up to three letters requesting a response, and those who fail to respond are referred to their licensing board. The Peer Review Committee then decides whether the practitioner is recommended for an academic detailing visit based on the practitioner's

[29] Prescription Drug Monitoring Program. PDMP Policies and Capabilities: 2023 Assessment Results. January 2024. www.pdmpassist.org/pdf/resources/PDMP%20Policies%20and%20Capabilities%202023%20Assessment%20Results_final_20240108.pdf.

[30] Academic Detailing to Enhance Overdose Prevention: An Implementation Guide for Organizations. National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, Department of Health and Human Services, 2022. www.cdc.gov/drugoverdose/pdf/academic-detailing-implementation-guide-508.pdf.

[31] Larson MJ, Browne C, Nikitin RV, Wooten NR, Ball S, Adams RS, Barth K, 2018. Physicians report adopting safer opioid prescribing behaviors after academic detailing intervention. Subst Abus. 39(2):218-224. doi.org/10.1080/08897077.2018.1449175.

response. Those chosen for academic detailing receive an initial email explaining the intent, and then receive two follow-up emails, two phone calls, and a final follow-up email.[32] An evaluation of 149 Illinois clinicians who received academic detailing found that 72 clinicians reported an intent to change their prescribing, while 77 reported no-to-moderate intent to change their prescribing. In the six months following the academic detailing intervention, there were 1.48 fewer total opioid prescriptions and 0.5 fewer high-dose opioid prescriptions per practitioner per month in the group who reported an intent to change their prescribing compared to those who reported no-to-moderate intent to change their prescribing. Illinois did not report whether practitioners increased their PDMP utilization after receiving academic detailing.[33]

Effective academic detailing requires that PDMP data be accessible by a reviewing body that identifies potential recipients for outreach and academic detailing based on the practitioner's prescribing behavior and lack of PDMP utilization. In Colorado, legislative changes concerning authorized PDMP access would be needed, and the labor-intensive nature of academic detailing means significant fiscal resources would be necessary for successful implementation. With these constraints, academic detailing should not be a near-term priority in Colorado to promote PDMP utilization.

PDMP Integration and Impact on Utilization

When PDMPs were initially established and developed, users could only access the database through an online web portal and typically spent several minutes to log in and manually query the database, and users often needed to pick through a number of potential results to find their patient's complete controlled substance history. When PDMPs are not integrated into practitioners' EHR or pharmacists' pharmacy management systems, the most widely cited reasons for not regularly utilizing PDMPs are the length of time required to query the database, the number of clicks and keystrokes required, cumbersome password requirements, and a lack of intuitive format of data presentation.[34] Without integrated access, practitioners and pharmacists typically report that "red flag" behaviors and unfamiliarity with a patient are the most common conditions prompting them to check the patient's PDMP report. Users also report that their PDMP utilization would significantly increase if the PDMP was integrated within their

[32] Pointer, Sarah; Huff, Eric; Illinois PDMP. Academic Detailing for PDMPs: Examples from Utah and Illinois. PDMP TTAC webinar, May 25, 2023. www.pdmpassist.org/pdf/resources/TTAC_webinar_Academic_Detailing_UT-IL_20230525.pdf

[33] Saffore, Christopher D. et al., 2020. Practice change intentions after academic detailing align with subsequent opioid prescribing. Journal of the American Pharmacists Association. 60(6):1001-1008. doi.org/10.1016/j.japh.2020.08.011.

[34] Rutkow L, Turner L, Lucas E, Hwang C, Alexander GC., 2015. Most primary care physicians are aware of prescription drug monitoring programs, but many find the data difficult to access. Health Aff (Millwood). 34(3):484-92. doi.org/10.1377/hlthaff.2014.1085.

EHR.[35] This is consistent with other studies that found those who can efficiently access the PDMP find the database to be a valuable tool and leverage it more regularly.[36,37]

The advent of integrations between the PDMP users' native health IT systems and improvements to patient matching algorithms have significantly decreased the time and effort required to access PDMP information. Over the past ten years, healthcare systems, pharmacies, and health information technology (IT) vendors have increasingly implemented integration capabilities with PDMPs. The PMP Gateway integration service is operated by PDMP vendor Bamboo Health (previously Appriss, Inc.) and connects systems with the National Association of Boards of Pharmacy's (NABP) PMP InterConnect hub. PMP Gateway implemented its first integration in September 2014 between the Wisconsin Statewide Health Information Network and the Wisconsin PDMP. In 2015, Kroger pharmacies in Ohio integrated with Ohio's PDMP, the Ohio Automated Rx Reporting System (OARRS). In Colorado, the University of Colorado, Boulder was the first entity to integrate its Electronic Health Records (EHR) with the Colorado PDMP via the PMP Gateway in December 2016, followed by Colorado's Kroger pharmacies in July 2017. As of January 2019, only 25 organizations had integrated their health IT systems with the Colorado PDMP. By January 2020, over 300 organizations had established an integrated connection. As of 2024, over 900 PMP Gateway licenses for organizations with facilities in Colorado have been approved, and practitioners and pharmacists at nearly 600 organizations in Colorado are currently utilizing the PMP Gateway service. This includes all major pharmacy chains and approximately 55% of Colorado practitioners who are actively prescribing controlled substances.

PDMP integration with users' native systems removes key barriers to utilization, but integration alone does not guarantee that practitioners will regularly utilize the PDMP. The 2018-2019 PDMP Task Force Annual Report to the General Assembly evaluated the effectiveness of several different PDMP integration strategies and noted that while PDMP integration is a necessary prerequisite for broader PDMP utilization by removing the time and effort-based constraints of accessing the PDMP, PDMP integration does not guarantee that providers will regularly access a patient's PDMP information.[38]

Internal review of practitioners' utilization rates shows highly variable utilization rates among practitioners with integrated PDMP access. A review of 11,897 DEA-licensed practitioners who accessed the Colorado PDMP via the PMP Gateway integration service between July and December 2023 found a broad range of utilization compared to controlled substance prescribing activity as summarized in Figure 1 below:

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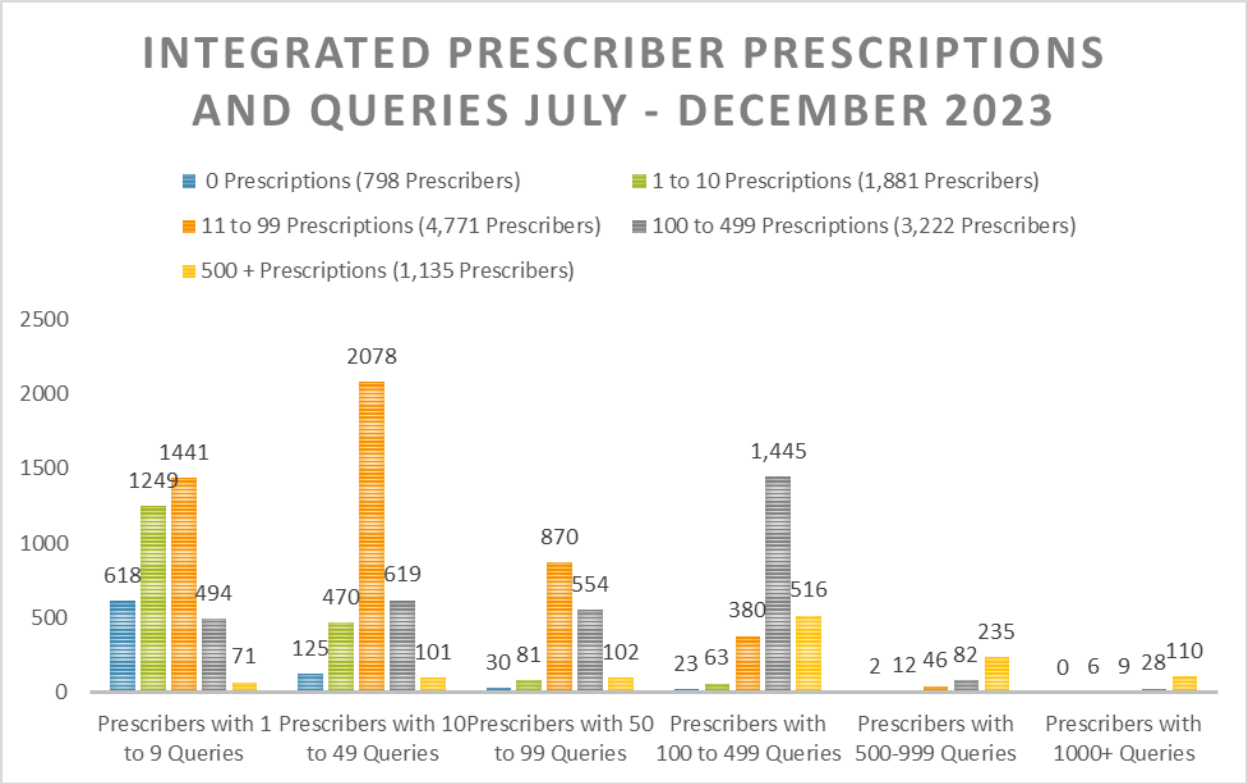
[35] Reist, Jeff, et al., 2020. Provider beliefs on the Barriers and Facilitators to Prescription Monitoring Programs and Mandated Use. Substance Use & Misuse. 55:1, 1-11. doi.org/10.1080/10826084.2019.1648512.

[36] Robert J. Smith, Austin S. Kilaru, Jeanmarie Perrone, Breah Paciotti, Frances K. Barg, Sarah M. Gadsden, Zachary F. Meisel, 2015. How, Why, and for Whom Do Emergency Medicine Providers Use Prescription Drug Monitoring Programs?, *Pain Medicine*. 16(6), pp. 1122–1131. doi.org/10.1111/pme.12700.

[37] Martin, Heather D.; Modi, Shikha S.; Feldman, Sue S., 2021. Barriers and facilitators to PDMP IS Success in the US: A systematic review. Drug and Alcohol Dependence, Vol. 219,108460. doi.org/10.1016/j.drugalcdep.2020.108460.

[38] Colorado General Assembly. Statutory Reports. Statutory Cite: 12-280-409(2). July 2019 report. www.leg.state.co.us/library/reports.nsf/ReportsDoc.xsp

Figure 1: PMP Gateway Integrated Prescriber Prescriptions and Queries, July - December 2023



Source: Colorado PDMP Prescription Data and PMP Gateway Audit Logs

Practitioners are authorized to query the PDMP for any current patient of the practitioner and are encouraged to query the PDMP for reasons beyond controlled substance prescribing considerations. Those who query the PDMP more often than they prescribe controlled substances are highly engaged with the PDMP, while those who infrequently query the PDMP compared to their controlled substance prescribing are less engaged, despite both having similarly efficient access to the PDMP. Clearly, integration alone does not guarantee utilization. Additional efforts are necessary to promote awareness, familiarity, and regular utilization for those who are not currently engaged with the PDMP.

Promoting PDMP Utilization with Clinical Decision Support Tools

Clinical decision support ("CDS") systems were first developed with the advent of EHRs and other electronic health information technology systems. CDS encompasses a variety of tools including, but not limited to: computerized alerts and reminders for providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support; and contextually relevant reference information.[39]

[39] FDASIA Health IT Report, p. 26, April 2014. www.healthit.gov/sites/default/files/fdasia_healthitreport_final.pdf.

Healthcare systems often independently design, build, and implement CDS tools using their EHR vendors' integration toolsets. In recent years, several new health technology standards have emerged to address the need for open-source resources to support interoperable and reusable CDS elements to support broader and faster adoption of sophisticated CDS tools. Several vendors and healthcare organizations have developed CDS tools that integrate with PDMPs and other data sources to provide a variety of features including enhanced visualizations to help practitioners interpret a patient's PDMP report or interruptive alerts that reference best practices in the electronic prescription workflow and prompt users to query the PDMP in certain situations. However, some features such as overdose risk scores have been criticized for a lack of external and/or peer-reviewed validation.

Clinical Decision Support - Enhanced Visualization of Data

Bamboo Health's NarxCare® is the most commonly-used data visualization CDS and analytics leveraging PDMP data in Colorado and nationwide. NarxCare provides clinical users with a patient's Narx Score for narcotic (opioid), sedative, and stimulant prescriptions along with an overall Overdose Risk Score between 000-999, with the third digit indicating the number of active prescriptions for a patient. NarxCare also provides visual chronological summaries of narcotic, buprenorphine, sedative, stimulant, and "other" prescriptions recorded in the PDMP and other state-specified indicators in addition to a list of the patient's prescriptions in the PDMP.[40] NarxCare's enhanced data visualizations can help users more efficiently interpret a patient's PDMP information, but NarxCare has also generated controversy. Some patients allege that NarxCare's proprietary algorithm used to generate an Overdose Risk Score has caused patients to face discrimination and be inappropriately denied care due to practitioners or pharmacists being over-reliant on these risk scores.[41,42,43] One study evaluated NarxCare's risk scores in a limited population and found them to be a useful initial screening tool for prescribers to determine whether a patient is at risk for opioid misuse.[44] However, others criticized this evaluation and argue that existing evaluations of NarxCare are insufficient, as they have only been technically validated and only evaluated a narrow cohort that cannot necessarily be generalized to the rest of the population.[45]

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[40] Bamboo Health. NarxCare. bamboohealth.com/solutions/narxcare.

[41] Oliva, Jennifer D., 2022. Dosing Discrimination: Regulating PDMP Risk Scores. California Law Review. 110(47). doi.org/10.2139/ssrn.3768774

[42] Siegel, Zachary. 2022. In a World of Stigma and Bias, Can a Computer Algorithm Really Predict Overdose Risk? Annals of Emergency Medicine. 79(6). doi.org/10.1016/j.annemergmed.2022.04.006.

[43] Miller, Andy; Whitehead, Sam, Aug. 30, 2023. Artificial Intelligence May Influence Whether You Can Get Pain Medication. KFF Health News. kffhealthnews.org/news/article/artificial-intelligence-pain-medication-narx-score.

[44] Cochran, G; Brown, J; Yu, Z,et al., 2021. Validation and threshold identification of a prescription drug monitoring program clinical opiod risk metric with the WHO alcohol, smoking, and substance involvement screening test. Drug and Alcohol Dependence. 228(1). doi.org/10.1016/j.drugalcdep.2021.109067.

[45] McElfresh, Duncan C., et al., 2023. Perspective: A call for better validation of opioid overdose risk algorithms. Journal of the American Medical Informatics Association. 30(10). doi.org/10.1093/jamia/ocad110.

NarxCare integrations can provide a patient's Overdose Risk Score within the link to the patient's full PDMP report without requiring users to view the full PDMP report. Though there is no statutory mandate for pharmacists to query the PDMP, anecdotes from pharmacists indicate that some pharmacy chains have internal policies requiring pharmacists to review a patient's PDMP report when a patient's Overdose Risk Score exceeds a particular threshold. Though questions remain regarding the extent to which clinicians should rely on risk scores, this is one example of how organizations can leverage third-party CDS tools available in PDMP integrations to implement policies to promote, encourage, or require clinicians to query the PDMP.

Another enhanced PDMP integration product available to Colorado practitioners is OpiSafe, a Colorado-based organization that can schedule PDMP queries and merge PDMP, toxicology lab, and patient reported outcomes into a clinical decision support dashboard for prescribers which can integrate into several major EHR systems.[46] The interface can also be customized to align with healthcare organization policies. These enhanced data visualizations are another option to engage practitioners and facilitate the interpretation of PDMP data.

Clinical Decision Support - Interruptive Alerts

Interruptive alerts are the most common way that CDS systems interact with healthcare practitioners. Most computerized provider order entry systems (CPOE) have the ability to enable and configure a number of CDS tools to trigger medication-related alerts. Analyses of interruptive medication prescribing alerts aimed at changing prescribing behavior and improving patient safety have found that a majority of alerts improved prescriber behavior or patient outcomes, but not all alerts are effective and limited evidence exists to demonstrate that one category of alerts is more effective than another.[47] CDS alerts are now extremely prevalent. A 2019 evaluation of VHA providers found that 70% of primary care practitioners reported EHR-based inbox notifications originally intended for communicating important clinical information to be of unmanageable volume, and efforts at VHA to reduce such alerts resulted in a reduction of average daily notifications from 122 to 112.[48] This high volume of interruptive alerts can create "alert fatigue" causing practitioners to ignore or override the vast majority of computerized order entry warnings, even critical alerts that warn of potentially severe harm, which threatens patient safety.[49]

CDS and CPOE tools for controlled substance prescribing can increase PDMP utilization by alerting practitioners by reminding them to query the PDMP and citing best practices, guidelines

[46] opisafe.com

[47] Page, N; Baysari, M.T.; Westbrook, J.I., 2017. A systematic review of the effectiveness of interruptive medication prescribing alerts in hospital CPOE systems to change prescriber behavior and improve patient safety. International Journal of Medical Informatics. Vol 105. doi.org/10.1016/j.ijmedinf.2017.05.011.

[48] Shah T, Patel-Teague S, Kroupa L, et al., 2019. Impact of a national QI programme on reducing electronic health record notifications to clinicians. BMJ Quality & Safety. 28:10-14. doi.org/10.1136/bmjqs-2017-007447.

[49] Patient Safety Network. Agency for Healthcare Research and Quality, 2019. Alert Fatigue.psnet.ahrq.gov/primer/alert-fatigue.

or policies, but organizations and developers must balance these potential benefits against the possibility that too many interruptive alerts can reduce the tools' effectiveness through alert fatigue. Several examples of interruptive CDS alerts designed, at least in part, to increase PDMP utilization are discussed below.

Clinician researchers at the University of Colorado Hospital system studied the effectiveness of interruptive CDS reminders that prompt practitioners to query the PDMP before prescribing an opioid in increasing PDMP utilization during emergency department (ED) visits when prescribing opioids in five EDs in the University of Colorado Hospital system between October 2016 and June 2018, before Colorado had a PDMP use mandate. Practitioners' PDMP utilization was assessed in five phases: 1) no EHR integration with the PDMP; 2) EHR integration with access to raw prescription data; 3) EHR integration with an earlier version of Bamboo Health's NarxCare (at the time, called NarxCheckPlus); 4) EHR integration with NarxCheckPlus AND an interruptive CDS alert within prescribers' workflow reminding prescribers to review the PDMP; 5) the CDS alert was removed, but the EHR integration with NarxCheckPlus remained. Overall, the PDMP was not frequently reviewed during an ED visit where an opioid was prescribed, though the interruptive alert modestly increased PDMP utilization, with the utilization rate increasing from approximately 20% to nearly 40% of patients receiving an opioid at one site. Additionally, PDMP utilization decreased after removing the interruptive alert. These findings demonstrate that interruptive alerts can promote PDMP utilization. The researchers also found that while the overall rate of opioid prescribing was was not affected by PDMP utilization, there was a significant reduction in the probability that an opioid was prescribed as the number of previous opioid prescriptions increased when the PDMP was utilized, but no such decrease was found when the PDMP was not reviewed. This indicates that patients' PDMP reports influenced emergency medicine practitioners' decision when an extensive history of opioid prescriptions was found through the PDMP.[50]

Another local evaluation of PDMP-EHR integrations compared the prescribing activity and PDMP utilization of 123 primary care Internal Medicine and Family Medicine physicians and advanced practice providers working at Denver Health and Hospital Authority before and after a PDMP-EHR integration that included clinical decision support which leveraged PDMP data reviews at scheduled interviews set by the clinicians with emailed updates and alerts when patients filled prescriptions. These clinicians were compared their behavior to a control group that did not receive PDMP-EHR integration within Denver Health and Hospital Authority and a second control group of practitioners within the Denver metropolitan area. Those who obtained integrated access in this study were also surveyed regarding the frequency and circumstances of PDMP use, perceived liability related to opioid prescribing, approach to concerns for opioid misuse or diversion, and respondent characteristics before and after the integration. Researchers found decreases in high-dose opioid prescriptions across all provider groups, but those with integrated PDMP access had the greatest decreases. They also found a significant decrease in overlapping

[50] Hoppe, Jason A, DO; Ledbetter, Caroline, MS; Tolle, Heather, PhD; Heard, Kennon, MD, PhD, 2023. Implementation of Electronic Health Record Integration and Clinical Decision Support to Improve Emergency Department Prescription Drug Monitoring Program Use. Annals of Emergency Medicine. 83(1). doi.org/10.1016/j.annemergmed.2023.07.002.

opioid prescription days for patients prescribed opioids by clinicians with integrated PDMP access, but no decrease for patients of clinicians without integrated PDMP access. Regarding clinician surveys, clinicians were more likely to report awareness of CDC guidelines to check the PDMP before opioid prescribing in the post-implementation survey (pre: 80.9%, post: 98.6%). Many reported checking the PDMP every time with opioid prescriptions, even when they had no concern for medication misuse or diversion (pre: 40.5%, post 66.7%). Most clinicians also reported checking the PDMP every time they had concern for medication misuse or diversion (pre: 55.1%, post: 87.5%). Nearly all clinicians reported using the PDMP integration after receiving access (95.8%), reported that the integration was useful (97.1%), and would recommend the integration program to their peers (97.1%).[51] These findings suggest that enhanced functionality within a PDMP integration can improve practitioner utilization and engagement with the PDMP.

In connection with the CDC's 2016 Guideline for Prescribing Opioids for Chronic Pain,[52] Houston Methodist Hospital developed a custom CDS tool to align opioid prescribing with several CDC recommendations, including the recommendation that practitioners review patients' PDMP data when starting opioid therapy and periodically thereafter. This CDS tool was integrated in Houston Methodist's EHR and included single-click access to the PDMP. They found that quarterly PDMP queries for patients on ongoing opioid therapy increased from 5.58% to 30.18% following the implementation of this tool, and found that this increased PDMP utilization has remained elevated beyond initial implementation.[53]

In an effort to promote the implementation and adherence of the CDC's 2022 Clinical Practice Guideline for Prescribing Opioids,[54] the CDC is working with the Office of the National Coordinator for Health Information Technology (ONC) to develop, refine, update and harmonize standards for clinical decision support and electronic clinical quality measurement focused on improving processes for the development of standardized, shareable, computable decision support artifacts using the 2022 CDC Clinical Practice Guideline as a model case.[55] These tools build on previous CDS tools designed to implement the CDC's 2016 guidelines.[56] Four pilot healthcare systems (Houston Methodist in Houston, TX; Montefiore Medical Center in Bronx, NY;

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[51] Calcaterra, Susan L., MD, MPH; Butler, Maria, MPH; Olson, Katie, MPH; Blum, Joshua, MD, 2022. The Impact of a PDMP-EHR Data Integration Combined With Clinical Decision Support on Opioid and Benzodiazepine Prescribing Across Clinicians in a Metropolitan Area. Journal of Addiction Medicine. 16(3). doi.org/10.1097/ADM.0000000000000905.

[52] Dowell D, Haegerich TM, Chou R., 2016. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 65(No. RR-1):1–49. doi.org/10.15585/mmwr.rr6501e1.

[53] Fink, Ezekiel, MD. Medical Director of Pain Management, Houston Methodist Hospital. Incorporating Electronic Clinical Decision Supports into Clinical Workflow to Support Evidence-Based Pain Care: Implementation Insights from Houston Methodist Hospital. Presentation at 2024 Rx and Illicit Drug Summit.

[54] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R., 2022. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 71(No. RR-3):1–95. DOI: dx.doi.org/10.15585/mmwr.rr7103a1.

[55] 2022 CDC Clinical Practice Guideline for Prescribing Opioids Implementation Guide. build.fhir.org/ig/cqframework/opioid-cds-r4/index.html.

[56] CDC Injury Center. Resources for Healthcare Administrators. Electronic Clinical Decision Support Tools: Safer Patient Care for Opioid Prescribing. www.cdc.gov/opioids/healthcare-admins/ehr/index.html

Stormont Vail Health in Topeka, KS; Lancaster General Health in Lancaster, PA) developed EHR-embedded CDS tools that align with the 2022 CDC Clinical Practice Guideline recommendations and are integrated within practitioners' clinical workflow. These tools include alerts, access to PDMP data, patient registries, auto-population of prescription fields, order sets, morphine milligram equivalent (MME) calculators, and templates for clinical notes and referrals. With these tools, Houston Methodist reported increased PDMP queries prior to a new opioid prescription for chronic pain and Stormont Vail Health reported that more than 85% of primary care practitioners now consult the PDMP before writing an opioid prescription. Evaluation of these pilot projects found that these tools can promote safer opioid prescribing and improve patient care. However, the design, validation and implementation process for these tools can be highly variable, and healthcare systems' capabilities and resources are critical in determining which CDS modules can be successfully implemented. Organizations that lack internal expertise or IT experience may not be able to develop their own tools due to the length of time to build, test, iterate and implement these custom CDS tools which limit their potential reach.[57] Therefore, while the implementation guide is freely available to organizations, the creation of custom CDS tools is currently limited to larger hospital systems and healthcare organizations that have sufficient in-house IT resources.

The Veterans Health Administration (VHA) developed the Stratification Tool for Opioid Risk Mitigation (STORM) which has been clinically and technically validated to predict risk of suicide- or overdose-related events using data extracted from VHA's EHR and predictive analytics. STORM can review risk factors for patients who are being considered for prescription opioid therapy and prioritizes patients for monitoring and intervention, and displays the patient's risk factors and associated risk mitigation interventions. The underlying risk model identified nearly twice as many patients who had future adverse events as did previously used approaches, and preliminary results indicate that mandating very-high risk patients receive an interdisciplinary review was associated with a decrease in all-cause mortality following identification by STORM. STORM developers emphasize that practitioners require training, technical assistance, and academic detailing to become familiar with the system, and successful implementation requires having a dedicated informatics team to manage all data analysis and reporting components of STORM.[58]

A machine learning-derived overdose risk model developed under a grant from the National Institute on Drug Abuse (NIDA) was created using Pennsylvania and Arizona Medicaid beneficiary information. Pennsylvania patients with a risk score in the top 1% according to this model were 14 times more likely to experience an opioid overdose within the following three months than the overall population, and Arizona patients with a risk score in the top 1% were approximately

[57] Sargent, Wesley, EdD, EdS, MA, LPC. Senior Health Scientist, Division of Overdose Prevention, CDC. Incorporating Electronic Clinical Decision Supports into Clinical Workflow to Support Evidence-Based Pain Care: Implementation Insights from Houston Methodist Hospital. Presentation at 2024 Rx and Illicit Drug Summit.

[58] Agency for Healthcare Research and Quality. Patient Safety Network. Jan. 7, 2022. Veterans Health Administration Stratification Tool for Opioid Risk Mitigation (STORM) Shows Promise for Targeting Prevention Interventions to Reduce Mortality in Patients Who Are Prescribed Opioids. psnet.ahrq.gov/innovation/veterans-health-administration-stratification-tool-opioid-risk-mitigation-storm-shows

20 times more likely to experience an opioid overdose in the following three months. Additionally, Pennsylvania patients in the top 20% of risk scores accounted for 73.8% of overdoses, and Arizona patients in the top 20% of risk scores accounted for 54.7% of overdoses.[59] This algorithm is estimated to accurately identify 70-90% of high-risk patients and exclude the large majority of prescription opioid users with negligible risk while evaluating the benefits and risk tradeoffs of prescription opioid use for high-risk patients. The second phase of this NIDA grant involved designing and developing a pilot CDS tool leveraging this risk score to warn clinicians about high-risk patients at University of Florida Health and in three primary care clinics.[60,61] This CDS tool notifies practitioners when patients have an elevated risk of opioid overdose and compares their risk to a baseline rate and provides recommendations to the practitioner. The tool also allows practitioners to view a page explaining the algorithm and risk. Patient outcomes for this cutting-edge technology are currently being evaluated.[62]

The Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) standard for electronic healthcare information exchange has the potential to simplify the development and implementation of CDS tools leveraging PDMP, and HL7 is currently developing a PDMP FHIR Implementation Guide.[63,64] FHIR simplifies information exchange implementation, but presents unique questions for PDMPs. FHIR integrations can receive responses from PDMPs as a URL to access a report containing the patient's PDMP history, or as discrete FHIR data that lists each element of a PDMP report as a separate data element. This discrete data could be leveraged by the receiving system to create and display a customized PDMP report or could be leveraged in certain analytics without presenting the patient's prescription history to the end user.[65] This could give PDMPs less visibility into how or whether the PDMP report was viewed by the end user because the receiving system could selectively display only certain data elements or could leverage PDMP data in the background of a CDS tool without the requester viewing the PDMP report. PDMP data transmission via FHIR could also allow for PDMP data to be ingested and stored in the receiving system. Though this data exchange format is ideal for a number of electronic health information exchange processes, it presents unique challenges for PDMPs with respect to law enforcement and regulatory oversight of PDMP utilization, as PDMPs may not always be able to determine whether the end user viewed a patient's PDMP report through a FHIR integration, which could present challenges for regulatory boards or law enforcement

[59] Lo-Ciganic, Wei-Hsuan, PhD; et al., 2022. Developing and validating a machine-learning algorithm to predict opioid overdose in Medicaid beneficiaries in two US states: a prognostic modelling study. The Lancet. 4(6):E455-E465.doi.org/10.1016/S2589-7500(22)00062-0.

[60] University of Florida College of Pharmacy. Aug. 11, 2021. New AI tool will predict patients at high risk for opioid use disorder and overdose. pharmacy.ufl.edu/2021/08/11/new-ai-tool-will-predict-patients-at-high-risk-for-opioid-use-disorder-and-overdose.

[61] Developing and Evaluating a Machine-Learning Opioid Prediction & Risk Stratification E-Platform (DEMONSTRATE). NIH RePORTER. Project Number 1R01DA050676-01A1. Project Leader Lo-Ciganic, Wei-Hsuan. reporter.nih.gov/search/fo_pDvbF5ECZ_-35MQQtQQ/project-details/10119030.

[62] Lo-Ciganic, Wei-Hsuan, PhD. Machine Learning for Precision Overdose Prevention. Presentation at 2024 Rx and Illicit Drug Summit.

[63] HL7 FHIR Release 5 Introduction. hl7.org/fhir/overview.html.

[64] HL7 FHIR US PDMP Implementation Guide. build.fhir.org/ig/HL7/fhir-pdmp.

[65] HL7 FHIR US Prescription Drug Monitoring Program. Operation Submission Options. build.fhir.org/ig/HL7/fhir-pdmp/submission-options.html.

when leveraging a user's PDMP utilization audit logs in regulatory or criminal enforcement actions. If or when PDMP integrations via FHIR become available, the Colorado State Board of Pharmacy should consider establishing requirements via rulemaking concerning PDMP integration data exchange formats and ingestion of PDMP data pursuant to the Board's authority to adopt all rules necessary to implement the Colorado PDMP under §12-280-404(2)(a).

Enhanced visualizations, algorithm-generated risk scores, and interruptive alerts can promote PDMP utilization and engagement, but these systems require training and education to ensure users understand how to leverage this information to assist with decision-making. Additionally, practitioners and organizations should be conscientious of the limitations of CDS tools and ensure practitioners' clinical judgment is not outweighed by CDS recommendations or alerts. Some CDS tools are available as an out-of-the-box solution and are available to a broad range of users, while customized systems are being developed by healthcare organizations' in-house IT professionals and are not readily adaptable to other settings. For many emerging CDS tools, the PDMP is merely one of many data sets being integrated into the EHR, and PDMPs will need to ensure their integrative capabilities are adaptable to a broad range of systems and contexts.

Recommendation: Task #1

The Task Force recommends that DPO continue to develop training materials and host periodic webinars to promote awareness of the Colorado PDMP and its use mandate. DPO should also work with the Consortium and professional associations representing Colorado practitioners to develop on-demand continuing education courses to further educate practitioners on Colorado's PDMP use mandate, how to effectively use the Colorado PDMP, how the Colorado PDMP tracks PDMP utilization, and the requirements for delegated user access. These materials may promote PDMP utilization and provide additional opportunities to meet training requirements. Additionally, the Task Force notes that DPO may benefit from coordinating with healthcare organizations to ensure the organizations are aware of Colorado's recently-expanded PDMP use mandate and encourage these organizations to enact policies consistent with Colorado's PDMP use mandate. The Task Force also analyzed academic detailing to promote PDMP utilization, but due to the resource-intensive nature of academic detailing and the fact that current law does not allow for a practitioner's prescribing history and PDMP utilization to be shared for training or academic detailing purposes, academic detailing is not currently a feasible method for promoting PDMP utilization in Colorado.

PDMP integration can alleviate the time and effort-related barriers to PDMP utilization, but inconsistent utilization among prescribing practitioners with integrated PDMP access demonstrates that integration alone does not guarantee practitioners will utilize the PDMP. Therefore, additional efforts should be made to promote PDMP utilization. The Task Force recommends that healthcare organizations, EHR vendors, and PDMP integration vendors continue to explore and develop enhanced PDMP integrations with clinical decision support tools, encompassing both enhanced data visualizations that help practitioners interpret PDMP data and interruptive alerts reminding practitioners to review the PDMP during the electronic

prescribing workflow to increase PDMP utilization. Some PDMP integrations currently utilize enhanced data visualizations and several systems identify patients at higher risk for adverse events. Advanced CDS tools that promote prescribing in alignment with CDC guidelines or leverage machine learning algorithms that identify higher-risk patients and recommend interventions are emerging but require significant administrative and IT development resources, which limits their potential availability until standardized tools become widely available through leading EHR vendors. These CDS tools therefore have great potential to promote PDMP utilization, but it will likely be several years before such tools become widely available. Such tools may become available for implementation in a wide variety of healthcare settings in coming years and could dramatically improve how PDMP data is utilized by practitioners and generate improved patient outcomes. Such technology holds great promise for the future, but may require rulemaking by the Colorado State Board of Pharmacy to specify the approved PDMP integration data exchange formats and how or whether health systems can display or ingest PDMP data. The Task Force recommends that healthcare practitioners, administrators, and regulators monitor this space as more sophisticated tools become more widely available.

Task #2: Evaluate the Risks and Benefits of Requiring Controlled Substances Administered or Directly Dispensed by Practitioners to be Reported to the Colorado PDMP

Current Colorado law does not require controlled substances that are directly dispensed by a practitioner to be reported to the Colorado PDMP. According to the PDMP Training and Technical Assistance Center, 46 states, the District of Columbia, and three U.S. territories may require controlled substance dispensations made directly by a practitioner to be reported to their PDMP. Additionally, 18 states and the District of Columbia may require controlled substance dispensations made directly by veterinarians to be reported to their PDMP. Evaluate the benefits and risks of requiring controlled substances administered or directly dispensed by practitioners and/or veterinarians to be reported to the Colorado PDMP.

Response to Task #2

Many states' PDMPs were established during the first wave of the opioid crisis (approximately 1999-2011), at a time when the overprescribing of prescription opioids was driving opioid diversion, misuse, and abuse, often led by "pill mills" that exploited lax federal and state regulatory and law enforcement oversight where controlled substances were liberally dispensed without a legitimate medical need. At that time, it was more common for some practitioners to directly dispense controlled substances to their patients, especially practitioners operating pill mills. For example, at a time when Florida led the nation in pill mills and attracted patients from across the United States, physicians in Florida purchased over 40 million dosage units (pills) of oxycodone for direct dispensation in the first six months of 2010, with 90 of the top

100 physician purchasers of oxycodone being from Florida.[66] This far surpassed the 927,213 dosage units of oxycodone purchased by practitioners in Ohio, which had the second-highest volume in the nation. During this time period, Colorado practitioners had purchased 121,085 dosage units of oxycodone, which was 13th in the nation.[67] To curtail practitioner dispensing of controlled substances, some states passed legislation limiting the dispensing of controlled substances by practitioners. For example, in 2011, Ohio passed House Bill 93, which limited practitioners from personally furnishing or dispensing more than 2,500 dosage units (pills) to all of their patients taken as a whole, and limited practitioners from dispensing more than a 72-hour supply to each patient while also mandating dispensing practitioners to report all controlled substance dispensations to Ohio's PDMP, the Ohio Automated Rx Reporting System (OARRS).[68] Florida passed legislation in 2010 and 2011 which required pain clinics to register with the state and have a physician-owner, created inspection requirements, and prohibited pain clinic physicians from dispensing more than a 72-hour supply of controlled substances to cash payer patients.[69,70] By 2013, the DEA reported that none of the top 100 oxycodone purchasing practitioners in the United States were from Florida.[71] Per the Ohio Automated Rx Reporting System (OARRS) 2021 Annual Report, overall opioid prescribing and the direct dispensing of opioids by practitioners have steadily declined since 2012. In 2012, 66,659 practitioners prescribed at least one opioid to 3,053,090 patients with an average quantity of 65.38 dosage units, and 198 practitioners personally dispensed at least one opioid prescription to 2,215 patients with an average quantity of 15.02 dosage units. In 2021, 39,886 practitioners prescribed at least one opioid to 1,501,544 patients with an average quantity of 58.97 dosage units per prescription, while only 29 practitioners personally dispensed at least one opioid prescription to 1,581 patients with an average quantity of 5 dosage units per prescription.[72] This legislation led to a precipitous decline in direct opioid dispensing by practitioners over the past decade, and practitioner-dispensed opioids now represent an extremely small proportion of all opioid prescriptions reported to OARRS.

With these efforts to shut down pill mills, opioids are no longer widely dispensed directly by practitioners. However, insights from other PDMPs and a review of voluntarily-reported practitioner dispensations to the Colorado PDMP indicates that some controlled substances such as weight-loss stimulants, testosterone and similar controlled androgens, buprenorphine for opioid use disorder, and ketamine for conditions including treatment-resistant depression,

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[66] US Drug Enforcement Agency. April 5, 2013. Florida doctors no longer among the top oxycodone purchasers in the United States. DEA Miami News press release. www.dea.gov/press-releases/2013/04/05/florida-doctors-no-longer-among-top-oxycodone-purchasers-united-states.

[67] Office of National Drug Control Policy. Fact sheet: prescription drug monitoring programs. 2011. obamawhitehouse.archives.gov/sites/default/files/ondcp/Fact_Sheets/pdmp_fact_sheet_4-8-11.pdf.

[68] Ohio 2011 House Bill 93. www.legislature.ohio.gov/legislation/134/hb93.

[69] Florida 2010 Senate Bill 2272: Controlled Substances. www.flsenate.gov/Session/Bill/2010/2272.

[70] Florida 2011 House Bill 7095: Prescription Drugs. www.flsenate.gov/Session/Bill/2011/7095.

[71] US Drug Enforcement Agency. April 5, 2013. Florida doctors no longer among the top oxycodone purchasers in the United States. DEA Miami News press release. www.dea.gov/press-releases/2013/04/05/florida-doctors-no-longer-among-top-oxycodone-purchasers-united-states.

[72] Ohio Automated Rx Reporting System 2021 Annual Report. State of Ohio Board of Pharmacy. www.ohiopmp.gov/documents/Annual%20Report%20(2021).pdf

other mental health conditions, and chronic pain, are directly dispensed and/or compounded and administered to patients by some practitioners. It also appears that these medications are often dispensed directly by practitioners when the medications are not covered by insurance. Without mandated reporting to the Colorado PDMP, it is unclear how frequently this is occurring. However, 10 practitioners voluntarily reported controlled substance dispensations to the Colorado PDMP in 2023. Five practitioners reported a total of 2,030 testosterone dispensations, four practitioners reported a total of 190 buprenorphine/naloxone dispensations for opioid use disorder, and one practitioner reported two dispensations of stimulants for weight loss.

The Task Force leveraged public reports and requested feedback from other state PDMPs through a survey disseminated by the Prescription Drug Monitoring Program Training and Technical Assistance Center (PDMP TTAC) to assess which controlled substances are most frequently directly dispensed by practitioners and the relative volume of controlled substances directly dispensed by practitioners. Other PDMPs reported that the most common drugs reported to their PDMPs by dispensing practitioners included testosterone and stimulant medications for weight loss such as phentermine, followed by small quantities of perioperative sedatives dispensed by dentists. However, many states exempt practitioner dispensations of 24-hour to 72-hour supplies of controlled substances from being reported to their PDMPs, which makes it difficult to fully assess the frequency or volume of controlled substance dispensations by practitioners when these dispensations are for small quantities and/or in a perioperative context. One state reported that fewer than 2,000 practitioner dispensations for either a controlled substance or gabapentin were reported to their PDMP annually, compared to approximately 7 million prescriptions reported by pharmacies. In this state, weight loss stimulants, testosterone, tramadol, and gabapentin were the primary drugs reported by dispensing practitioners.

The Task Force analyzed other states' laws with respect to the entities required to report dispensations to their PDMPs and found that 46 states require human medicine practitioners to report certain controlled substance dispensations to their PDMP and at least 17 states require veterinarians to report certain controlled substance dispensations to their PDMPs. Many states exempt the dispensing of manufacturer's samples or small volumes of medication ranging from 24-hour to 72-hour supply from these reporting requirements.

§12-280-408, C.R.S. exempts hospitals or prescription drug outlets located within a hospital that dispense no more than a 24-hour supply of a controlled substance from reporting these dispensations to the Colorado PDMP, but any dispensations of greater than a 24-hour supply from a prescription drug outlet within a hospital are required to be reported to the PDMP. Colorado Senate Bill 21-094 allows hospital employees or agents authorized by law to administer or dispense medications to an emergency room patient from a 24-hour supply to a 72-hour supply.[73] 72-hour supply dispensations from emergency department employees are typically performed in situations where a patient may be challenged to receive a prescription from a

[73] SB 21-094. leg.colorado.gov/bills/sb21-094.

pharmacy such as weekends and/or in rural settings. Because these dispensations are performed by hospital employees (as opposed to dispensations by a prescription drug outlet within a hospital), they are not required to be reported to the Colorado PDMP.

Colorado Senate Bill 21-094 provides specific authorization to dispense a 72-hour supply of a controlled substance by a hospital employee, but this is not the only scenario in which practitioners are authorized to personally dispense controlled substances. Colorado law has relatively few limitations on the dispensing of medication by practitioner, but it appears that this is relatively uncommon. Practitioners are subject to disciplinary action for administering, dispensing, or prescribing a habit-forming drug or controlled substance to a person other than in the course of legitimate professional practice,[74] but practitioners are authorized to personally compound and dispense for any patient under the practitioner's care any drug that the practitioner is authorized to prescribe and that the practitioner deems desirable or necessary in the treatment of any condition being treated by the practitioner,[75] except the Medical Practice Act prohibits the dispensing or injecting an anabolic steroid for the purpose of hormonal manipulation that is intended to increase muscle mass, strength, or weight without a medical necessity to do so or for the intended purpose of improving performance in any form of exercise, sport or game, or dispensing or injecting an anabolic steroid unless the anabolic steroid is dispensed from a pharmacy prescription drug outlet pursuant to a prescription order or is dispensed by any practitioner in the course of the practitioner's professional practice.[76] However, Colorado Medical Board Policy 40-11 advises that the in-office sale of products, including prescription drugs, potentially creates a financial conflict of interest, which can be limited by removing the element of financial gain from the transaction, limiting the appropriateness of sales to those circumstances that serve the immediate and pressing needs of patients, and disclosing to the patient the practitioner's financial arrangements with the manufacturer or supplier of the product. Policy 40-11 also states that in-office sales of health-related products for which the practitioner claims to offer a unique benefit to patient health and are available only through licensees raises concern for the potential of a coercive relationship or other boundary violation.[77]

Dispensing Reporting Exemptions in Other States

Many states that require dispensing practitioners to report their dispensations to the PDMP exempt practitioners from reporting the dispensation of samples or small quantities of controlled substances. Four states explicitly exempt the dispensation of manufacturers' samples, one state exempts the dispensation of a 24-hour supply, 11 states exempt up to a 48-hour supply, and three states exempt up to a 72-hour supply. Kansas exempts practitioners who dispense 10 or fewer controlled substances each month, and Missouri exempts dispensations in

[74] §12-240-121(1)(c); §12-255-120(1)(s); §12-220-201(1)(c); §12-290-108(3)(h); §12-275-120(1)(x); §12-315-112(1)(y).
[75] §12-280-120(6), C.R.S.
[76] §12-240-121(1)(o-p), C.R.S.
[77] Colorado Medical Board Policy 40-11. Sales of Products in Medical Offices. dpo.colorado.gov/Medical/LawsRulesPolicies.

conjunction with a patient's discharge from a hospital. If the Colorado General Assembly chooses to require practitioners to report direct dispensations to the Colorado PDMP, it would be reasonable to exempt dispensations of a 72-hour supply, as such small quantities are unlikely to contribute to the diversion, misuse, or abuse of controlled substances, and requiring such dispensations to be reported would create significant resource burden for practitioners such as physicians or dentists who dispense small quantities of medications at discharge from an emergency department or in a perioperative context.

Compliance Monitoring Strategies in Other States

States that mandate reporting by dispensing practitioners have a variety of strategies to identify dispensing practitioners and monitor their compliance with their data submission requirements. Colorado and 27 other states have a single license requirement for controlled substance authority, meaning their practitioner license includes controlled substance prescriptive authority. A second controlled substance license is required in 22 states.[78] States that issue secondary controlled substance licenses typically require practitioners to declare whether they order, administer, and/or dispense controlled substances. Some require practitioners to answer questions regarding whether they order controlled substances from distributors under their personal DEA license during initial license application and/or license renewal, or require they periodically answer this question when logging in to their PDMP account to identify which practitioners may also be dispensing controlled substances. Some states leverage the DEA's Automation of Reports and Consolidated Orders System (ARCOS) to identify which practitioners are ordering controlled substances from distributors,[79] and require those who order controlled substances from distributors to declare whether these medications are administered to patients in a manner exempt from reporting or if they also dispense controlled substances to patients which would require PDMP reporting. Some states require practitioners who do not dispense controlled substances to submit an exemption or waiver form attesting that they do not dispense controlled substances. Others rely on practitioners to voluntarily self-report their dispensations. Twenty three states require dispensing practitioners to obtain a special permit, license, or other certification.[80] Of these, the Task Force was only able to locate publicly available lists of active dispensing practitioner licenses in Louisiana, Nevada, and Utah. As of May 2024, there were 50 active Louisiana controlled substance dispensing practitioner permits, 411 active Nevada dispensing practitioner licenses, and 22 active Utah dispensing practitioner licenses.

PDMP administrative staff in other states advised that some dispensing practitioners' electronic health technology automatically submits dispensation reports to their PDMP, but many practitioners rely on office staff to manually report their dispensations. If new legislation

[78] US Drug Enforcement Administration. Practitioner's State License Requirements. www.deadiversion.usdoj.gov/drugreg/reg_apps/pract-state-lic-require.html.
[79] US Drug Enforcement Administration. Automation of Reports and Consolidated Orders System (ARCOS). www.deadiversion.usdoj.gov/arcos/arcos.html
[80] Dispense Doc. State Regulations for Dispensing Practitioners. www.dispensedoc.com/resources/state-regulations.

creates new reporting requirements for dispensing practitioners in Colorado, this may place additional resource burdens on some practitioners who lack the ability to automate this reporting, but the value of this additional information being reported to the Colorado PDMP may outweigh this additional burden for those whose electronic health technology cannot automate such reporting. Though practitioners' controlled substance dispensations are likely to be in the lower thousands compared to the approximately seven million controlled substance prescriptions dispensed by pharmacies, the General Assembly should weigh the importance and value of practitioners and pharmacists being aware of a patient's history of obtaining stimulants for weight loss or testosterone and similar controlled hormones directly from dispensing practitioners.

Veterinary Reporting Requirements in Other States

According to a review of other states' statutes, rules and other public documents, it appears that 17 states require veterinarians that dispense controlled substance prescriptions from their facilities to report certain dispensations to their PDMP. In 2016, Alabama and Arizona had at one point mandated reporting of veterinary dispensations but since exempted veterinarians from PDMP reporting requirements,[81] and Alaska exempted veterinary dispensation reporting in 2023 in response to the fact that the time, effort, and costs associated with this reporting outweighed the potential benefits of collecting this information. Additionally, it appears that veterinary "doctor shopping" is extremely rare, and that veterinarians are a minimal source of diverted or misused controlled substances.[82]

States that require PDMP reporting by dispensing veterinarians experience significant challenges with timely reporting. One vendor offers an automated dispensing machine for veterinary practices that also automates PDMP reporting of dispensations from the automated dispensing machine, but these machines are not in common use. No other veterinary practice management software has the ability to automate PDMP reporting, and the differences in information recorded in veterinary management software versus required information for PDMP reporting means such automation is highly unlikely to be developed in the future. This means all veterinary dispensations must be manually reported to PDMPs using a Universal Claim Form, which is a labor-intensive process that can take four to six hours of administrative time each week for veterinary practices.[83] Because of these challenges, many states have less stringent requirements than dispensing pharmacies and dispensing human medicine practitioners, either by exempting dispensations below a certain days-supply threshold or mandating reporting on a weekly, monthly, or quarterly basis. California requires veterinarians to report dispensations

[81] Cima, Greg. January 19, 2017. States Track Dispensing to Counter Drug Fraud. American Veterinary Medical Association. JAVMA News. www.avma.org/javma-news/2017-02-01/states-track-dispensing-counter-drug-fraud.
[82] Simpson, Robert John, D.V.M., May 2014. Prescription Drug Monitoring Programs: Applying a One Size Fits All Approach to Human and Veterinary Medical Professionals, Custom Tailoring is Needed. Journal of Animal and Environmental Law, Vol. 5. www.researchgate.net/publication/262872553_Prescription_Drug_Monitoring_Programs_Applying_A_One_Size_Fits_All_Approach_to_Human_and_Veterinary_Medical_Professionals_Custom_Tailoring_is_Needed
[83] National Association of State Controlled Substance Authorities (NASCSA) webinar, *Controlled Substance Management in Veterinary Medicine*. January 31, 2024. Webinar is only accessible by NASCSA members.

on a weekly basis, Tennessee requires veterinarians to report every two weeks, and Arkansas only requires veterinarians to report dispensations monthly. Connecticut, Maine, Michigan, New Hampshire, and North Carolina exempt veterinary dispensations of up to a 48-hour supply from reporting. Indiana exempts veterinary dispensations of up to a 72-hour supply, Virginia exempts veterinary dispensations of up to a 7-day supply, and Washington state exempts veterinary dispensations of up to a 14-day supply from reporting.

Veterinary dispensation reporting appears to be cumbersome for veterinarians, and evidence suggests veterinarians do not significantly contribute to prescription misuse or diversion. The Task Force could not find compelling reasons to require reporting of veterinary controlled substance dispensations, and feedback from other states indicates that the level of effort by veterinary offices and state PDMP administrators likely outweighs the potential benefits of collecting this information.

Opioid Treatment Program (OTP) Data Sharing with PDMPs

Title 42 of the Code of Federal Regulations (CFR) Part 2: Confidentiality of Substance Use Disorder Patient Records was first promulgated in 1975 and placed strong privacy protections around a patient's substance use disorder records associated with participation in Opioid Treatment Programs (OTPs) and prohibited the disclosure of these records in many contexts. OTP clinics were initially the only entities authorized to provide treatment for opioid use disorder (OUD) and dispensed daily doses of methadone. However, treatment options for OUD have evolved significantly over the past 50 years. From 1972 to 2002, methadone was the only controlled substance authorized for the treatment of OUD in the United States. Buprenorphine-based medications were first approved by the U.S. Food and Drug Administration (FDA) for the treatment of opioid use disorder in 2002.[84] In 2003, the Substance Abuse and Mental Health Services Administration (SAMHSA) authorized OTPs to dispense buprenorphine-based medications in addition to methadone.[85] The Drug Addiction Treatment Act of 2000 expanded access to medication for opioid use disorder (MOUD) by authorizing qualified physicians to dispense or prescribe buprenorphine-based medications for OUD.[86] SAMHSA subsequently adopted regulations requiring the issuance of a special waiver (often known as a DEA X-Waiver) to practitioners who completed specialized training for the treatment of OUD and allowed practitioners to treat up to 30 patients during their first year after obtaining a waiver, and 100 patients thereafter,[87] though a 2016 update allowed those with a 100-patient waiver for at least a year to treat up to 275 patients at a time.[88] The Comprehensive Addiction and Recovery Act of 2016 temporarily allowed certain nurse practitioners and physician assistants to prescribe buprenorphine for OUD,[89] and the 2018 SUPPORT for Patients and Communities Act made this

[84] U.S. Food and Drug Administration. Drug Approval Package. Subutex, Suboxone. www.accessdata.fda.gov/drugsatfda_docs/nda/2002/20-732_20-733_subutex.cfm
[85] 42 C.F.R. § 8.12(h)(2).
[86] Children's Health Act of 2000, Pub. L. No. 106-310, 114 Stat. 1101, § 3501-3502.
[87] 21 U.S.C. § 823(h)(2)(B)(amended 2022); 21 C.F.R. § 1301.28(b)(1).
[88] 42 C.F.R. § 8.610.
[89] 21 U.S.C. §§ 823(g)(2)(G)(iv)(I)) (2016).

authorization for nurse practitioners and physician assistants permanent.[90] In March 2020, as part of the COVID-19 public health emergency, SAMHSA established methadone take-home flexibilities allowing for all stable patients in an OTP to receive up to 28 days of take-home doses of medication for OUD, and in April 2020, SAMHSA exempted OTPs from the requirement to perform an in-person physical examination if the patient could be adequately evaluated via telehealth for the duration of the COVID-19 pandemic.[91,92] In 2023, Section 1262 of the Consolidated Appropriations Act removed the DEA X-Waiver requirement and granted any practitioner whose DEA license included Schedule III authority the ability to prescribe or dispense buprenorphine for opioid use disorder in their practice if permitted by applicable law.[93] In 2024, SAMHSA published the first substantial changes to OTP treatment and medication delivery standards in more than 20 years. These changes include making the COVID-19 related telemedicine flexibilities permanent, granting practitioners greater autonomy and reducing barriers to receiving care by encouraging and enabling mobile treatment units, granting practitioners the authority to determine when patients can receive take-home medication.[94] Current Colorado OTP take-home dose protocols allow certain patients to receive take-home doses after 90 consecutive days of treatment, and patients are eligible for additional take-home doses after four months, six months, nine months, and one year of consecutive OTP enrollment if the patient meets other eligibility criteria.[95] Colorado is one of seven states that prohibit take-home doses during the first 90 days of care and is one of ten states with additional stability criteria to be eligible for take-home doses from an OTP.[96]

While buprenorphine-based medications that are prescribed by practitioners and dispensed by pharmacies are reported to state PDMPs, similar information from OTPs has historically been subject to far more stringent privacy requirements than other medical and prescription records. With the significant evolution in how patients can obtain treatment for OUD, SAMHSA updated its Rules in 2020 to allow OTPs to report information to state PDMPs concerning patients enrolled in an OTP, subject to patient permission and state laws requiring that this information be reported to their PDMP. These regulations require PDMPs to remove a patient's OTP participation information from the PDMP if the patient rescinds permission for this information sharing and prohibit PDMPs from sharing this information with law enforcement. These updated rules also allow non-OTP participating practitioners to access states' OTP Central Registries

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[90] Davis, C.S., 2019. The SUPPORT for Patients and Communities Act - What Will It Mean for the Opioid-Overdose Crisis?, 380 N ENGL J MED. www.nejm.org/doi/10.1056/NEJMp1813961.

[91] Opioid Treatment Program (OTP) Guidance. March 16, 2020. SAMHSA. www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf

[92] FAQs: Provision of methadone and buprenorphine for treatment of Opioid Use Disorder in the COVID-19 emergency. April 21, 2020. SAMHSA. www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf.

[93] 21 U.S.C. 823(h)(1).

[94] Medications for the Treatment of Opioid Use Disorder. 89 FR 7258, pp 7528-7563, 42 C.F.R. § 8. www.federalregister.gov/documents/2024/02/02/2024-01693/medications-for-the-treatment-of-opioid-use-disorder.

[95] Colorado Department of Human Services, Behavioral Health. 2 CCR 502-1. Rule 21.320.81 Take-Home Dose Protocols. www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=5432.

[96] The PEW Charitable Trusts. Overview of Opioid Treatment Program Regulations by State. September 2022. www.pewtrusts.org/-/media/assets/2022/09/overview-of-opioid-treatment-program-regulations-by-state.pdf

that track patient participation.[97] Though these updates were developed to make OTP information more accessible while giving patients the authority to determine whether this information is shared, only Illinois, Kentucky, Maine, and Ohio have passed such legislation and currently incorporate OTP patient enrollment information to their PDMPs, which is reported from their states' OTP Central Registries. Connecticut, Mighican and Nevada passed legislation allowing OTP information to be shared with their PDMP, but have not yet implemented such reporting as of May 2024.

OTPs in Colorado are required to initiate a clearance inquiry to the Colorado Behavioral Health Administration's Central Registry prior to admitting applicants for treatment. This central registry validates that individuals are not simultaneously enrolled in more than one OTP clinic. Though the 2020 changes to 42 CFR Part 2 allowed non-OTP providers to query their state's central registry, these central registries are not utilized to nearly the degree of PDMPs, which is why information sharing with PDMPs is likely to make this information far more accessible to a patient's non-OTP providers. Colorado PDMP administrators have received dozens of inquiries from practitioners in recent years regarding the reporting of OTP participant information to the Colorado PDMP, indicating at least anecdotal evidence that practitioners would value such information in the PDMP.

The regulation of OTPs and other behavioral health entities (BHEs) is currently undergoing a number of changes pursuant to Colorado House Bills 19-1237, 22-1278, and 23-1236. Colorado House Bill 19-1237 combined the various licenses previously issued by the Colorado Department of Public Health and Environment (CDPHE) and the Colorado Department of Human Services (DHS) to entities that provide behavioral health services into a single license as a behavioral health entity (BHE).[98] Colorado House Bill 22-1278 established the Behavioral Health Administration (BHA) in the Colorado Department of Human Services (DHS) which replaced the previous Office of Behavioral Health (OBH) within DHS.[99] Colorado House Bill 23-1236 made additional updates to the BHA.[100] As of January 1, 2024, the authority to issue BHE licenses transitioned to BHA from CDPHE and replaced the previous structure of Substance Use Disorder treatment licenses, Community Mental Health Center designations, and Community Mental Health clinic designations in Colorado. This agency transition is expected to continue into early 2025.[101]

The Task Force recommends that the General Assembly allow BHA to complete the transition process of licensing BHEs before considering any new mandates for BHEs or BHA. If the General Assembly chooses to require the reporting of OTP enrollment information to the Colorado PDMP,

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[97] Confidentiality of Substance Use Disorder Patient Records. SAMHSA. 85 FR 42986, pp 42986-43039. RIN 0930-AA32. www.federalregister.gov/documents/2020/07/15/2020-14675/confidentiality-of-substance-use-disorder-patient-records.

[98] HB19-1237. Licensing Behavioral Health Entities. leg.colorado.gov/bills/hb19-1237.

[99] HB22-1278. Behavioral Health Administration. leg.colorado.gov/bills/hb22-1278.

[100] HB23-1236. Implementation Updates To Behavioral Health Administration. leg.colorado.gov/bills/hb23-1236.

[101] Colorado Behavioral Health Administration. Laws and Rules update Dec. 5, 2023. bha.colorado.gov/resources/laws-and-rules.

DPO and BHA would need to establish interagency agreements governing how each respective agency would handle enforcement of PDMP reporting requirements to BHEs which are not licensed by DPO. Though this presents logistical challenges, many other states whose PDMPs are operated by state health departments have established policies and/or agreements between the health departments and the licensing boards that regulate pharmacies to report data submission delinquencies to the appropriate regulatory body.

Controlled Substance Administration Reporting and Ketamine Therapy Clinics

Recent clinical studies have found ketamine, a Schedule III anesthetic, can provide rapid relief in treatment-resistant depression.[102] In 2019, the FDA approved esketamine (the s-enantiomer of ketamine) nasal spray, in conjunction with an oral antidepressant, for treatment-resistant depression. Esketamine is only available through a restricted distribution system which requires the patient to self-administer the nasal spray under the supervision of a health care provider, and the medication cannot be taken home. The patient must be observed for several hours, and the healthcare provider determines when the patient is ready to leave.[103] Ketamine is not FDA-approved for the treatment of any mental health disorder or chronic pain, but ketamine infusion clinics and online ketamine therapy providers that prescribe and/or administer ketamine as an off-label treatment for depression, anxiety, post-traumatic stress disorder, and chronic pain have dramatically increased in recent years. While ketamine infusion clinics are legal as long as a DEA-licensed practitioner prescribes the drug, these clinics exist with minimal oversight and are largely unregulated. Ketamine infusion treatments are not generally covered by insurance, and while the typical dose of ketamine costs a clinic about $1, one source estimates the costs to be $600 to $1,000 per treatment.[104] Another estimates that ketamine infusions for depression usually cost between $400 and $800 per treatment and usually require a series of six treatments over two to three weeks or four treatments over one to two weeks, while ketamine treatments for pain typically range from $700 to $2,000 per treatment.[105] A recent market analysis estimated ketamine clinic revenues at $3.1 Billion in 2022 and are expected to grow to $6.9 billion by 2030. Just over half of the ketamine market was through online therapy providers that prescribed ketamine to patients for at-home use in combination with therapy, while on-site therapy in which practitioners administer ketamine to a patient during a therapy session accounted for just under half of this market share. Treatment for depression accounted for approximately 30% of the ketamine treatment market in 2022.

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[102] Marcantoni WS, Akoumba BS, Wassef M, Mayrand J, Lai H, Richard-Devantoy S, Beauchamp S., 2020. A systematic review and meta-analysis of the efficacy of intravenous ketamine infusion for treatment resistant depression: January 2009 - January 2019. J Affect Disord. 277:831-841. doi.org/10.1016/j.jad.2020.09.007.

[103] FDA News Release. March 5, 2019. FDA approves new nasal spray medication for treatment-resistant depression; available only at a certified doctor's office or clinic. www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified.

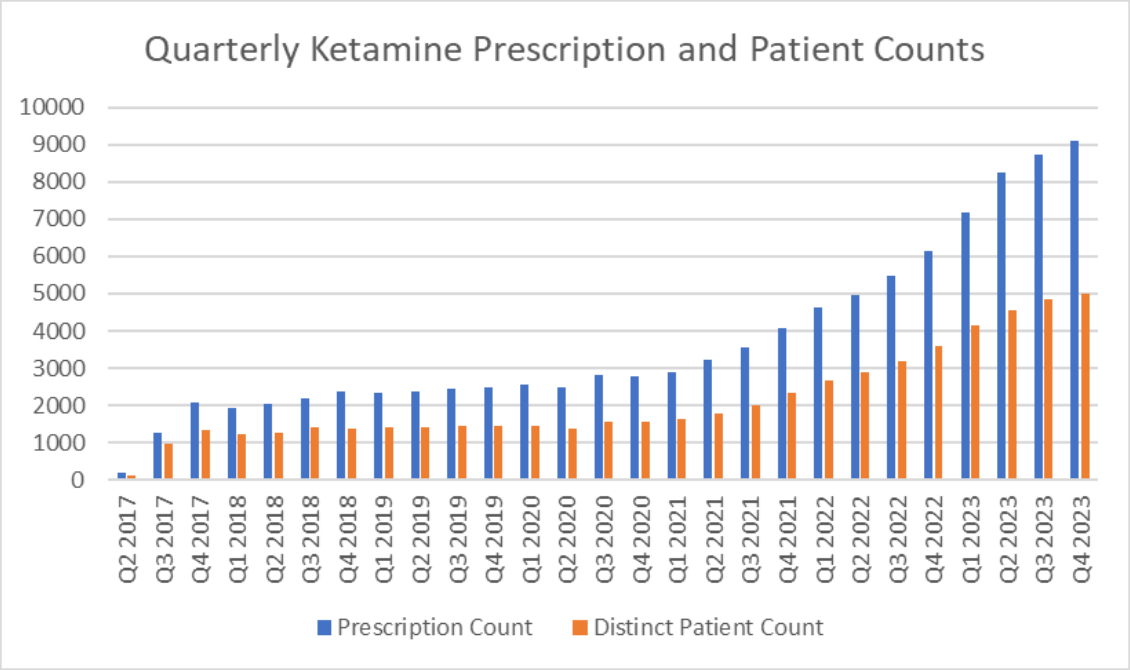
[104] Megli, Dawn, Jan. 31, 2024. The ketamine economy: New mental health clinics are a 'Wild West' with few rules. KFF Health News. kffhealthnews.org/news/article/ketamine-therapy-hallucinogenic-mental-health-unregulated.

[105] Ketamine Therapy: How Much Does it Cost & Who Is Eligible? Psychedelic Spotlight. January 13, 2023. psychedelicspotlight.com/ketamine-therapy-how-much-does-it-cost-who-is-eligible.

It is difficult to determine how many ketamine infusion clinics are currently operating in the United States. One recent report estimated there were 500-750 clinics operating in the United States by the end of 2022.[106] Dr. Patrick Oliver, a board-certified emergency medicine physician and medical director of MindPeace Clinics which has been providing ketamine infusions since 2017, reported in 2023 that in 2017, his clinic was about the 25th clinic in the United States, and as of 2023 there were somewhere between 750 and 1,000 clinics nationwide.[107] An online search in April 2023 for ketamine clinics in Colorado found 41 clinics advertised offering ketamine therapy.

From Q3 2017 to Q4 2023, the number of ketamine prescriptions reported to the Colorado PDMP increased 629%, from 1,248 in Q3 2017 to 9,092 in Q4 2023, and the number of Colorado patients receiving ketamine prescriptions increased 424%, from 954 in Q3 2017 to 5,003 in Q4 2023.

Figure 2: Quarterly Ketamine Prescription and Patient Counts, Q2 2017 - Q4 2023



Source: Colorado PDMP dispensation data

While ketamine prescriptions dispensed by a pharmacy are reported to PDMPs (as is done by online ketamine therapy providers and some ketamine clinics), if a practitioner orders ketamine for office stock from a distributor and compounds and administers the ketamine to a patient through an infusion, these administrations are exempt in nearly every state from reporting to PDMPs. A review of clinics advertising ketamine therapy in Colorado found that several practitioners offering ketamine therapy had no record of ketamine prescriptions in the Colorado PDMP, while several others had records of ketamine prescriptions in the PDMP. This suggests

[106] Grand View Research. U.S. Ketamine Clinics Market Size, Share & Trends Analysis Report By Treatment (Depression, Anxiety, PTSD), By Therapy (On-site Therapy, Online Therapy), And Segment Forecasts, 2023 - 2030. Report ID: GVR-4-68040-092-1. www.grandviewresearch.com/industry-analysis/us-ketamine-clinics-market-report.
[107] Buckanavage, Jack and Lee, Randall, 2023. Ketamine Therapy Goes Mainstream: How Clinics are Meeting the Growing Demand. URGENT Matters. Paper 15. hsrc.himmelfarb.gwu.edu/smhs_URGENT_Matters/15

that some ketamine clinics may be ordering ketamine from distributors as office stock and are compounding and administering the medications directly to patients, which is not reported to the Colorado PDMP and is allowed under §12-280-120(6), C.R.S. Other ketamine clinic practitioners may be ordering patient-specific compounded ketamine prescriptions from pharmacies and administering this to their patients, though it is unclear whether the ketamine prescriptions reported to the Colorado PDMP are a complete record of these practitioners' ketamine prescribing or administration activity.

Because ketamine treatment is not generally covered by insurance, prescribers do not receive information regarding insurance payer claims, meaning patients' other treating providers are typically unaware of their patients' ketamine therapy. Only Kentucky requires controlled substance administrations to be reported to their PDMP, but the recent rapid expansion of ketamine therapy through in-clinic administrations and online therapy in conjunction with at-home ketamine self-administration may prompt states to mandate PDMP reporting requirements for practitioners administering ketamine directly to patients. The General Assembly should monitor developments in other states surrounding the regulation of ketamine therapy clinics. If other states begin mandating PDMP reporting for these clinics and/or establish other regulations, the Task Force could further research the implications, costs and benefits of such regulations.

Recommendation: Task #2

Though the vast majority of practitioners do not typically directly dispense controlled substances to patients, some specialty clinics focusing on weight loss and low testosterone treatment may commonly dispense controlled substance stimulants for weight loss, testosterone and similar hormones to treat low testosterone. Additionally, some practitioners treating opioid use disorder (OUD) in areas that lack access to facilities that treat OUD may be directly dispensing buprenorphine-based medications to patients. With all states except Colorado, Montana, New Jersey, and Texas mandating the reporting of certain controlled substance dispensations by human medicine practitioners, the General Assembly should consider requiring certain direct dispensations by practitioners to be reported to the Colorado PDMP. To reduce the resource burden on practitioners, the General Assembly should consider exempting small dispensations of up to a 72-hour supply from PDMP reporting requirements which would exempt dispensations from emergency departments, dispensations of single doses of perioperative medications, and other isolated dispensations of small quantities from reporting while mandating reporting for those who routinely dispense larger quantities of controlled substances.

If the General Assembly chooses to mandate that practitioners report their controlled substance dispensations to the Colorado PDMP, the General Assembly would additionally need to delineate a practitioner's PDMP reporting requirements and how compliance-related information could be handled between the Colorado State Board of Pharmacy, which oversees the Colorado PDMP, and practitioners' respective licensing boards. Colorado's prescribing boards would also likely

need to implement Rules regarding PDMP data submission requirements and develop methods to identify practitioners who directly dispense controlled substances, and/or may need to coordinate with the Colorado State Board of Pharmacy to determine specify scenarios in which data submission non-compliance could be reported to a prescribing practitioner's board.

If the General Assembly chooses to require practitioners to report controlled substance dispensations to the Colorado PDMP, the Division could identify dispensing practitioners through a robust communication strategy along with questionnaires or attestations in the initial license application and during license renewal and leverage information from the DEA's ARCOS database to determine which practitioners are ordering controlled substances.

The Task Force could not find significant justification for mandating that veterinarians report their dispensations to the Colorado PDMP, considering the resource burden on veterinarians that would come with mandating veterinary dispensation reporting, the extent of exemptions in several states, the relatively lax reporting requirements in other states, and the fact that veterinary controlled substance dispensations do not appear to contribute to prescription drug abuse, misuse, or diversion.

With the significant changes to federal OTP regulations that grant OTP providers greater ability to provide up to a 28-day supply of take-home doses of medication for OUD and federal authorization for OTP registrant information to be reported to state PDMPs, subject to patient authorization and state laws requiring such reporting to PDMPs, the Task Force recommends that the General Assembly further evaluate enacting legislation that would require OTPs to report information regarding their enrolled patients and/or their practitioners' controlled substance dispensations to the Colorado PDMP. However, the General Assembly should not consider enacting any additional requirements for OTPs until BHA completes its transition in licensing OTPs and other facilities under the new BHE structure in Colorado.

In recent years, clinics providing off-label ketamine therapy for a variety of mental health conditions including depression, anxiety and PTSD, and for chronic pain have expanded rapidly with minimal regulations. Nearly every state's PDMP statutes exempt controlled substance administrations from reporting, but most of these laws were established before ketamine treatment clinics existed. The Task Force recommends that the General Assembly monitor whether and how states implement laws or regulations governing these clinics.

Appendix A: Requests from the DORA Executive Director

COLORADO
Department of Regulatory Agencies
Executive Director's Office

January 11, 2024

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 2022-2023 Task Force Report. The Consortium's support and expertise this past year was invaluable.

Section 12-280-409, Colorado Revised Statutes (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, 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, 2024.

Task #1: Evaluate the Impact of PDMP Integration on Utilization

The 2019-2020 PDMP Task Force Annual Report noted that although PDMP integration is a key prerequisite to increased utilization by healthcare practitioners, integration alone does not guarantee utilization. I request that the Task Force evaluate the extent to which integration impacts PDMP utilization and evaluate factors or activities that could increase PDMP utilization by practitioners with integrated PDMP access who are not regularly utilizing the PDMP.

Task #2: Evaluate the Risks and Benefits of Requiring Controlled Substances Administered or Directly Dispensed by Practitioners to be Reported to the Colorado PDMP

Section 12-280-407(1), C.R.S. requires prescription drug outlets to submit completed controlled substance dispensing transactions to the Colorado PDMP. Current law does not require controlled substances that are directly dispensed by a practitioner to a patient to submit these dispensations to the Colorado PDMP. According to the PDMP Training and Technical Assistance Center, 46 states, the District of Columbia, and three U.S. territories may require controlled substance dispensations made directly by a practitioner to be reported to their PDMP. Additionally, 18 states and the District of Columbia may require controlled substance dispensations made directly by veterinarians to be reported to their PDMP. I request that the Task Force evaluate the benefits and risks of requiring controlled substances administered or directly dispensed by practitioners and/or veterinarians to be reported to the Colorado PDMP.

Sincerely,

Patty Salazar
Executive Director
Colorado Department of Regulatory Agencies

Appendix B: PDMP Work Group Members

Last Name	First Name	Organization	Date Joined
Hoppe	**Jason, DO (Co-Chair)**	University of Colorado	
Kunin	**Dmitry (Co-Chair)**	DORA Board of Pharmacy	
Micucci	**Shayna (Program Manager)**	CCPDAP Program Manager	6/1/2022
Akerlund	Ashley	Gunnison County Public Health	3/7/2023
Archuleta	Dan	Southern Colorado Harm Reduction Association	9/8/2020
Barker	Eric	CCPDAP External Relations Strategist - SW	4/10/2023
Barron	Betsy	CU Anschutz	9/14/2021
Belford	Kerry	HardBeauty	4/28/2021
Bemski	Julie, MD	St. Josephs Hospital	1/31/2018
Bernier	Benjamin, RN	Children's Hospital	
Bhutani	Aminta	DEA	8/13/2020
Biehle	Ryan	Colorado Academy of Family Physicians	
Bonaguidi	Angela, LCSW, LAC	UC School of Medicine, ARTS	
Borgelt	Laura	University of Colorado School of Pharmacy	
Brasselero	Scott	Crossroads Turning Points	12/19/2018
Brooks	Marta, PharmD	Rueckert-Hartman College for Health Professions	
Brown	Amanda	CCAR	11/10/2022
Bryant	Hilary	CCPDAP Program Manager	6/20/2022
Brydon	Katie	Road to Recovery	6/10/2019
Canon	Megan	CDPHE	7/20/2020
Cantwell	Teresa	CCPDAP Business Operations	11/1/2022
Carpenter	Kristin	CCPDAP External Relations Strategist - SE	7/20/2022
Casey	Alice	Pickens Technical College	
Casper	Alana	Community Member	10/28/2021
Casucci	Charlene	Community Member	10/28/2021
Cathie	Scott	Sadas	
Cavalino	Nicole	Safe-Rx	5/22/2023
Chang	Soojin	UC Denver School of Pharmacy	1/24/2018
Cluff	William L., DO	Concierge/Virtual Practice	6/1/2023
Cochran	Cody	Threshold for Recovery	5/6/2023
Coonan	Brian	Array Behavioral Health	1/11/2023
Corvin	Andrea Y.	Allied Steps	11/17/2023
Creviston	Dawn	Community Member	6/13/2023
Davidson	Michael	CCPDAP Communications Professional	5/4/2017
De la Cerda	Dionisia	UC Denver Department of Family Medicine	12/19/2018

DeHerrera-Smith	Dayna	Front Range Clinic	1/14/2019
Denberg	Tom, MD	Pinnacol	
Dinkelberg	Pauline	Vereniging Afbouwmedicatie	4/19/2022
Eaddy	Jessica Lauren	CCPDAP Program Manager	5/15/2017
Esquibel	José	CCPDAP Associate Director	4/29/2019
Feffer	Sophie	CDPHE	1/26/2022
Fischer	Matthew	Colorado Health Network	7/16/2020
Flores	Roland, MD	CU School of Medicine	
Gabella	Barbara, PhD, MSPH (Co-chair)	Colorado Department of Public Health & Environment (CDPHE)	
Gauna	Danielle	Opioid Advisory Group/BOCO	4/4/2018
Gibbens	Sally	Urban Peaks Rehab	1/25/2023
Gorman	Fran, DNP ANP-C RN	RN	
Grace	Elizabeth S., MD	Center for Personalized Education for Physicians (CPEP)	
Griggs	Connie	Digital	4/17/2023
Guerrero	Andres	CDPHE	
Hara	Cheryl	Center for Personalized Education for Physicians (CPEP)	
Harden	Michelle, Esq.	Messner Reeves, LLP	
Harris	Helen	Epidemiologist, El Paso County Health	
Harrison	J.M., MD	MD	
Hart	Krystle, RN	Registered Nurse	3/21/2019
Heath	Angela	Community Member	6/1/2022
Hemler	Douglas, MD	Colorado Medical Society	
Herting	Devon	Community Member	10/11/2022
Higgins	PJ	Community Health Partnership	1/22/2020
Hill	Kyle Dijon	Helping End the Opioid Epidemic (HEOE)	3/3/2018
Hoover	Lorraine	Raymond Roundtree Jr Foundation	11/26/2021
Howlett	Corinne	School of Pharmacy	5/7/2021
Illias	Rachel	Mountain Family Health Centers	1/18/2024
Iwanicki	Janetta	Rocky Mountain Poison and Drug Center	
Jackson	Pam	Retired, Attorney General's Office	6/29/2019
Katanova	Raisa	Mile High Treatment and Recovery	7/7/2023
Keane	Ashli	Gusto	9/1/2020
Koons	Mike	Pinnacol Assurance	
Krische	Elizabeth	A Way Forward	2/19/2021
Kross	Kelly	HCA Healthcare	5/17/2023
Krueger	Jessica, MD	CU Anschutz	6/4/2021

Kumar	Anita, MD	Axis Health Systems	7/7/2022
Latta	Lucy	Colorado State University	11/26/2021
Leach	Kara, MD	M.D.	
Leonard	Joanna	Colorado Coalition for the Homeless	8/23/2022
Li	Qing	Epidemiologist	
Litke	Brenda	Community Member	10/19/2023
Long	Mila	Denver Recovery Group	10/12/2022
Lopez	Elaine	Community Member	12/28/2022
Mackender	Jennifer	CCPDAP External Relations Strategist - NE	8/20/2023
Matt	Diane	Colorado Veterinary Medical Association	9/27/2023
Mattox	Tamara	Crowe LLP	5/18/2023
McBurney	Christa, RN	UC Health	10/5/2018
McCarty	Craig, MD	Haxtun Hospital District	
McDevitt	Kim	Mile High Health Alliance	3/14/2022
Meury	Kathleen	Community Member	5/17/2021
Mihok	Kristi	Walgreens	
Miranda	Inez	Community Member	1/11/2023
Mitchell	Kaitlin	CU Anschutz Dept of Psychiatry	5/10/2023
Mullokand	Dana	Mile High Treatment and Recovery	5/25/2023
Mulvihill	Sharon	Riverstone Health	1/12/2019
Murphy	Paul	Office of e Innovation	7/10/2020
Myers	Megan	Telligen	1/8/2024
Newlands	Sydney	Community Member	12/2/2022
O'Keefe	Dawn	Summit Stone Health	2/18/2022
O'Keefe	Julie	Pharmacist	
Olberding	Gina	CCPDAP Assistant Director	3/20/2017
Patel	Nashel	SSPPS Pharmacy Student	7/1/2018
Patterson	Kevin, DDS, MD	Metropolitan Denver Dental Society/Colorado Dental Association	10/14/2018
Paykoc	Carrie	Innsena	2/13/2023
Pellegrino	Robyn	RN Manager	12/4/2017
Perez	Brooke	KK Fearless, Inc.	8/25/2023
Perry	Robert	M.D.	
Pike	Erica	Colorado Academy of Family Physicians	1/6/2022
Piotti	Louis	Sober AF Entertainment	2/18/2022
Platts	Debbie	A Way Forward, Inc.	3/4/2021
Prieto	Jose Tomas	Denver Health	
Primavera	Rep. Dianne	Lt. Governor	
Ramirez	Melissa	Community Member	7/6/2023
Ramzy	Nagy	Pharmacist, Retired	

Reibel	Lynda, MD	Community Member	
Reid	Ashley	Children's Hospital	
Reiskin	Julie	Colorado Cross-Disability Coalition	1/19/2023
Renner	Lindsey	San Luis Valley Behavioral Health Group	
Robbins	Emily, RN	UC Health	5/7/2018
Rollman	Anna	Pharmacy	1/18/2023
Rorke	Marion, MPH	Denver Environmental Health	
Rubio	Chelsea	Signal Behavioral Health Network	6/10/2022
Rumely	Duke	Sober AF Entertainment	2/24/2020
Ryan	Courtnay	Telligen	12/9/2019
Schreiber	Terri	The Schreiber Research Group	12/21/2017
Sentence	Melinda	Pueblo Dept of Public Health & Environment	9/15/2022
Shehzad	Riaz Ul Haq	MD	8/12/2022
Shepard	Cristel	Attorney General's Office	6/7/2022
Shuler	James, MD	SUD Consultants	
Sihler	Bonnie	Valley View Hospital	8/26/2020
Simbeye	Lindsey	CCPDAP External Relations Strategist - NW	1/21/2020
Smith	Theresa	Arapahoe County	8/30/2022
Stack	Kelly	Bamboo Health	6/13/2022
Stewart	Stephanie	UC Denver	
Sullivan	Katherine	CDPHE	
Swan	Sarah E.	State Gov Affairs & Alliance Development, Bristol Myers Squibb	
Thomas	Andrea Y.	Voices for Awareness Foundation	4/29/2019
Thompson	Evan	CU Forensic Psychiatry Program	12/17/2021
Tiernan	Shane	L.A. Healthcare	4/4/2018
Toney	Faith	CU Anschutz	11/27/2023
Valuck	Robert, PhD	CCPDAP Director	1/1/2013
Vanderveen	Kevin, MD	Emergency Services, Kaiser Permanente of CO	
Veeneman	Hayes	Community Member	
Wall	Lawrence	Wall Consulting	8/14/2018
Walsh	Kori	CAHEC	12/28/2022
Weir	Mike	Office of e Innovation	7/10/2020
White	Kasondra	Sober Living	7/13/2023
Whitney	Kaitlyn	CU Dept. of Orthopaedics	3/2/2023
Wipf	Justin	DORA	8/1/2019
Wolf	Katie	Wolf Public Affairs	
Zimdars-Orthmann	Marjorie	Community Member	

Appendix C: 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. 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 ("DPO").

- In 2015, DORA was awarded a grant through the US Department of Justice Bureau of 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 certain exceptions. 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)83 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.

- 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.

- In 2023, House Bill 23-1072 (HB 23-1071) authorized the creation of a prescriptive authority certificate to certain psychologists which authorizes the psychologist to prescribe psychotropic medications. Psychologists with a prescriptive authority certificate will be authorized to obtain a DEA license to prescribe psychotropic controlled substance medications. These prescribing psychologists will be subject to the PDMP requirements applicable to DEA-licensed practitioners.

- In 2023, Senate Bill 23-144 (SB 23-144) clarified that practitioners are not subject to disciplinary action for prescribing a dosage of an opioid above a morphine milligram equivalent (MME) recommendation or threshold specified in state or federal opioid prescribing guidelines or policies. It also prevented practitioners from being required to taper a patient's medication dosage solely to meet predetermined dosage recommendations and prohibited pharmacies, health insurance carriers, pharmacy benefit managers, health-care practices and clinics from having a policy that requires the practitioner to refuse to prescribe, administer, fill, or dispense a prescription for an opioid solely because the prescription exceeds a predetermined MME dosage recommendation or threshold.

- In 2023, CDPHE was awarded the five-year CDC Overdose Data to Action in States (OD2A-S) grant. CDPHE and DORA entered into an inter-agency agreement with funding from the OD2A-S grant. This inter-agency agreement funds a Program Analyst position at DORA for the PDMP, prescriber scorecards, maintenance costs for the RxCheck hub, and other tools to enhance the PDMP.

- In 2024, Senate Bill 24-047 (SB 24-047) authorized practitioners with prescriptive authority who lack controlled substance prescriptive authority to access the PDMP, exempted veterinarians from the PDMP use mandate, authorized the Department of Health Care Policy and Finance to access the PDMP for the purposes of care coordination, utilization review, and federally required reporting, and allowed medical directors or their delegates to access the PDMP for any patient at a facility under the medical director's supervision.