COLORADO CONSORTIUM
for Prescription Drug Abuse Prevention

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, 2021

RE: 2021 Prescription Drug Monitoring Program Task Force Report

The Colorado Consortium for Prescription Drug Abuse Prevention (Consortium) submits the enclosed report on behalf of the Prescription Drug Monitoring Program (PDMP) Task Force pursuant to 12-280-409(2), C.R.S. This report details the Consortium's work on: a) analyzing the viability and appropriateness of user experience testing of available PDMP software interfaces; b) developing a plan for directly measuring PDMP utilization in connection with controlled substance prescriptions; and c) recommendations for the future state of the technical architecture of the Colorado PDMP.

Respectfully,

Colorado Consortium for Prescription Drug Abuse Prevention

COLORADO ELECTRONIC

PRESCRIPTION DRUG MONITORING PROGRAM

2020-2021 TASK FORCE REPORT

July 1, 2021

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COLORADO ELECTRONIC PRESCRIPTION DRUG MONITORING PROGRAM

2020-2021 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; and

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.

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 highlights the recommendations of the Task Force to the Executive Director consistent with the directive to explore ways to make the program a more effective tool for prescribers and pharmacists in order to reduce prescription drug abuse in Colorado.

History of Consortium and PDMP:

Established in 2013, the Consortium is a coordinated, statewide, inter-university/inter-agency network. It now supports 10 different work groups with more than 800 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 progression of the Colorado PDMP includes the following milestones:

- In 2005, House Bill 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 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.[1] This access also allows CDPHE to work with healthcare organizations to evaluate the effectiveness of PDMP integration and other organizational initiatives related to controlled substance prescribing and PDMP utilization, including CDPHE's PDMP integration pilot project evaluation and the University of Colorado's PDMP integration.

    - Prescribers and pharmacists were authorized to designate up to three delegates to access the PDMP on their behalf with proper authorization.

    - The Colorado PDMP was authorized to issue unsolicited reports (Push Notices) to prescribers and pharmacies that inform them of their patients being prescribed controlled substances by multiple prescribers, at multiple pharmacies, over set periods of time. These Push Notices reduce potential patient misuse, abuse, and diversion of controlled substances, while increasing patient safety.

- In 2014, the Colorado Dental Board, Colorado Medical Board, State Board of Nursing, State Board of Pharmacy and the Nurse-Physician Advisory Task Force for Colorado Healthcare collaborated to develop *The Policy for Prescribing and Dispensing Opioids* to provide meaningful guidance to prescribers and dispensers of opioids in Colorado. This Policy was subsequently adopted by the State Board of Optometry and the Colorado Podiatry Board and endorsed by the Colorado State Board of Veterinary Medicine. This policy was the first of its kind to be adopted across numerous healthcare boards and groups within the Division of Professions and Occupations ("the Division").

- In 2015, DORA was awarded a grant through the US Department of Justice Bureau of Justice Assistance (BJA). DORA contracted with the University of Colorado as a grant sub-recipient 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 2016, the PDMP created a five-minute online informational video to teach potential delegates and their corresponding supervising prescriber or pharmacist how to set up a delegate account and begin accessing the PDMP on the prescriber or pharmacist's behalf.

- In 2017, Senate Bill 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:

[1] Colorado Department of Public Health and Environment. 2017. Prescription Drug Data Profiles. https://www.colorado.gov/pacific/cdphe/prescription-drug-data-profiles

- 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* ("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 began prohibiting a prescriber from prescribing more than a seven-day supply of an opioid to a patient who has not had an opioid prescription in the last twelve months by that prescriber, with exceptions for chronic pain, cancer pain, post-surgical pain, or transfer of care from another prescriber who had prescribed an opioid to the patient. The law also restricts 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 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, is 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 created six PDMP tutorial documents and hosted four tutorial webinars concerning prescriber registration and use of the PDMP, delegate registration and use of the PDMP, unsolicited reporting and bulk patient searches. These materials were posted to a new PDMP Training webpage at dpo.colorado.gov/PDMP/Training.

- 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)[2] to expand integrated PDMP access for Medicaid providers.

- In 2021, Senate Bill 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. Additionally, the bill authorized deputy coroners to access PDMP data on behalf of a coroner.

- In 2021, House Bill 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.

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

- In 2021, DORA began work on building out the requirements for the next PDMP RFP as the current vendor's contract is nearing expiration. In tandem with this effort, the Division of Professions and Occupations led a Market Research effort to collect feedback from various private and government stakeholders, through individual and large stakeholder meetings, which solicited feedback to ensure the PDMP RFP Requirements work was holistic and comprehensive. The Division anticipates the PDMP RFP to be released sometime in the Fall of 2021.

The PDMP and the Colorado Health IT Roadmap

Colorado's Health IT Roadmap[3] is the state's strategic plan for promoting and advancing the secure, efficient, and effective use of health information, and to inform, encourage, and influence future health IT initiatives. As PDMP data is uniquely situated within the Colorado Board of Pharmacy, the PDMP presents unique opportunities and challenges with respect to other health information. Significant federal funding opportunities from the Centers for Medicare and Medicaid Services (CMS), Bureau of Justice Assistance (BJA), and the Centers for Disease Control and Prevention (CDC) may be available to implement more widespread integration. The integration of PDMP data into electronic health records (EHRs) and health information exchanges (HIEs), and other PDMP integration initiatives should be consistent with the goals and strategies of other Colorado health information technology stakeholders.

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

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

Table 1: Characteristics of Controlled Substance Prescriptions Dispensed, Colorado, 2014-2020

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

In 2014, NPI was used to identify unique prescribers and pharmacies as DEA numbers were not available until 2015
Data Source: Colorado Prescription Drug Monitoring Program, DORA; Data Analysis by: CDPHE, 2021

[3] Colorado's Health IT Roadmap (2017). Office of eHealth Innovation. https://www.colorado.gov/pacific/sites/default/files/atoms/files/Colorado%20Health%20IT%20Roadmap%20FINAL%2011-15-2017.pdf

Table 2: Characteristics of Opioid Prescriptions Dispensed, Colorado, 2014-2020

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

Data Source: Colorado Prescription Drug Monitoring Program, DORA; Data Analysis by: CDPHE, 2021

Figure 1: Annual Controlled Substance and Opioid Prescription Totals, 2014-2020

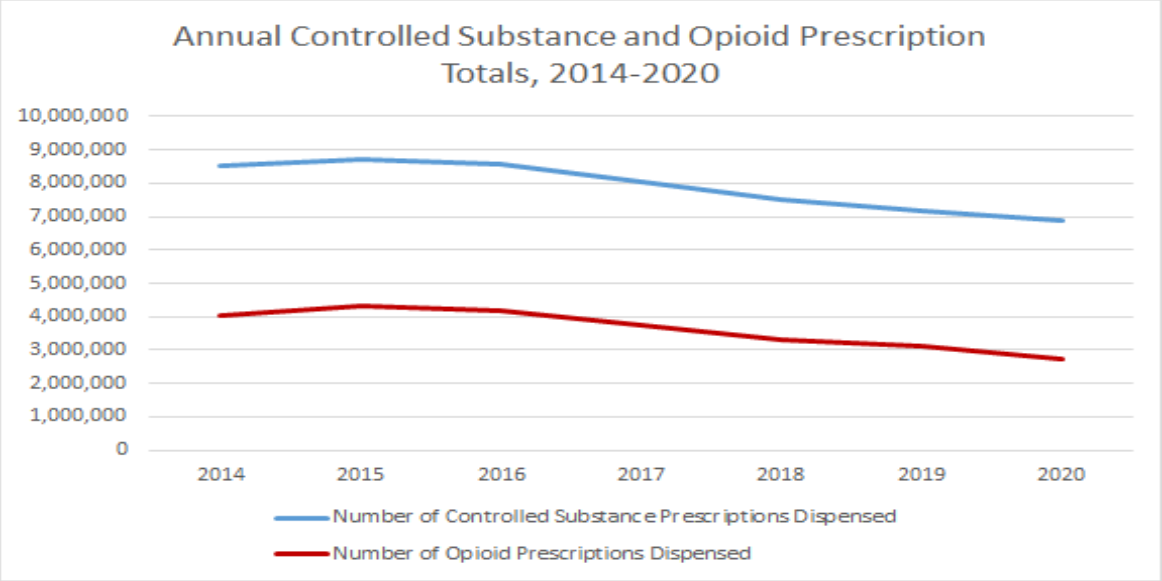
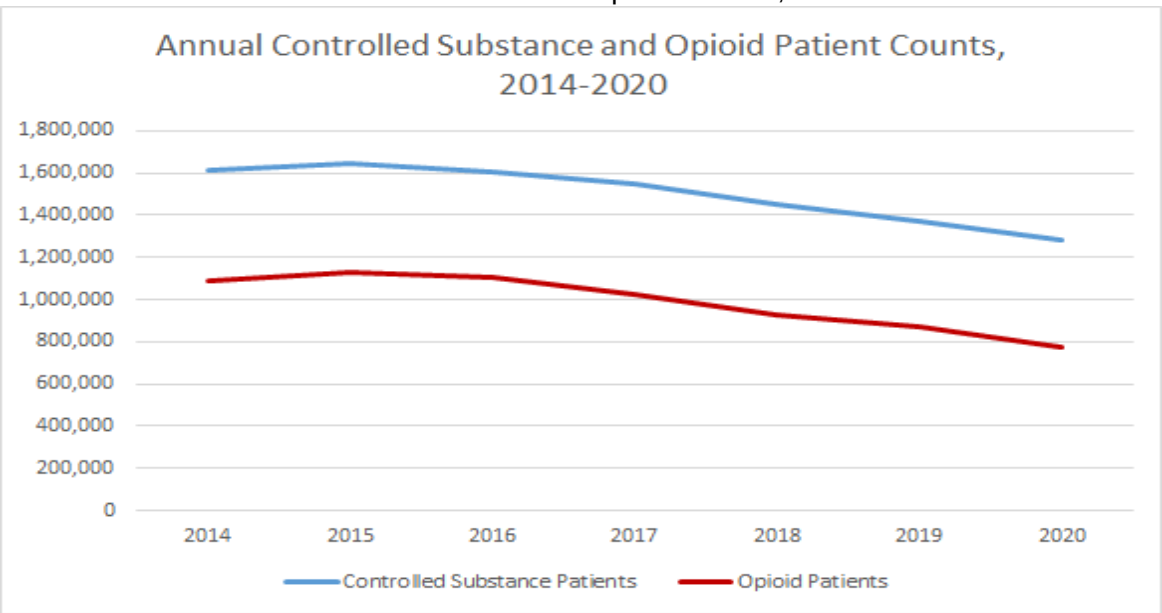


Figure 2: Annual Patients Controlled Substance and Opioid Patients, 2014-2019



As referenced in Tables 1 and 2 and Figures 1 and 2 above, total controlled substance prescriptions decreased by 19.0% from 2014 to 2020, and decreased by 3.8% from 2019 to 2020. Patients receiving at least one controlled substance prescription decreased by 20.6% from 2014 to 2020, and decreased by 6.5% from 2019 to 2020. Total opioid prescriptions decreased by 32.6% from 2014 to 2020, and decreased by 13.3% from 2019 to 2020. Patients receiving at least one opioid prescription decreased by 28.4% from 2014 to 2020, and decreased by 9.2% from 2019 to 2020.

High-Risk Prescribing Practices and Patient Behaviors

BJA's PDMP Training and Technical Assistance Center's Prescription Behavior Surveillance System (PBSS) uses several measurements and metrics to gauge the effectiveness of statewide PDMP systems. The definition of PBSS Measures[4] provides key metrics to monitoring and determining the success of PDMPs, which are developed in collaboration with the CDC to monitor trends in controlled substance prescribing and dispensing. The PBSS' measurements include: overall usage within drug classes and for selected individual drugs; daily dosage; overlapping prescriptions within each drug class; across the opioid and benzodiazepine classes; across dosage forms of opioid analgesics (i.e., immediate vs. extended release); questionable activity within a class or classes; inappropriate prescribing measures; and pharmacy-based measures of possible inappropriate dispensing.[5]

Table 3: High Risk Prescribing Practices, Colorado, 2014-2020

Characteristics	2014	2015	2016	2017	2018	2019	2020
Percent of patients receiving over 90 MME per day	10.3%	8.9%	8.7%	8.2%	7.3%	6.5%	6.1%
*Rate of multiple provider episodes per 100,000 residents	170.1	124	93.6	68	40.3	25.1	14.0
Percent of patients prescribed long duration opioids who were opioid-naïve	18.2%	17.6%	15.8%	15.1%	12.1%	11.0%	10.7%
Percent of patient prescription days with overlapping opioid prescriptions	22.3%	21.5%	21.4%	20.5%	19.4%	18.2%	17.3%
Percent of patient prescription days with overlapping opioid and benzodiazepine prescriptions	12.1%	11.6%	11.2%	9.9%	8.9%	7.7%	6.5%

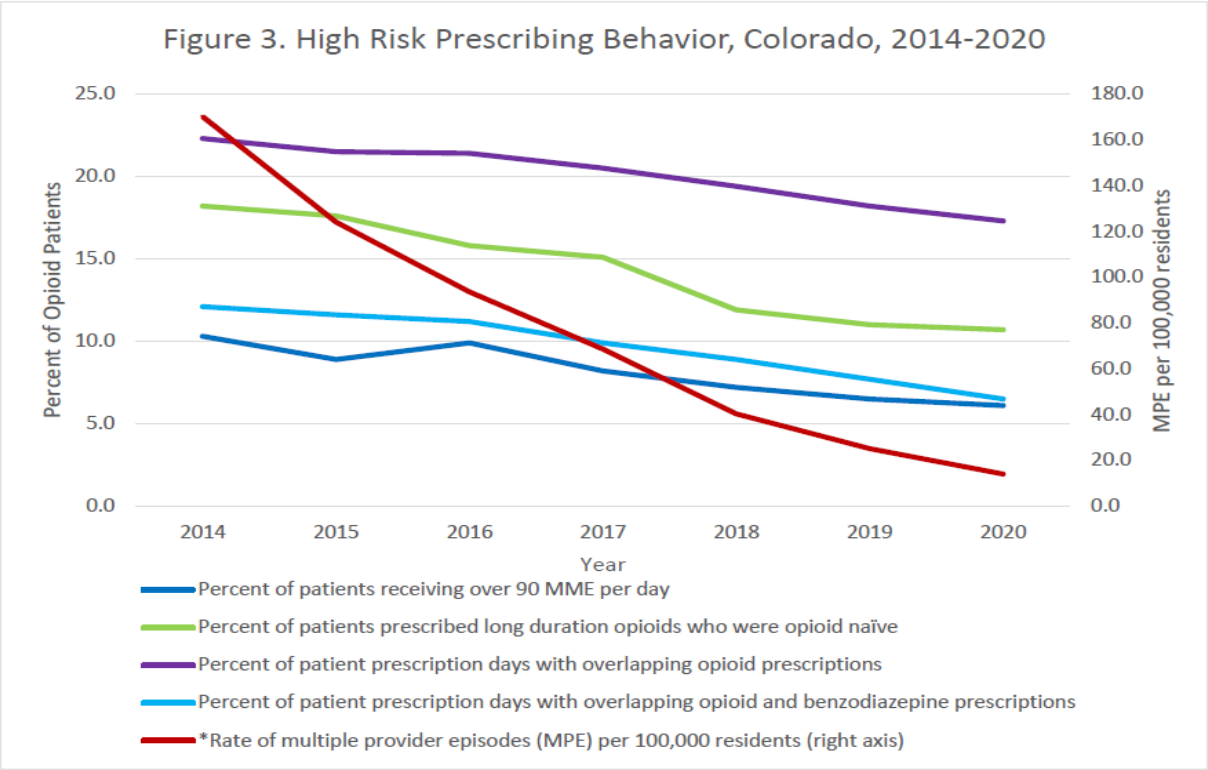
*2020 rates are calculated with 2019 population estimates as 2020 estimates are not yet available. Annual percentages are based on average of quarterly percentages

Data Source: Colorado Prescription Drug Monitoring Program, DORA; Data Analysis by: CDPHE, 2021

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

[5] PDMP Training and Technical Assistance Center, PBSS website, http://www.pdmpassist.org/content/prescription-behavior-surveillance-system

Figure 3: High Risk Prescribing Behavior, 2014-2020



As referenced in Table 3 and Figure 3 above, the percent of opioid patients receiving over 90 Morphine Milligram Equivalents (MME) decreased by 40.8% from 2014 to 2020, and decreased by 6.2% from 2019 to 2020. The rate of multiple provider episodes per 100,000 residents, defined as patients receiving controlled substance prescriptions from five or more providers and at five or more pharmacies within 90 days, decreased by 91.8% from 2014 to 2020, and decreased by 44.2% from 2019 to 2020. The percent of opioid-naïve patients prescribed long-duration opioids decreased by 41.2% from 2014 to 2020, and decreased by 2.7% from 2019 to 2020. The percent of patient prescription days with overlapping opioid prescriptions decreased 22.4% from 2014 to 2020, and decreased 4.9% from 2019 to 2020. The percent of patient prescription days with overlapping opioid and benzodiazepine prescriptions decreased 46.3% from 2014 to 2020, and decreased 15.6% from 2019 to 2020.

Requests for 2021 Task Force Report

Following the issuance of the 2020 PDMP Task Force Annual Report, DORA's Executive Director requested the Task Force to:

(1) Evaluate the risks and benefits of adding diagnostic information to PDMP data

(2) Analyze the appropriateness of implementing new or additional unsolicited reports or clinical alerts for prescribers and pharmacies

(3) Provide an analysis of costs for the future state of the technical architecture of the Colorado PDMP

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

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

The Task Force assigned the Executive Director's request to its PDMP Work Group, composed of representatives with medical, legal, or health information technology expertise, interested patients and family members, members of the Colorado legislature, as well as representatives from various state and federal agencies. A full list of the PDMP Work Group members and their corresponding organizations may be found in Attachment B.

The Task Force makes the following recommendations in furtherance of its objective to make the PDMP a more effective tool to improve medication safety and reduce prescription drug abuse and misuse in Colorado.

Task 1: Evaluate the Risks and Benefits of Adding Diagnostic Information to PDMP Data

Please evaluate whether collecting diagnostic information is consistent with the PDMP's statutory authority to collect any "data elements necessary to determine whether a patient is visiting multiple practitioners or pharmacies, or both, to receive the same or similar medication" (12-280-403(1)(f), C.R.S.) and to consider the clinical value to practitioners or pharmacies of collecting this diagnostic information as well as the analytical value for PDMP administration and public health researchers.

Response to Task 1

As discussed in the 2019-2020 PDMP Task Force Annual Report, assessing prescriber compliance with the requirements of Senate Bill (SB) 18-022 found in Section 12-30-109, C.R.S. is problematic since the PDMP does not collect diagnostic information that would help the PDMP determine why a prescription was written. Therefore, it is not possible to definitively determine whether an initial opioid prescription or second fill is for acute pain or for a condition exempt from the requirements of SB 18-022, nor is it possible to definitively determine how frequently second fills to opioid naïve patients are prescribed and dispensed for conditions where the requirements of SB 18-022 apply. In addition to considering whether diagnostic information should be included in the prescription record to help assess compliance with the opioid prescribing limits of SB 18-022, it should be noted that current statute prevents the Colorado PDMP from taking action based solely on the information in the PDMP if compliance with these restrictions could be definitively determined. Per 12-30-109(3), C.R.S.:

> A violation of this section does not create a private right of action or serve as the basis of a cause of action. A violation of this section does not constitute negligence per se or contributory negligence per se and does not alone establish a standard of care. Compliance with this section does not alone establish an absolute defense to any alleged breach of the standard of care.

University of Colorado and CDPHE SB 18-022 Assessment

In May 2018, the Colorado state legislature enacted Senate Bill 18-022, which limits the number of opioid pills a provider may prescribe an opioid naïve patient to a 7-day supply and requires the review of the Colorado Prescription Drug Monitoring program (PDMP) prior to issuing a

second 7-day supply with a few exceptions. While PDMP policies and practices such as these hold great promise to reduce misuse and abuse of controlled medications, evidence-based research to support these practices remains sparse. In 2019, the Colorado Department of Public Health and the Environment (CDPHE), in collaboration with researchers at the University of Colorado School of Medicine, initiated a plan to evaluate SB18-022 by investigating the effects of statutory compliance on patient outcomes across the UCHealth system. The project was initiated in the setting of gradual reductions in overall opioid prescribing and growing visibility of the societal cost of the ongoing opioid epidemic.

Progress on this evaluation has been slowed by the COVID-19 pandemic, but data has been obtained and validated, the analyses are ongoing. When complete, the project will provide insight on the effects of SB18-022 on the days supply and dose of opioid prescriptions, use of the PDMP prior to prescribing, and whether compliance with the statute was associated with less long-term opioid use. Analyses are expected in the fourth quarter of 2021. The collaborative nature of this evaluation of statutory changes with both prescription and patient outcomes will address important knowledge gaps and inform future policy decisions.

ICD-10 Codes

Diagnostic information is collected in healthcare settings with the International Classification of Disease 10th Edition (ICD-10) diagnosis codes, which are used for prior authorizations and claims payment processing. This is a diagnosis coding system for diseases and signs, symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or disease.[6] There are nearly 70,000 ICD-10-CM ("clinical modification") codes used for classifying medical conditions. A separate coding system for classifying medical procedures, ICD-10-PCS has over 86,000 codes that are used only in inpatient hospital settings.[7]

Only six state PDMPs currently collect ICD-10 codes, and discussions with several of these states revealed that these states are not currently able to use the codes for proactive compliance monitoring with respect to their states' use mandates or statutory restrictions on opioid prescriptions. States reported challenges related to the vast number of codes, lack of uniformity in reporting these codes by prescribers, and logistical challenges in grouping these codes and mapping them to specific reasons a prescription was written. It appears that these codes do not provide a straightforward solution for allowing the PDMP to determine which prescriptions are subject to Colorado's statutory Days Supply restrictions on opioid prescriptions for acute pain to opioid-naïve patients or for the statutory mandate to query the PDMP before authorizing a second fill of an opioid to an opioid-naïve patient for acute pain.

Collecting ICD-10 codes within a patient's PDMP record would also result in significantly more sensitive health information being collected by the PDMP. The Colorado PDMP is authorized by Section 12-280-403(1)(f), C.R.S. to collect:

(a) The date the prescription was dispensed;
(b) The name of the patient and the practitioner;
(c) The name and amount of the controlled substance;

[6] ICD Diagnosis Code Requirements, Version 5.3. July 10, 2017. Centers for Medicare and Medicaid Services. https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Mandatory-Insurer-Reporting-For-Non-Group-Health-Plans/NGHP-Training-Material/Downloads/ICD-Diagnosis-Code-Requirements-Part-I.pdf
[7] http://www.icd10codesearch.com/coding.php

(d) The method of payment;
(e) The name of the dispensing pharmacy; and
(f) Any other data elements necessary to determine whether a patient is visiting multiple practitioners or pharmacies, or both, to receive the same or similar medication.

With Colorado statute authorizing only the data necessary to determine whether a patient is visiting multiple practitioners or pharmacies to receive the same or similar medication, it does not appear that diagnostic information concerning a patient's medical conditions would be necessary for this purpose.

Opioid Prescription Treatment Type Codes

Rather than collecting ICD-10 codes which would present logistical challenges and patient privacy concerns, the newest data format for PDMP data submission, American Society for Automation in Pharmacy (ASAP) 4.2B, contains a new data field that could indicate the reason a prescription was written using one of the below 12 Treatment Type codes. This could provide an efficient and straightforward method of determining which opioid prescriptions are for acute pain or for other common reasons. However, codes 03-11 cited below could only be reported if the state mandates that this information be provided by the prescriber on the prescription.

01 – Not used for opioid dependency treatment
02 – Used for opioid dependency treatment
03 – Pain associated with active and aftercare cancer treatment
04 – Palliative care in conjunction with a serious illness
05 – End-of-life hospice care
06 – A pregnant individual with a pre-existing prescription for opioids
07 – Acute pain for an individual with an existing opioid prescription for chronic pain
08 – Individuals pursuing an active taper of opioid medications
09 – Patient is participating in a pain management contract
10 – Acute Opioid Therapy
11 – Chronic Opioid Therapy
99 – Other (non-opioid prescription or other agreed upon reason)

If these codes were required by Colorado law, these codes would present far fewer logistical concerns than the collection of ICD-10 codes. Though these codes would provide the PDMP with less specific information related to a patient's condition, this would not completely alleviate the privacy concerns related to collecting information related to a patient's medical condition. Additionally, requiring these Treatment Type codes may require practitioner training, especially for those who do not electronically prescribe opioids. Requiring such information would also necessitate updates by electronic prescribing systems and pharmacy management systems to capture and report these codes. Because 12-30-109(3), C.R.S. specifies that a violation of the opioid Days Supply restriction and PDMP utilization mandate "does not create a private right of action or serve as the basis of a cause of action," requiring Treatment Type codes may help PDMP administration assess compliance with this statute but would not allow PDMP administration to proactively enforce the opioid Days Supply restrictions or the PDMP utilization mandate. With recent programmatic and statutory changes, it is expected that the Colorado State Board of Pharmacy will need to implement updates to Board of Pharmacy Rule 23 concerning the PDMP. Updating to ASAP 4.2B would provide the PDMP with the prerequisite

data format which would allow for the collection of the above Treatment Types if mandated by Colorado law in the future.

Recommendation: Task 1

Collecting ICD-10 codes is not allowed by Colorado statute, which limits the data elements that can be collected to those that are necessary to determine whether a patient is visiting multiple practitioners or pharmacies, or both, to receive the same or similar medication. Additionally, these codes do not represent an effective or efficient solution to proactively assess prescriber compliance with the statutory limitations of certain opioid prescriptions in Senate Bill 18-022. The Board of Pharmacy should consider updating the data format from ASAP 4.2 (released in 2011) to ASAP 4.2B (released in 2020) through rulemaking which could accommodate the collection of a limited number of Treatment Type codes concerning opioid prescriptions. The 12 Treatment Type codes available in the most current PDMP data submission format could be collected to efficiently and broadly categorize opioid prescriptions while collecting more limited information related to a patient's condition than what would be collected through ICD-10 codes. However, implementing the use of Treatment Type information would only be possible if mandated by Colorado law and this information would have limited value with PDMP administration lacking the ability to proactively enforce the PDMP use mandate.

Task 2: Analyze the Appropriateness of Implementing New or Additional Unsolicited Reports or Clinical Alerts for Prescribers and Pharmacies

12-280-404(8), C.R.S. requires the Board of Pharmacy to consult with the Colorado's prescribing boards to "develop criteria for indicators of misuse, abuse, and diversion of controlled substances and, based on those criteria, provide unsolicited reports of dispensed controlled substances to prescribing practitioners and dispensing pharmacies for purposes of education and intervention to prevent and reduce occurrences of controlled substance misuse, abuse, and diversion." I ask the Task Force to evaluate whether additional unsolicited reports for other criteria should be implemented with respect to the potential clinical benefits for practitioners and pharmacies, potential "alert fatigue" concomitant with high volumes of alerts, and the risks of additional alerts potentially impeding the appropriate utilization of these medications for legitimate medical purposes.

Response to Task 2

As reflected in the legislative declarations found in 12-280-401, C.R.S., prescription drug misuse occurs at times due to the deception of practitioners by patients who seek controlled substances for treatment and when the practitioner is unaware of the patient's other medical providers and treatments. The Colorado PDMP's core mission is to inhibit prescription drug misuse, abuse and diversion by ensuring providers are made aware when a patient may be visiting multiple providers, pharmacies, or both, to receive the same or similar medications. In furtherance of this mission, the Colorado PDMP sends unsolicited reports to prescribers and pharmacies concerning patients who meet the Board of Pharmacy's multiple provider episode confidential threshold, sometimes called "doctor shopping." These unsolicited reports include a disclaimer that the reports are sent in support of the program's core mission to identify and inhibit the misuse and abuse of prescription drugs in a manner that will not impede the appropriate utilization of these medications for legitimate medical purposes, and the PDMP does not make any conclusions or judgments based solely on the information recorded in the

PDMP. Therefore, these unsolicited reports must be interpreted by the patient's treating provider to determine whether the patient's prescriptions are appropriate.

Analysis of the effectiveness of unsolicited reports is limited, but data suggests that these reports can influence prescriber and pharmacist behavior and utilization of the PDMP. However, these unsolicited reports may be less effective than laws or policies that require or encourage more frequent PDMP utilization. A study in Nevada found that prescribers who received an unsolicited report were 13% less likely to continue prescribing to the patients identified in the unsolicited report than prescribers who did not receive a report. However, many patients found other providers to replace those who discontinued treatment. Therefore, the use of unsolicited reports had, at most, a small effect on patients' use of multiple providers and the authors concluded that requiring providers to review their patients' prescription histories was likely to be a more effective use of PDMP resources than unsolicited reporting.[8] An evaluation of unsolicited reporting in 2010-2011 in Massachusetts found that patients with an average daily dose of less than 100 morphine milligram equivalents (MMEs) whose providers received unsolicited reports had significant decreases in the number of Schedule II opioid prescriptions, the number of prescribers visited, number of pharmacies used, dosage units, total days' supply, and total morphine milligram equivalents (MME) and average daily MME. However, their analysis found far less of an effect for patients with an average daily dose over 100 MME and the researchers indicated that mandatory PDMP use was likely to have a greater effect on reducing multiple provider episodes.[9] Another study in Massachusetts surveyed prescribers who received unsolicited reports. Of the respondents, only 8.4% were aware of most or nearly all of the other prescribers listed on the patients' reports, and of those who reported they had sufficient information to make a judgment, nearly 70% felt the prescriptions were unwarranted. Over 85% of respondents felt the unsolicited reports were useful in tracking their patients' prescriptions.[10]

Though unsolicited reports are commonly used by PDMPs, there is not a commonly agreed-upon multiple provider/multiple pharmacy threshold for generating these unsolicited reports, and the optimal criteria for unsolicited reporting may vary state by state.[11] Although a particular criterion for potentially unsafe prescribing or dispensing may produce false positives, prescribers and dispensers following up on a PDMP report make the final determination on whether a patient's controlled substance behavior warrants intervention.. However, too many false positives may produce "alert fatigue" among recipients and undermine the credibility of

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[8]McDonald D, Carlson K, Jalbert S. An Experimental Test of the Effectiveness of Unsolicited Reporting by a Prescription Drug Monitoring Program in Reducing Inappropriate Acquisition of Opioids. Pain Medicine. 2018;0:1-11.

[9] Young L, Kreiner P, Panas L. Unsolicited Reporting to Prescribers of Opioid Analgesics by a State Prescription Drug Monitoring Program: An Observational Study with Matched Comparison Group. American Academy of Pain Medicine. 2017;19:1396-1407.

[10] Thomas, C., Kim, M., Nikitin, R., Kreiner, P., Clark, T., Carrow, G. Prescriber response to unsolicited prescription drug monitoring program reports in Massachusetts, Pharmacoepidemiology & Drug Safety, 23(9) 2014: 950-957, http://onlinelibrary.wiley.com/doi/10.1002/pds.3666/abstract.

[11] Prescription Drug Monitoring Program Center of Excellence, Guidance on PDMP Best Practices: Options for Unsolicited Reporting (Waltham, MA: Brandeis University, October 2014; Updated May 2016). https://www.ojp.gov/pdffiles1/bja/247133.pdf

the PDMP, so a reasonable degree of specificity is needed.[12] Additionally, as prescribing trends change due to a variety of factors, the specific threshold set by a state should be periodically evaluated and may need adjustment over time. It should also be noted that these studies were conducted several years ago when integration with electronic health systems was far more limited and PDMP utilization rates were often significantly lower than they are today.

Like Colorado, many states keep confidential the specific threshold used for generating these multiple provider and multiple pharmacy threshold alerts. The Task Force reviewed the state profiles curated by the Prescription Drug Monitoring Program Training and Technical Assistance Center (PDMP TTAC)[13] concerning unsolicited reporting and received information regarding the specific thresholds used by other states where available from PDMP TTAC, with the understanding that specific thresholds used by states not be shared publicly. A review of these thresholds shows significant variation among states. Though there is not a national standard for multiple provider thresholds, the Bureau of Justice Assistance's (BJA) Harold Rogers PDMP Grantees report to BJA the number of patients receiving controlled substance prescriptions from five or more prescribers and five or more pharmacies within three months. The Colorado PDMP's Prescriber Reports (discussed below) notifies prescribers the number of the prescriber's patients who received controlled substance prescriptions from five or more prescribers over the six-month reporting period and the number of patients who received controlled substance prescriptions from five or more pharmacies over the six-month reporting period.

As shown in Table 3 above, the rate of Multiple Provider Episodes in Colorado, defined as patients receiving controlled substance prescriptions from five or more providers and at five or more pharmacies within 90 days, has decreased by 91.8% since 2014. Because there have been numerous initiatives to reduce prescription drug misuse, abuse and diversion, at the federal, state and healthcare organization levels as well as more frequent PDMP utilization facilitated by increased PDMP integrations with other health information systems, it is difficult to attribute these reductions in multiple provider episodes to any particular initiative. Practitioners are more likely to be aware of at-risk patients than they were several years ago when PDMPs were less mature or sophisticated and utilization was less common. However, as prescribers do not always query the PDMP before prescribing and many prescribers in Colorado do not have integrated PDMP access, unsolicited reporting still has a role in notifying prescribers and pharmacies of potentially unsafe prescribing.

Multiple Provider and Multiple Pharmacy Unsolicited Reports in Colorado

The Colorado PDMP currently sends unsolicited reports known as Push Notices or Patient Alerts to prescribers and pharmacies that prescribed or dispensed controlled substance prescriptions to patients who meet the Board of Pharmacy's confidential multiple provider and multiple pharmacy threshold. The Board of Pharmacy was initially authorized to send these unsolicited reports in HB 14-1283 and these alerts were first sent to prescribers and pharmacies in September 2014. Throughout 2014 and 2015, PDMP staff saw a decline in the number of Push Notices sent to prescribers and pharmacists, which signaled that fewer patients were meeting the threshold previously set by the Board of Pharmacy. As a result, the Board of Pharmacy consulted with the prescribing Boards (Medical, Dental, Nursing, Optometric and Podiatric) to determine if the multiple provider and multiple pharmacy should be changed. At its September

[12] Morgan, et al. The Use of Prescription Monitoring Programs to Reduce Opioid Diversion and Improve Patient Safety, Journal of Pain & Palliative Care Pharmacotherapy. 2013;27:4–9

[13] https://www.pdmpassist.org/State

2016 meeting, the Board of Pharmacy voted to immediately modify the thresholds that govern the production of Push Notices in Colorado, determining that more effective public protection would be maintained with this modification in place. Consequently, beginning in October 2016, the number of Push Notices prepared by the PDMP staff increased significantly because of the Board's modification of the threshold.

These Push Notices are delivered electronically to prescribers' PDMP user accounts and prescribers receive an email advising that an alert is available to view within their PDMP account and are mailed to affected prescribers without a PDMP user account. Previously, these alerts were mailed to all pharmacies and addressed to the pharmacy manager. Since April 2020 the PDMP has leveraged the pharmacy manager information on file for each in-state pharmacy to link that pharmacy manager's PDMP user account to their pharmacy to electronically deliver these alerts to the pharmacy manager. This has significantly reduced the number of mailed alerts, giving the Colorado PDMP greater administrative capacity to process higher alert volumes if an adjustment is implemented by the Board of Pharmacy.

Though the number of patients meeting the Board of Pharmacy's threshold varies each month, fewer than 100 patients statewide are meeting this threshold, with approximately 60 or fewer patients meeting the threshold each month since February 2020 (see Figure 5). With approximately 400,000 patients receiving at least one controlled substance prescription each month, the Board of Pharmacy should consult with Colorado's prescribing Boards to evaluate the effects of adjusting this threshold to a lower prescriber and pharmacy count and/or a broader time period to ensure prescribers and pharmacies are aware of patients who may be visiting multiple prescribers, multiple pharmacies, or both to obtain controlled substance prescriptions. When determining which threshold is most appropriate, the Boards should consider the increased likelihood of the program generating alerts for patients who are receiving appropriate treatment if the prescriber and/or pharmacy threshold is lowered or if the time frame for generating an alert is expanded. To address this, the specific language used in these alerts should continue to advise that the PDMP sends these alerts for informational purposes only and makes no judgments based solely on the information in the PDMP, and that practitioners should use their clinical judgment in determining what is appropriate for the patient. Additionally, PDMP administration may consider formally evaluating the impact of these Push Notices to better understand the impact of these notices on prescriber behavior and patient care.

Figure 4: Monthly Push Notices Generated: September 2014-May 2021

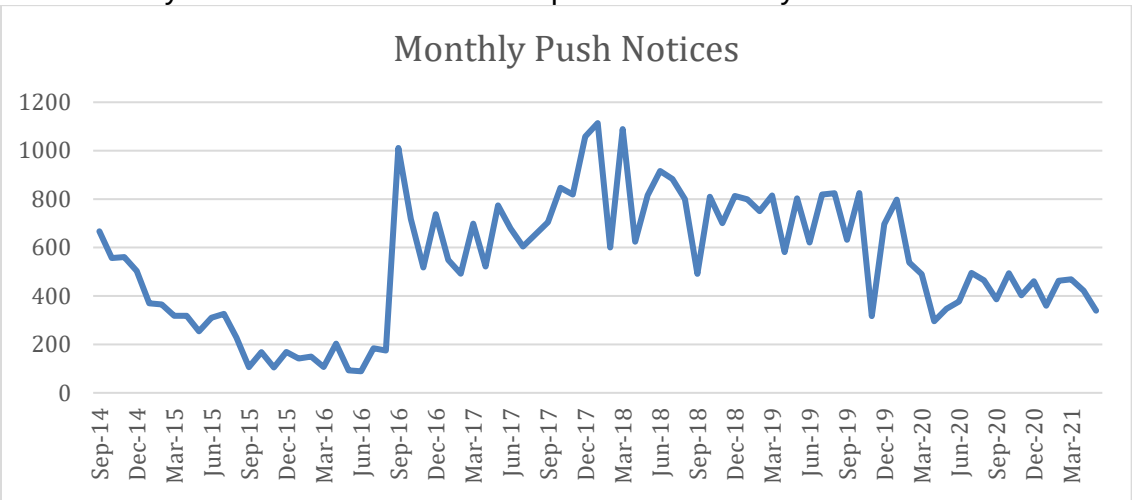
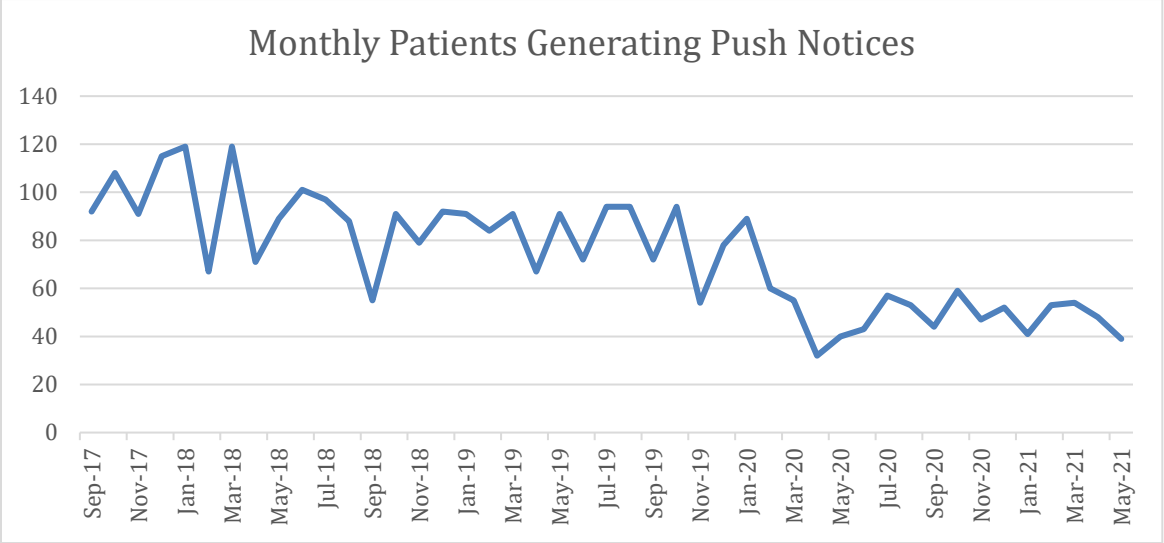


Figure 5: Patients Generating a Push Notice: September 2017-May 2021 (note: patient counts are not available before September 2017)



Clinical Alerts, Enhanced Displays and Risk Scores

As PDMP systems become more sophisticated, many states are implementing clinical alerts or clinical decision support tools with enhanced PDMP data displays to help users more efficiently identify potentially at-risk patients. These alerts or enhanced metrics may identify patients with concurrent opioid and benzodiazepine prescriptions, high dosage opioid prescriptions, or extended opioid treatment durations and may take the form of a notice on the patient's PDMP patient report or a "risk score."

An evaluation of the prescription history of 1,687 individuals who died of accidental drug overdoses in Ohio reviewed those individuals' NARxCHECK® scores (which have a range of 0-999, where the last digit reflects the number of active prescriptions) found that NARxCHECK scores above 650 were closely associated with an elevated overdose risk.[14] Another study of enhanced displays of PDMP data found that prescribers were better able to identify high-risk prescription histories including multiple providers, overlapping opioid and benzodiazepine prescriptions, and patients traveling long distances to have a prescription filled. These authors propose that the enhanced displays are most helpful for the more nuanced cases where the provider is undecided about prescribing or for identifying patient safety concerns such as overlapping opioid and benzodiazepine prescriptions or high daily MME.[15] A third study provided 93 physicians with one of three patient vignettes with corresponding standard and enhanced PDMP profiles and conducted brief interviews with the physicians. These authors found that enhanced profiles could increase ease of comprehension and time burden and aid in

[14] Huizenga, et al. NARxCHECK® Score as a Predictor of Unintentional Overdose Death. October 2016. Appriss, Inc. https://apprisshealth.com/wp-content/uploads/sites/2/2017/02/NARxCHECK-Score-as-a-Predictor.pdf

[15] Weiner, et al. Advanced visualizations to interpret prescription drug monitoring program information. *Drug Alcohol Depend.* 201:260-265. August 2019. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6737934/

communicating with patients about opioid risks, but physicians also expressed concern about liability for prescribing when the enhanced profile indicates risk and cautioned against any implication that risk warnings should override clinical judgment based on the patient's complete medical history or presenting condition.[16]

These risk scores have also been criticized by advocates for chronic pain patients who argue that the use of these risk scores may result in discrimination against patients with complex, chronic pain and make it more difficult for patients with legitimate medical need to access appropriate care.[17] If the Colorado PDMP chooses to implement any clinical alerts or risk scores, it should make clear that the PDMP makes no judgments or conclusions based solely on PDMP data and that any unsolicited reports, enhanced displays or risk scores are to be used solely for clinical decision support and should not override the practitioner's clinical judgment.

Clinical Alerts

Colorado's PDMP vendor offers a Clinical Alert package that could be used to generate alerts to prescribers and dispensers for a variety of potentially unsafe prescribing situations. Alerts can be implemented for a multiple prescriber and multiple pharmacy threshold, for patients with a daily active MME above a certain threshold such as over 50 MME, 90 MME or 200 MME, for a patient with concurrent or recent opioid and benzodiazepine prescriptions, and for patients with opioid prescriptions for consecutive days above a certain threshold such as 30 days, 90 days, 180 days or one year. Depending on the settings, these alerts could be visible to any PDMP user who views the patient's prescription history or only to those prescribers who previously prescribed to the patient and the pharmacy managers for pharmacies that dispensed to the patient. Those who prescribed or dispensed to the patient could also have these alerts loaded to their PDMP account dashboard, which could include an email to the prescriber or pharmacy manager advising that an alert was loaded to their PDMP account to ensure the prescriber or pharmacy manager is made aware of the alert.

Because these clinical alerts could result in a significant increase in the number of unsolicited reports sent by the Colorado PDMP, the Task Force solicited stakeholder input regarding these available clinical alerts through an informal survey which was sent to the 580 members of the Colorado Consortium's PDMP, Provider Education and Treatment Work Group members to evaluate which of these potential alerts would be the most useful to providers and to determine which display and delivery method(s) would be preferred. The survey received 28 responses and no consensus emerged from this survey regarding the value of any of the potential alerts. The survey requested that respondents assess each category on a four-point scale of very valuable, valuable, somewhat valuable or not valuable. Seventeen of the 28 respondents stated that a multiple prescriber/multiple pharmacy threshold and a daily active MME threshold would be either very valuable or valuable. Twenty respondents stated that opioid and benzodiazepine co-prescribing alerts would be very valuable or valuable. Fourteen respondents indicated that alerts for patients receiving opioids for over three months would be either very valuable or valuable while 11 respondents indicated that patients receiving opioids for over six months and 12 respondents indicated that patients receiving opioids for one year were considered very valuable or valuable. Regarding the preferred delivery method for any alerts, 13 preferred the

[16] Leichtling, et al. Physician Responses to Enhanced Prescription Drug Monitoring Program Profiles. *Pain Medicine,* 2020 Feb 1;21(2):e9-e21. https://pubmed.ncbi.nlm.nih.gov/30698811/

[17] Odell, Rochelle. What Every Patient Should Know About NarxCare. May 19, 2018. www.painnewsnetwork.org/stories/2018/5/19/what-every-patient-should-know-about-narxcare

alert only display within a patient's PDMP report while three preferred the alert both display on a patient's PDMP report and have an alert loaded to the prescriber and pharmacy manager's PDMP account and 12 preferred the alert be displayed in a patient's PDMP report with an alert loaded to the prescriber and pharmacy manager's PDMP account along with an email sent to the prescriber and pharmacy manager notifying them of the alert.

Because of the low number of responses and a lack of consensus by respondents, these informal survey results should be considered only a starting point for evaluation, and the Colorado State Board of Pharmacy and the Colorado prescribing boards may want to further disseminate this survey to a broader range of stakeholders before further considering implementing any of these clinical alerts. Additionally, the Colorado PDMP should send communications to all PDMP users before implementing any of these clinical alerts to explain any new alerts are being used solely for clinical decision support and to ensure practitioners do not misconstrue the alerts or interpret them to mean the patient or practitioner is being scrutinized or investigated by their licensing board to minimize the impact of such alerts for patients receiving appropriate care.

Prescriber Scorecards in Colorado

Among the PDMP landscape, 38 state PDMPs send Scorecards (also called Prescriber Reports) to prescribers, which provide a high-level summary of the individual's prescribing activity in comparison with their peers. The Colorado PDMP's Scorecards are funded through an inter-agency agreement between DORA and CDPHE. The initial version of these Scorecards was sent to opioid prescribers with an active Colorado PDMP user account and a Healthcare Specialty on file. These reports were first disseminated in February 2018 and were sent on a quarterly basis thereafter. This first version of these scorecards included prescriber-specific and peer-group averages concerning the number of patients prescribed opioids, percentages of patients within opioid treatment duration and MME ranges, total opioid prescription volumes, patients receiving opioid and sedative prescriptions, patients receiving multiple provider thresholds, and PDMP search activity.

In connection with the initial distribution of these Scorecards, a survey was disseminated by CDPHE in 2018 to approximately 29,000 prescribers, to which 3,784 responded. The survey was developed with input from the Colorado PDMP Work Group consisting of prescribers, community members, pharmacists, members of the Colorado Medical Association, a representative from DORA, CDPHE, and researchers familiar with the PDMP. Overall, 49% of respondents recalled receiving the report, with those in practice for 1-5 years having the highest proportion reporting receiving the report at 72%. Among those who reported receiving the report, 87% indicated they were easy to understand while 83% indicated it provided information that was new to them. Additionally, 40% of respondents reported that they planned to change their prescribing behaviors because of the information provided and two thirds of prescribers thought the reports accurately reflected their prescribing practices. Approximately half of those who received a report indicated that the most useful metrics in the report were the number of patients for whom they prescribed opioids, the number of prescriptions written, the number of patients with multiple provider episodes and the number of patients receiving dangerous combination therapy. Alternatively, respondents found the total MME dosages, opioid treatment duration and PDMP searches to be less valuable.[18]

[18] Alishahi, et al. "Provider Reactions to Opioid Prescribing Report Cards." *Journal of Public Health Management & Practice*. May 13, 2021. doi: 10.1097/PHH.0000000000001382. https://pubmed.ncbi.nlm.nih.gov/34016911

A second version of these reports made several changes and expanded dissemination to all prescribers with an active PDMP user account and a Healthcare Specialty on file who prescribed at least one opioid, stimulant or sedative over the six-month reporting period beginning in January 2020.

Key information in the current version of these Scorecards includes:

- The prescriber's average monthly per-patient opioid, buprenorphine, sedative and stimulant prescription counts and average prescription quantities
- The prescriber's average monthly per-patient opioid MME dosages
- How the above averages compare to those with the same healthcare specialty listed on their PDMP user account profile, reported monthly
- The number of opioid, buprenorphine, sedative and stimulant patients for the prescriber within the six-month reporting period
- The number of their patients with five or more prescribers within the reporting period
- The number of their patients with five or more pharmacies within the reporting period
- The number of patients receiving opioids with a daily MME dosage at or above 90
- The number of patients receiving opioids with a daily MME dosage at or above 120
- The number of patients potentially dangerous combinations of opioids and benzodiazepines from the prescriber
- The number of patients receiving a potentially dangerous combinations of opioids and benzodiazepines and carisoprodol from the prescriber
- The number of patients receiving a potentially dangerous combination where the prescriber wrote at least one of the prescriptions
- The number of PDMP searches performed

Though this second version made several refinements to the scorecards, the reports are a static document generated on a quarterly basis that does not give prescribers the ability to review the information in greater detail, such as identifying the specific patients who met the multiple provider or multiple pharmacy threshold or those who had potentially dangerous combinations. With the reports generated quarterly, there is also a lag time between the quarterly report and the practitioner's prescribing activity. There are plans to allow prescribers to view the specific patients that were identified as receiving prescriptions from five or more prescribers and five or more pharmacies and those who received potentially dangerous combinations, but an implementation date has not been determined. Colorado should consider performing another evaluation of this new version of the Scorecards to determine prescriber satisfaction with the information on the reports and to determine whether any new or different information should be considered in the future.

Recommendation: Task 2

The multiple provider and multiple pharmacy threshold currently used for generating Push Notices (also known as Patient Alerts) has not been adjusted since 2016, and approximately 60 patients per month meet the current threshold for these alerts. With many initiatives contributing to the significant decreases in multiple provider episodes in recent years, it is difficult to discern the impact of Push Notices on prescribing behavior. Formal evaluation of these notices could help the PDMP better understand whether the notices have influenced prescriber behavior or affected patient care. The Task Force recommends that the Colorado State Board of Pharmacy consult with the Colorado prescribing Boards (Medical, Dental, Nursing, Optometric and Podiatric) to evaluate the current multiple provider threshold used by

the Colorado PDMP to generate Push Notices to prescribers and pharmacies and determine if the threshold should be adjusted to ensure prescribers and pharmacies are aware of patients who are potentially "doctor shopping." Additionally, the Board of Pharmacy and the prescribing Boards should evaluate the potential use of Clinical Alerts to make certain information more readily available to users. However, any changes should be accompanied with extensive communication to practitioners to ensure any new unsolicited reports or alerts are not misinterpreted by prescribers or pharmacies.

Task 3: Provide an Analysis of Cost for the Future State of the Technical Architecture of the Colorado PDMP

Evaluate the costs and benefits of various integration models as they relate to the preferences of Colorado stakeholders, the goals of Colorado's Health IT Roadmap, and the needs of end users. Additionally, analyze how each integration model has the ability to reduce healthcare costs in Colorado. How can the PDMP best achieve the objectives of integration usability and healthcare cost savings within the broader goals of Colorado's Health IT Roadmap?

Response to Task 3

As discussed in the 2020 PDMP Task Force Annual Report, PDMP integrations are being implemented in a variety of clinical contexts and health information systems. Pharmacy management systems leverage integrated PDMP access in the prescription review process. Direct EHR integrations allow practitioners to review a PDMP report when the practitioner opens a patient's chart, providing access at many points in a patient encounter. Integrations with HIEs allow a practitioner to access PDMP reports when retrieving other data from the HIE, with the HIE serving as a one-stop shop for externally-held patient data. PDMP integrations with electronic prescribing tools allow a practitioner to review a patient's PDMP report within the electronic prescribing workflow.

PDMP integration with a practitioner's electronic health technology is a key prerequisite for more frequent utilization. Integration significantly reduces the time and effort to access PDMP data to as little as a single click whereas web portal users must log in to an external website and manually search the PDMP. However, integrating the PDMP within a healthcare organization's technology requires work by health IT vendors and/or healthcare organizations to develop connections between their platforms and the PDMP integration solution. Though many leading health IT vendors have developed connectivity with integration solutions, health IT vendors may charge healthcare organizations one-time implementation fees to implement a PDMP integration. Additionally, healthcare organizations in Colorado must pay annual license fees for integrated PDMP access because Colorado's contract with Appriss does not include the subscription costs related to integrated PMP Gateway access.

PMP Gateway Integration

The PMP Gateway was launched in 2014 to integrate PDMP data with electronic health IT systems through the PMP InterConnect data sharing hub. The PMP Gateway currently supports 43 of the 54 PDMPs in the United States and offers integrated access to over one third of prescribers nationwide. Since 2019, the number of active PMP Gateway-connected physicians

and prescribers throughout the United States has nearly doubled to over 970,000.[19] As reported in the 2020 PDMP Task Force Annual Report, over 5,000 prescribers in Colorado had integrated PDMP access through PMP Gateway in May 2020 and performed over 82,000 patient searches through PMP Gateway. In May 2021, nearly 9,000 prescribers in Colorado had integrated PDMP access through PMP Gateway and performed over 136,000 patient searches through PMP Gateway. However, these integrated prescribers represent less than half of DEA-licensed prescribers and medical residents in Colorado. While Colorado has seen significant growth in the number of healthcare organizations and prescribers integrating their electronic health technology with the PDMP, it would take several years at this rate for a large majority of Colorado's prescribers to have integrated PDMP access.

RxCheck Integration

As of December 2020, 21 hospital organizations, five pharmacies and four HIEs across the United States have integrated with their state PDMPs through the RxCheck inter-state data sharing and integration hub, which is far less than the number of integrations currently enabled through PMP Gateway. These integrations are primarily in states which have developed their PDMPs in-house or are using a different PDMP vendor than Colorado.

RxCheck is in the process of implementing a significant upgrade to its platform, which is expected to be implemented in Colorado sometime in the future. Colorado's upcoming PDMP Request for Proposals will request applicants to explain how RxCheck could be leveraged to integrate in-state healthcare organizations and facilitate integrated interstate PDMP exchanges with neighboring states that do not currently support PMP Gateway integrations.

PDMP Integration Grants

In February of 2020, Colorado released a competitive Request for Applications (RFA) to reimburse healthcare organizations for PDMP integration implementation costs. This RFA was funded by the CDC Overdose Data to Action (OD2A) grant which was awarded to CDPHE. OD2A funds were appropriated to DORA through an interagency agreement between DORA and CDPHE for the Colorado PDMP. With the timing of this first RFA coinciding with the onset of the COVID-19 pandemic, Colorado received only one response. In October 2020 Colorado released a second RFA to reimburse healthcare organizations for costs related to integrating the PDMP with their health technology platforms as well as one year of licensing fees for integrated access. This second RFA had a total of 13 available grants ranging from $5,000 to $30,000 with a total fund pool of $155,000.

Despite a robust communication strategy including a 30-day advance notice of the upcoming RFA to a wide variety of stakeholders via email and a public webinar explaining the RFA hosted by the Colorado Consortium for Prescription Drug Abuse Prevention, Colorado received only nine applications and awarded only seven grants ranging from $1,450 to $5,006. With this RFA

[19] "Appriss Health and NABP Celebrate 10th Anniversary of PMP InterConnect." Appriss Press Release. April 6, 2021. https://apprisshealth.com/press-release/appriss-health-and-nabp-celebrate-10th-anniversary-of-pmp-interconnect/

process not accomplishing its objectives in awarding all available funding to facilitate PDMP integration by reimbursing the implementation costs of integration, DORA and CDPHE are evaluating other ways to provide financial assistance to healthcare organizations interested in integrating their electronic health technology with the Colorado PDMP.

Though this RFA process did not achieve its objectives in disseminating all available funding to healthcare organizations, Colorado gained some insight into the integration implementation costs charged by health IT vendors. Awardees were reimbursed for the costs of Change Orders from their health IT vendors to implement the integrations which ranged from $900 to $1,600 in addition to the annual PMP Gateway license fees. Such implementation fees may not be charged by all health IT vendors, but this limited evidence suggests that healthcare organizations may incur implementation costs for integrating their IT systems with the PDMP. Larger healthcare organizations frequently have in-house IT staff who may be able to implement such integrations within their health IT platforms, but smaller healthcare organizations are often dependent on their health IT vendors to perform this work.

PDMP Integration Costs

Appriss' Statewide Interoperability Program has significantly increased PDMP integration in participating states. With this program, the PMP Gateway license fees for all practitioners are paid through a state's contract with Appriss. The program also provides a consistent onboarding process and ongoing support as well as ongoing development of integrations with various health IT systems. While this structure would cost significantly more than what Colorado currently pays for PDMP service, the overall cost of PMP Gateway access for all practitioners is significantly less than if all healthcare organizations or individual practitioners paid their own PMP Gateway licensing fees. This approach resulted in over 90% of providers being integrated in Oregon within two years and within three years in Michigan and Indiana. Appriss has previously estimated that EHR integration via PMP Gateway using a Statewide Interoperability Program could be deployed to nearly all Colorado providers within an estimated 18 to 24 months. As demonstrated by these initiatives to promote PDMP integration in other states, providing PDMP integration options to all users without additional license fees and with an efficient onboarding process will be critical to further expanding the number of integrated users in Colorado.

While the Appriss Statewide Interoperability program is structured so that healthcare organizations have no ongoing licensing fees for integrated access, this program does not cover implementation costs that may be charged by EHR vendors to implement the PDMP integration so healthcare organizations could be responsible for implementation costs. However, as more EHR platforms develop integrated connections with PDMPs and EHR vendors increasingly implement these integrations, implementation costs appear to be decreasing. If Colorado wishes to completely eliminate the financial barriers to PDMP integration, it should consider how grant funds or other external funding sources might be used to reimburse potential integration implementation costs charged by health IT vendors.

Upcoming PDMP Request for Proposals

Colorado's five-year contract with the current PDMP vendor, Appriss, will expire in 2022, and a Request for Proposals (RFP) will be released in the latter part of 2021. In preparation for this RFP, DPO has conducted numerous market research stakeholder meetings with individuals and organizations to collect feedback regarding the current system's strengths, weaknesses and key opportunities for the future. This stakeholder outreach was intended to ensure transparency, broad stakeholder engagement, complete documentation of system requirements and a competitive RFP process. DPO has also contacted several other states to gather lessons learned with the hope of incorporating the necessary requirements into the RFP. With integration being identified as a prerequisite for practitioners' efficient and consistent use of the PDMP as a clinical decision support tool, providing PDMP integration options to healthcare organizations with the fewest technological and logistical challenges and at the lowest possible costs to end users will be an important focus of this RFP, among others. It is expected that this RFP will request that vendors submit bids that include the costs of providing healthcare organizations with integrated access to the PDMP with the costs of supporting these integrations borne by the state.

Recommendation: Task 3

Although PDMP integration in Colorado continues to increase, less than half of Colorado's prescribers currently have integrated PDMP access through their health IT platforms. The integration implementation costs and ongoing license fees for integrated access can be a barrier to integration for some healthcare organizations, which other states have addressed by providing integration options with no ongoing fees to end users or healthcare organizations. Though providing integration options without ongoing fees can significantly reduce these costs, health IT vendors may charge implementation fees to install an integrated connection between an organization's health IT platform and the PDMP. Colorado's future PDMP RFP should solicit proposals that include integrated PDMP access for Colorado's users to further Colorado's objective to achieve the objectives of integration usability and healthcare cost savings within the broader goals of Colorado's Health IT Roadmap. If Colorado wishes to further reduce the costs of integration, the state may consider how federal or state funding could be leveraged to offset the integration implementation fees that health IT vendors may charge healthcare organizations.

Conclusion

Though Senate Bill 18-022 and HB 21-1276 place Days Supply restrictions on certain opioid prescriptions and requires prescribers to query the Colorado PDMP before authorizing opioid and benzodiazepine prescriptions to patients in certain situations, current law does not authorize the PDMP to collect diagnostic information that would help the PDMP identify which prescriptions may be subject to the Days Supply restriction and PDMP use mandate and the PDMP is unable to proactively enforce compliance with these requirements. Additionally, collecting ICD-10 diagnostic codes would present patient privacy concerns and are not an efficient method of identifying prescriptions subject to the statutory restrictions. A more limited set of Treatment Type codes would be a more efficient way of determining the reason an opioid was prescribed but could only be implemented if Colorado were to mandate this

information be reported on a prescription and implementing such requirements would increase the reporting burden of prescribers and pharmacies.

The Colorado PDMP has been sending unsolicited patient alerts to prescribers and dispensers regarding patients who meet the State Board of Pharmacy's confidential multiple provider and multiple pharmacy threshold since 2014, but the threshold has not been adjusted since 2016. The State Board of Pharmacy should evaluate adjusting this threshold and should consider whether additional clinical alerts may be warranted, though any change in such unsolicited reporting should include a robust communication plan to practitioners and pharmacies and a plan to evaluate the impact of such notices on patients and prescribing.

Integrating the PDMP with other health information systems including EHRs, HIEs and electronic prescribing software provides PDMP data within a provider's workflow and is a key prerequisite for broad PDMP utilization. As Colorado prepares to solicit proposals for a PDMP vendor later this year, it will be important to solicit proposals that include providing PDMP integration options to healthcare organizations with the fewest technological and logistical challenges and at the lowest possible costs to end users.

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

December 23, 2020

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 2019-2020 Task Force Report. The Consortium's support and expertise this past year was invaluable.

Section 12-280-409, C.R.S. requires the Executive Director of the Department to consult with and request assistance from the Consortium as the PDMP Task Force. To that end, on behalf of the Executive Director, I am requesting assistance from the Consortium to examine issues and opportunities regarding the PDMP and to make recommendations on ways to make the PDMP a more effective tool to reduce prescription drug abuse in Colorado. In doing so, please prepare and submit an annual report to the Executive Director and the Colorado General Assembly detailing the Consortium's findings and recommendations by July 1, 2021.

Task #1: Evaluate the Risks and Benefits of Adding Diagnostic Information to PDMP Data

This year's report discussed the challenges in assessing prescriber compliance with the PDMP utilization requirements enacted in Senate Bill 18-022 for opioid second fills to opioid-naïve patients due to a lack of diagnostic information within prescription records reported to the PDMP. For the next report, I ask the Task Force to evaluate whether collecting diagnostic information is consistent with the PDMP's statutory authority to collect any "data elements necessary to determine whether a patient is visiting multiple practitioners or pharmacies, or both, to receive the same or similar medication" (12-280-403(1)(f), C.R.S.) and to consider the clinical value to practitioners or pharmacies of collecting this diagnostic information as well as the analytical value for PDMP administration and public health researchers.

Task #2: Analyze the Appropriateness of Implementing New or Additional Unsolicited Reports or Clinical Alerts for Prescribers and Pharmacies

12-280-404(8), C.R.S. requires the Board of Pharmacy to consult with the Colorado's prescribing boards to "develop criteria for indicators of misuse, abuse, and diversion of controlled substances and, based on those criteria, provide unsolicited reports of dispensed controlled substances to prescribing practitioners and dispensing pharmacies for purposes of education and intervention to prevent and reduce occurrences of controlled substance misuse, abuse, and diversion." Currently, the Colorado PDMP sends unsolicited reports to prescribers and pharmacies that prescribed or dispensed prescriptions to patients who meet the Board's confidential multiple provider and multiple pharmacy threshold. I ask the Task Force to evaluate whether additional unsolicited reports for other criteria should be implemented with respect to the potential clinical benefits for practitioners and pharmacies, potential "alert fatigue" concomitant with high volumes of alerts, and the risks of additional alerts potentially impeding the appropriate utilization of these medications for legitimate medical purposes.

Task #3: Provide an Analysis of Cost for the Future State of the Technical Architecture of the Colorado PDMP

Evaluate the costs and benefits of various integration models as they relate to the preferences of Colorado stakeholders, the goals of Colorado's Health IT Roadmap, and the needs of end users. Additionally, analyze how each integration model has the ability to reduce healthcare costs in Colorado. How can the PDMP best achieve the objectives of integration usability and healthcare cost savings within the broader goals of Colorado's Health IT Roadmap?

Sincerely,

Ronne Hines
Director
Division of Professions and Occupations
Colorado Department of Regulatory Agencies

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

PDMP Work Group Roster (current as of 5/17/21) Page 1 of 4		
Name/Date Joined	**Organization**	**Email**
Hoppe, Jason, DO (Co-chair)	University of Colorado	jason.hoppe@ucdenver.edu
Dmitry Kunin (Co-chair)	DORA Board of Pharmacy	Dmitry.kunin@state.co.us
Payne, Tyler (Program Manager)	PDMP Work Group	Tyler.payne@cuanschutz.edu
Acre, Callie (4/2/21)	Regis University	calliecacre@icloud.com
Archuleta, Dan (9/8/20)	Southern Colorado Harm Reduction Association	danoruns@gmail.com
Aubert, Justin, CPHIT, CPEHR	CFO, Quality Health Network	jaubert@qualityhealthnetwork.org
Baldessari, Kelly (11/28/17)	SurgOne, PC	kbaldessari@surgone.com
Belford, Kerry (4/28/21)	HardBeauty	kerry@hardbeauty.life
Batchelder, Krista (6/29/19)	Attorney General's Office	Krista.Batchelder@coag.gov
Bergfalk, KJ (9/8/20)	Southern Colorado Harm Reduction Association	Kj.bergfalk@socoharmreduction.org
Bemski, Julie, MD (1/31/18)	St. Josephs Hospital	jbemski@gmail.com
Bernier, Benjamin, RN	Children's Hospital	benjaminben.bernier@childrenscolorado.org
Bhutani, Aminta (8/13/20)	DEA	DenverDiversionOutreach@usdoj.gov
Biehle, Ryan	Colorado Academy of Family Physicians	ryan@coloradoafp.org
Bonaguidi, Angela (4/20/18)	UC Denver Addiction Research & Treatment Services	Angela.bonaguidi@ucdenver.edu
Borgelt, Laura	University of Colorado School of Pharmacy	laura.borgelt@ucdenver.edu
Brasselero, Scott (12/19/18)	Crossroads Turning Points	sbrasselero@crossroadstp.org
Brooks, Marta J. PharmD	Rueckert-Hartman College for Health Professions	mbrooks008@regis.edu
Brown, Mary	Retired from Quality Health Network	marytaylorbrown@gmail.com
Brydon, Katie (6/10/19)	Road to Recovery	Kate.brydon@gmail.com
Canon, Megan (7/20/20)	CDPHE	Megan.canon@state.co.us
Casey, Alice	Pickens Technical College	amcasey@aps.k12.co.us
Chang, Soojin, PharmD Cand. (1/24/18)	UC Denver School of Pharmacy	Soojin.chang@ucdenver.edu
Clapp, Jonathan, MD	Physician Pain Consultants, L.L.C.	jclappmd@gmail.com
Cooke, Arlene (9/18/20)	Otero/Crowley Public Health Department	acooke@oterogov.org
Cooper, Susanna	CCPDAP Program Manager	Susanna.cooper@ucdenver.edu
Davidson, Michael	CCPDAP Communications Professional	michael.davidson@ucdenver.edu
DeHerrera-Smith, Dayna (1/14/19)	Front Range Clinic	ddeherrera@frontrangeclinic.com
De la Cerda, Dionisia	UC Denver Department of	Dionisia.delacerda@ucdenver.edu

(12/19/18)	Family Medicine	
Denberg, Tom, MD	Pinnacol	tom.denberg@pinnacol.com
Eaddy, Jessica	CCPDAP External Relations Strategist	Jessica.eaddy@ucdenver.edu
Esquibel, Jose	CCPDAP Associate Director	Jose.A.Esquibel@cuanschutz.edu
Feld, Jamie	CCPDAP External Relations Strategist	Jamie.feld@ucdenver.edu
Ferries, Erin, PhD, MPH	Humana	eferries@humana.com
Fischer, Matthew (7/16/20)	Colorado Health Network	Matthew.fischer@coloradohealthnetwork.org
Flores, Roland, MD	University of Colorado School of Medicine	roland.flores@ucdenver.edu
Gabella, Barbara	CDPHE	info@corxconsortium.org
Gauna, Danielle (4/4/18)	Opioid Advisory Group BOCO	Danielle.gauna@gmail.com
Goodman, Amy Berenbaum, JD, MBE (1/17/19)	Colorado Medical Society	Amy_goodman@cms.org
Gorman, Fran	RN	frann63@gmail.com
Grace, Elizabeth S., MD	Center for Personalized Education for Physicians	esgrace@cpepdoc.org
Guerrero, Andres	CDPHE Prescription Drug Overdose Unit	andres.guerrero@state.co.us
Hanson, Greg	Walgreens	gregory.hanson@walgreens.com
Hara, Cheryl	Center for Personalized Education for Physicians	chara@cpepdoc.org
Harden, Michelle, Esq.	Messner Reeves, LLP	mharden@messner.com
Harris, Helen	Epidemiologist, El Paso County Public Health	HelenHarris@elpasoco.com
Harrison, J.M.	MD	JMHarrisonMD@gmail.com
Hart, Krystle (3/21/19)	Registered Nurse	Khart1217@gmail.com
Hemler, Douglas, MD	Colorado Medical Society	dehmd@comcast.net
Higgins, P.J. (1/22/20)	Community Health Partnership	Pj.higgins@ppchp.org
Hill, Kyle Dijon (3/5/18)	Helping End the Opioid Epidemic (HEOE)	Kdijon1587@gmail.com
Hogue, Adina (1/6/20)	Community Member	adinahogue@gmail.com
Howlett, Corinne (5/7/21)	School of Pharmacy	Corinne.howlett@cuanschutz.edu
Iwanicki, Janetta	Rocky Mountain Poison and Drug Center	janetta.iwanicki@rmpdc.org
Jackson, Pam (6/29/19)	Retired, Attorney General's Office	jacksonpammmd@msn.com
Jenkins, Tom (2/12/18)	Western Colorado Health Network	Tom.jenkins@coloradohealthnetwork.org
Kato, Lindsey	CDC National Opioid Response Strategy	Lindsey.kato@ucdenver.edu
Keane, Ashli (9/1/20)	Gusto	Akeane0126@yahoo.com
Koons, Mike	Pinnacol Assurance	Mike.koons@pinnacol.com

Krische, Elizabeth (2/19/21)	A Way Forward	Liz.krische@gmail.com
Kunin, Dmitry (6/10/19)	DORA	Dmitry.kunin@state.co.us
Larson, Carly (6/10/19)	Rocky Mountain Crisis Partners	carlyl@rmcrisispartners.org
Leach, Kara	M.D.	karaleach@gmail.com
Li, Qing	Epidemiologist	Qing.li@mail.sdsu.edu
McBurney, Christa, RN (10/5/18)	UC Health	christaMcBurney@gmail.com
McCarty, Craig, MD	Haxtun Hospital District	awmphd@yahoo.com
Meury, Kathleen (5/17/21)	Community Member	Meury4@hotmail.com
Mihok, Kristi	Walgreens	kristi.mihok@walgreens.com
Moulton, Kara (1/6/19)	Centennial Mental Health Center	karamo@centennialmhc.org
Mulvihill, Sharon (1/12/19)	Riverstone Health	Sharon.mul@riverstonehealth.org
Murphy, Paul (7/10/20)	Office of e Innovation	Pmurphy5280@gmail.com
Nickels, Sarah	Childrens Hospital Colorado	Sarah.nickels@childrenscolorado.org
O'Keefe, Julie	Pharmacist	Julieokeefe4@gmail.com
Olberding, Gina	CCPDAP Assistant Director	gina.olberding@ucdenver.edu
Patel, Nashel	Pharmacy Student	nashel.patel@ucdenver.edu
Patterson, Kevin, DDS, MD (10/14/18)	Metropolitan Denver Dental Society, CDA	drp@dmoms.com
Paykoc, Carrie	Governor's Office of eHealth Innovation	carrie.paykoc@state.co.us
Pellegrino, Robyn, RN (12/4/17)	RN Manager	Robyn.pellegrino@hotmail.com
Perry, Robert	M.D.	robert.perry@ucdenver.edu
Place, Jen (5/2018)	CCPDAP Program Manager	Jennifer.place@ucdenver.edu
Prieto, Jose Tomas	Denver Health	JoseTomas.Prieto@dhha.org
Primavera, Dianne	Lt. Governor	dianne.primavera@state.co.us
Proffitt, Alexandra, RN (5/16/18)	Centura	Blayr5@aol.com
Ptak, Amber (11/14/19)	Community Health Partnership	amber.ptak@ppchp.org
Ramzy, Nagy	Pharmacist, Retired	NagyRamzy@gmail.com
Reid, Ashley	Childrens Hospital	Ashley.reid@childrenscolorado.org
Ricards, Luke (2/1/18)	Cordant Health Solutions	lricards@cordanths.com
Riebel, Lynda	Community Member	303elle@gmail.com
Robbins, Emily RN (4/28/18)	UC Health	esdanner@gmail.com
Rorke, Marion, MPH	Denver Environmental Health	marion.rorke@denvergov.org
Rosenthal, Allison	CDPHE	Allison.rosenthal@state.co.us
Ryan, Courtnay (12/9/19)	Telligen	cryan@telligen.com
Schreiber, Terri	The Schreiber Research Group	terri@tsrg.org

Bonnie Sihler (8/26/20)	Valley View Hospital	bsihler@hotmail.com
Simbeye, Lindsey (1/21/20)	CCPDAP External Relations Strategist	Lindsey.simbeye@cuanschutz.edu
Sisson, C.B., MD (1/10/18)	Colorado Clinic	cbsisson@coloradoclinic.com
Solano, Judy, RN	CCPDAP External Relations Strategist	Judy.Solano@ucdenver.edu
Sonn, Edie	Pinnacol Assurance	edie.sonn@pinnacol.com
Stewart, Stephanie	UC Denver	Stephanie.stewart@ucdenver.edu
Sullivan, Katie (5/7/21)	CDPHE	Katherine.sullivan@state.co.us
Swan, Sarah E.	State Govt. Affairs, Bristol Myers Squibb	sarah.ehrlich@bms.org
Thomas, Andrea Y. (4/29/19)	Voices for Awareness Foundation	andrea@voicesforawareness.com
Tiernan, Shane (4/4/18)	L.A. Healthcare	sotiernan@gmail.com
Tuetken, Tiffany	Cordant Health Solutions	ttuetken@cordanths.com
Turtle, John, PharmD	Pharmacist	johnjturtle@gmail.com
Valuck, Robert, PhD	Center Director	robert.valuck@ucdenver.edu
Vanderveen, Kevin, MD	Kaiser Permanente of Colorado	Kevin.R.Vanderveen@kp.org
Veeneman, Hayes	Community Member	hhvehvcmv@gmail.com
Wall, Lawrence	Wall Consulting	lswalljr@yahoo.com
Weir, Mike (7/10/20)	Office of e Innovation	Mike.weir@state.co.us
White, LeeAnn (11//9/18)	Telligen	lwhite@telligen.com
Wipf, Justin	DORA	Justin.wipf@state.co.us
Wolf, Katie	Wolf Public Affairs	katie@wolfpublicaffairs.com
Ziegler, Katie (2/14/20)	CDPHE	Katie.ziegler@state.co.us
Zimdars-Orthman, Marjorie	Community Member	Zorthman1@gmail.com