Report of the Department of Health Professions

2021 Annual Report
Virginia Prescription Monitoring Program

To the Joint Commission on Health Care, pursuant to *Code of Virginia* § 54.1-2523.1.

To the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health, pursuant to Chapters 113 and 406 Enactment Clause 3 (Regular Session, 2016).

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Preface

The following report meets two legislative requirements. First, per Enactment Clause 3 of Chapters 113 and 406 (Regular Session, 2016), the Prescription Monitoring Program (PMP) was directed to report on utilization of the PMP by prescribers and dispensers to include any impact on the prescribing of opioids. Additionally, *Code of Virginia* § 54.1-2523.1 specifies as follows:

> The Director shall develop, in consultation with an advisory panel which shall include representatives of the Boards of Medicine and Pharmacy, the Department of Health, the Department of Medical Assistance Services, and the Department of Behavioral Health and Developmental Services, criteria for indicators of unusual patterns of prescribing or dispensing of covered substances by prescribers or dispensers and misuse of covered substances by recipients and a method for analysis of data collected by the Prescription Monitoring Program using the criteria for indicators of misuse to identify unusual patterns of prescribing or dispensing of covered substances by individual prescribers or dispensers or potential misuse of a covered substance by a recipient. *The Director, in consultation with the panel, shall annually review controlled substance prescribing and dispensing patterns and shall (i) make any necessary changes to the criteria for unusual patterns of prescribing and dispensing required by this subsection and (ii) report any findings and recommendations for best practices to the Joint Commission on Health Care by November 1 of each year.*

In addition to meeting requirements set forth legislatively, the 2021 Annual Report provides a review of Virginia's PMP activities and an analysis of prescription data collected.

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Executive Summary

The Virginia Prescription Monitoring Program (PMP) is a statewide electronic database containing information on dispensed Schedule II-V prescriptions, naloxone, and cannabis dispensed from an in state pharmaceutical processor. The primary purpose of the PMP is to promote safe prescribing and dispensing practices for covered substances by providing timely and essential information to healthcare providers. Both the *Code of Virginia* (§54.1-25.2) and Virginia Administrative Code (18VAC76-20) contain laws and regulations applicable to the PMP.

In addition to the utility for healthcare providers, the data collected can be useful in identifying unusual patterns of prescribing and dispensing for review by the applicable regulatory board. Investigative findings by regulatory boards and analysis methodologies are regularly reviewed and refined. Notably, 14% of cases initiated through this process resulted in a violation; by comparison, only 8% of complaint-driven cases involving patient care resulted in a violation. The section entitled *Identifying unusual patterns of prescribing and dispensing*, beginning on page 7, describes this process and case findings in depth.

The disruption to the healthcare system caused by Covid-19 also impacted observed trends in dispensations reported and PMP use. The most pronounced changes occurred abruptly in the early months of the pandemic but quickly reverted and continues to follow expected trends. More specifically, following continuous increases over the last several years, quarterly requests to the PMP declined for the first time in 2020Q2 but quickly rebounded and continue to rise.

Notable findings in the 2021 Annual Report

- A central utility of the PMP is to monitor a patient's use of multiple prescribers and pharmacies in acquiring controlled substances. Multiple provider episodes, defined as five or more prescribers and five or more pharmacies in a six-month period, has decreased markedly in the last several years. In early 2018 the rate was 10.6 per 100,000 residents and as of mid-2021 was 2.0 per 100,000 residents.
- *Regulations Governing Prescribing of Opioids and Buprenorphine* (18VAC85-21-10), promulgated by the Board of Medicine, became effective in March 2017 and imposed limits on prescribing buprenorphine without naloxone (mono-product) for opioid use disorder due to the potential for misuse and abuse. Since that time, mono-product buprenorphine prescriptions declined by two-thirds (66%).
- Pursuant to *Code of Virginia* § 54.1-3408.02, any prescription containing an opioid must be transmitted electronically (e-prescribed) from the prescriber to the dispenser. Within one-year of the law taking effect in July 2020, 86% of opioids were e-prescribed.

Initiatives and accomplishments

Integration and Interoperability

Virginia's PMP is integrated with most electronic health records (EHR) and all major pharmacy management systems (PMS) to display PMP information within the clinical workflow. Both interoperability with other PMPs nationally and integration within the EHR/PMS have contributed positively to the marked increase in overall database utilization as measured by requests for a patient's prescription history. Prescribers and dispensers at approximately 5,000 facilities statewide are currently accessing PMP within the clinical workflow, including all Veterans Health Administration facilities. Prescription data from 40 jurisdictions and the Department of Defense's Military Health System is available to Virginia PMP users.

Virginia's PMP also conducted an email marketing campaign to increase uptake of integration among practitioners not currently integrated. As result of the campaign, requests to integrate with PMP rose exponentially and three-quarters were directly attributable to the emails. Prescriber penetration, defined as prescribers accessing PMP via integrated EHR as a percent of total prescribers actively prescribing controlled substances, is a key metric by which to monitor integration uptake. Similarly, prescriber penetration rose by almost 3% to 62%.

Integrating PMP Data into Emergency Departments

The 2017 General Assembly (HB2209) established the Emergency Department Care Coordination (EDCC) program in the Department of Health to provide a single, statewide technology solution to connect all hospital emergency departments and facilitate real-time communication and collaboration to improve the quality of patient care. Covered substance prescribing and dispensing collected by the PMP must be automatically delivered within the clinical workflow to meet program requirements. A ribbon in the EDCC program's platform, EDie, displays four three-digit scores assessing risk for misuse of controlled substances based on a patient's two-year prescription history. These risk assessment algorithms, with scores ranging from 0-999, are an additional tool for practitioners in the ED to inform treatment decisions.

Utilization of the PMP database

Authorized users of the PMP are able to search within the database for a patient's prescription history; each search is referred to as a request. There are three types of requests: NarxCare, interoperability (PMPi), and integration (Gateway). NarxCare requests are those that are submitted via the web-based application. PMPi facilitates interoperability and interstate data sharing among states' PMPs. Gateway integrates PMP data into electronic health records (EHR) and pharmacy management systems (PMS) and is viewable within the clinical workflow. Integration within the workflow is a significant advancement in ease of use and efficiency and has contributed positively to overall utilization.

PMP use by prescribers, pharmacists, and their delegates as a risk management tool continues to increase in support of safer prescribing. Requests for a patient's prescription history have grown exponentially in recent years (Fig. 1). This rapid rise in use of the PMP is primarily the result of expansions in integration within the EHR/PMS. Virginia PMP was an early adopter of integration; the recent increases in out of state Gateway requests are reflective of other jurisdictions implementing integration and the tremendous impact that ease of use has on overall usage (Fig. 2). Concurrent with increases in integration requests, use of the web application (NarxCare) has declined.

The disruption to the healthcare system as a result of Covid-19 is evident in PMP usage. Following continuous increases, requests declined for the first time in 2020Q2 but quickly rebounded (Fig. 2).

Figure 1. Prescription history requests, 2012-2021

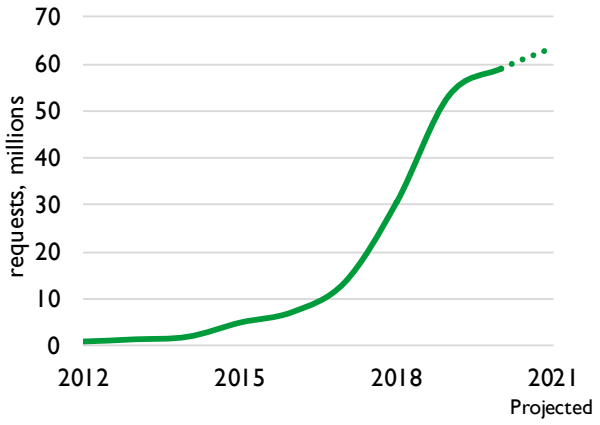

Fig. 1. Requests for a patient's prescription history increased 69x over nine years

Figure 2. Prescription history requests by type, January 2020-June 2021

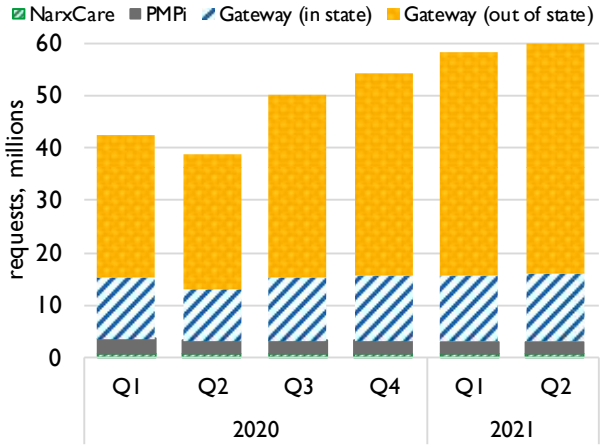

Fig. 2. Volume changes in requests by type: NarxCare, -13%; PMPi, -16%; Gateway (in state), 12%; Gateway (out of state), 63%

Interoperability allows users of Virginia's PMP to access a patient's prescription history from 38 other states, the District of Columbia, Puerto Rico, and the Military Health System (Fig. 3).

Figure 3. Virginia PMP interoperability, October 2021

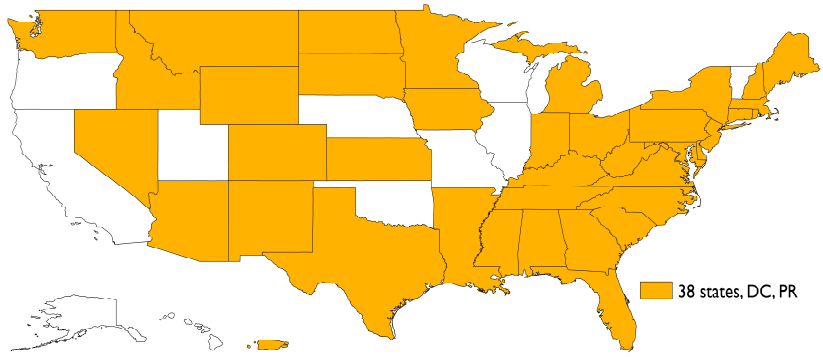

Fig. 3. Interoperable with 38 states, District of Columbia, Puerto Rico, and Military Health System

Impact on prescribing

As requests for a patient's prescription history have increased markedly in recent years, prescribing for opioids has decreased. Morphine milligram equivalent (MME) is a way to calculate the relative potency of opioids and account for differences in opioid drug type and strength. As MME increases, overdose risk increases. The *Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain*, published in March 2016, recommends that clinicians carefully consider increasing daily dosage to 50 MME or greater and to avoid dosages of 90 MME per day or greater due to risk for fatal overdose.[1] Further, Virginia imposes specific requirements on practitioners when prescribing daily dosages exceeding 50 and 120 MME thresholds (18VAC85-21-10, effective March 2017).

Between 2015 and 2020, daily MME per prescription decreased precipitously. Specifically, prescriptions for daily dosages of 50 to 90 MME (≥50 to <90) decreased by 59% from 11.8 to 4.8 per 100 Virginians and prescriptions for 90 to 120 MME (≥90 to <120) per day declined by 54% from 3.6 to 1.7 per 100 Virginians (Fig. 4). However, the greatest decrease—61%—was in prescriptions for daily dosages 120 MME or greater (≥120) from 5.7 to 2.2 per 100 Virginians.

Figure 4. Prescription history requests and opioid daily dosage by prescription, 2015-2020

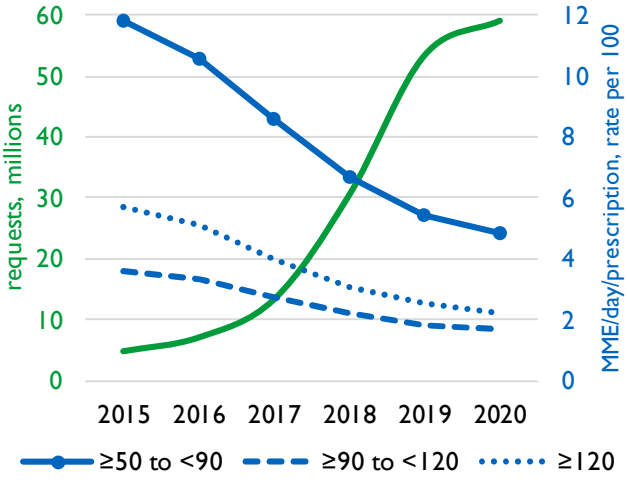

Fig. 4. Requests for a patient's prescription history increased 12x (solid green); percent change in rate of daily MME per prescription: ≥50 to <90, -59% (round marker blue); ≥90 to <120, -54% (dashed blue); ≥120, -61% (dotted blue)

Dispensing of covered substances

Medications dispensed by drug class

Opioid, benzodiazepine, stimulant, gabapentinoid, and nonbenzodiazepine sedative hypnotics represent over 90% of all dispensations reported to PMP. Stimulants are often prescribed to treat attention-deficit hyperactivity disorder (ADHD). The gabapentinoid class includes gabapentin and pregabalin (Lyrica®). Sleeping medications, such as zolpidem, are classified as nonbenzodiazepine sedative hypnotics. Prescriptions dispensed for opioids decreased by 10% with the most pronounced change between 2020Q1 and 2020Q2 at the beginning of the Covid-19 pandemic (Fig. 5). Benzodiazepine and nonbenzodiazepine sedative hypnotic prescriptions each decreased by 6% and stimulants decreased by 1%. Only prescriptions for gabapentinoids increased (4%).

Figure 5. Prescriptions dispensed by drug class, January 2020-June 2021

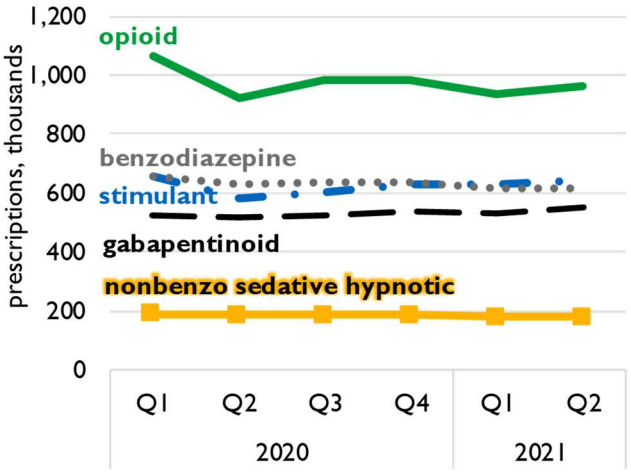

Fig. 5. Percent change by drug class: opioid, -10% (solid green); benzodiazepine, -6% (dotted gray); stimulant, -1% (dash-dot blue); gabapentinoid, 4% (dashed black); nonbenzo sedative hypnotic, -6% (square marker yellow)

Buprenorphine for opioid use disorder

Buprenorphine is an evidence-based treatment for opioid use disorder (OUD). By alleviating withdrawal symptoms, reducing opioid cravings, and decreasing the response to further drug use, patients treated with buprenorphine are less likely to return to misusing opioids and risking fatal overdose.[2] While increasing numbers of buprenorphine prescriptions in general indicates increased treatment usage (24% increase since early 2017), buprenorphine without naloxone (mono-product) is more likely to be abused than buprenorphine bound to naloxone. *Regulations Governing Prescribing of Opioids and Buprenorphine* (18VAC85-21-10), promulgated by the Board of Medicine and effective March 2017, imposed a limit on mono-product prescribing. An immediate decline in mono-product prescribing occurred between the first and second quarters of 2017 as a result and continues to decrease marginally (Fig. 6). The overall decline of two-thirds (66%) in mono-product buprenorphine prescriptions as of June 2021 is indicative of progress toward improved prescribing practices.

Figure 6. Buprenorphine prescribing for OUD, January 2017-June 2021

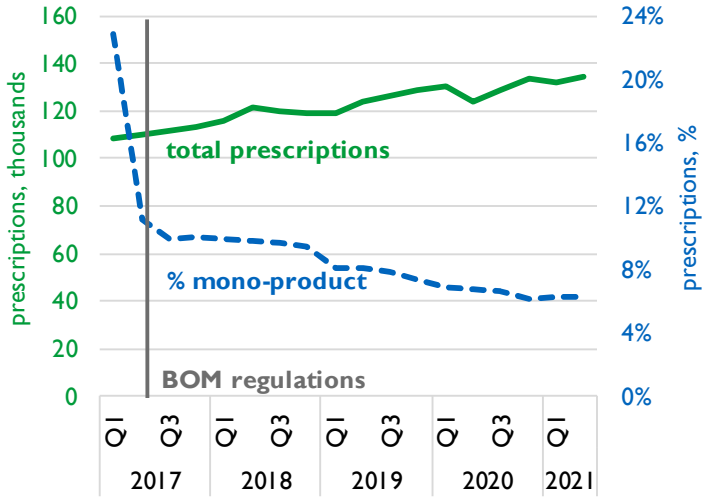

Fig. 6. Total buprenorphine prescriptions for OUD increased 24% (solid green); percentage of buprenorphine prescriptions for mono-product decreased from 23% to 6% (dashed blue); date Board of Medicine regulations promulgated (solid gray, March 2017)

Opioids

Prescription opioids are often used to treat acute and chronic pain and, when used appropriately, can be an important component of treatment. [3] However, there are serious risks associated with their use including misuse, opioid use disorder (addiction), overdoses, and death. Fewer prescriptions for fewer days and at lower dosages is indicative of progress toward safer prescribing.

Among Virginians receiving opioid prescriptions, the quarterly percentage of patients with an average dose at or above 90 MME per day remained stable (6%). However, MME per prescription decreased 4% between January 2020 and June 2021. Each opioid prescription provided an average of 16 days supply of medication. Frequency of multiple provider episodes, defined as a recipient obtaining opioids from a minimum of five prescribers and five dispensers within a six-month time period, decreased from 5.5 to 2.0 per 100,000 residents throughout the 18-month period. Overlapping opioid prescriptions, which increase a patient's daily MME, and concurrent opioid and benzodiazepine prescribing both increase the risk of overdose. Between January 2020 and June 2021, both the percentage of days with overlapping opioid prescriptions and overlapping opioid and benzodiazepine prescriptions remained relatively stable at an average of 14%.

In 2020, the number of opioid prescriptions was 39.5 prescriptions per 100 Virginians. According to analyses conducted by the Centers for Disease Control and Prevention (CDC), Virginia was below the United States overall (37.6 per 100 Virginians; 43.3 per 100 Americans).[4] Virginia PMP analyses are not directly comparable those nationally due to differences in data source and methodology.

Opioid dispensing varies geographically across Virginia. Per capita, more potent opioids, as measured by MME, are dispensed in southwest and more rural areas (Fig. 7). Dispensing was highest to patients in Dickenson and lowest in Arlington. The potency of opioids dispensed to

Dickenson residents was almost 17 times higher than in Arlington and nearly five times greater than in Virginia overall.

Figure 7. Opioid dispensing by county, 2020

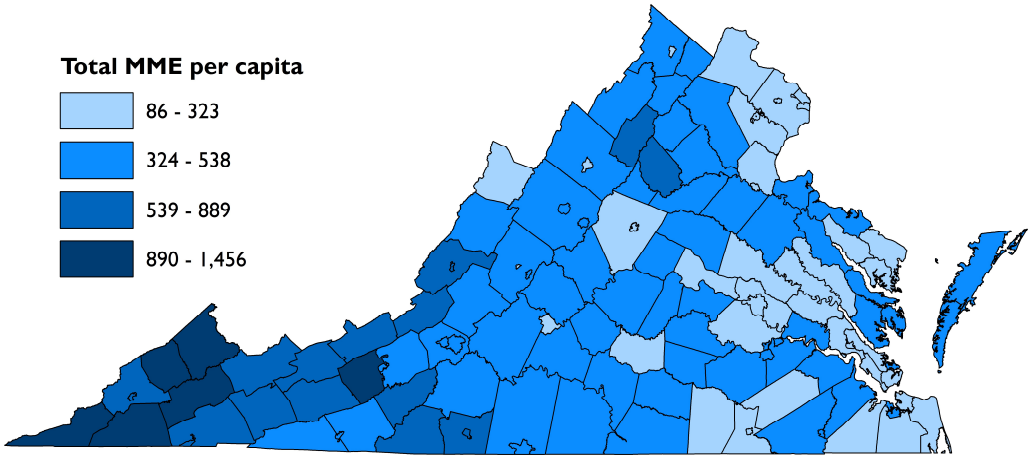

Fig. 7. MME per capita by patient residence

Electronic prescribing

Pursuant to *Code of Virginia* § 54.1-3408.02, any prescription containing an opioid must be transmitted electronically (e-prescribed) from the prescriber to the dispenser. Prior to July 2020 prescriptions for Schedule II controlled substances (opioids, stimulants) could be written (§ 54.1-3410) or electronic. Within a year following the law's effective date, 86% of opioids were e-prescribed (among prescriptions with a mode of transmission reported; Fig. 8).

Figure 8. Opioid prescriptions by transmission type, January 2020-June 2021

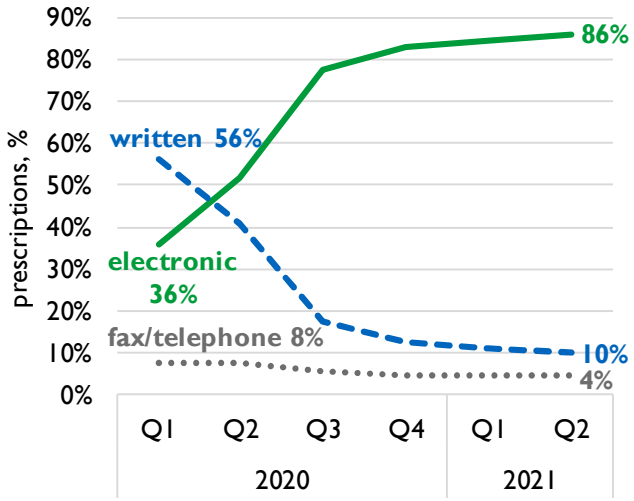

Fig. 8. Opioid prescriptions by transmission: written, decreased from 56% to 10% (dashed blue); fax/telephone, declined minimally from 8% to 4% (dotted gray); electronic, increased 36% to 86% (solid green)

Overdose reversal medications

Naloxone is a medication that rapidly reverses opioid overdose. As an opioid antagonist, naloxone binds to opioid receptors and can block the effects of other opioids. Naloxone can be

administered as a nasal spray or injection and became reportable to PMP on July 1, 2018. *Regulations Governing Prescribing of Opioids and Buprenorphine* (18VAC85-21-10) require a practitioner to prescribe naloxone for patients with a daily opioid dosage of 120 MME or more, concurrent benzodiazepine use, or history of prior overdose or substance misuse must be co-prescribed naloxone.

In November 2016, the State Health Commissioner declared a Public Health Emergency for the opioid epidemic and issued a standing order authorizing pharmacists in Virginia to dispense naloxone. The standing order serves as a prescription written for the general public, rather than specifically for an individual. The pharmacist dispensing naloxone provides counseling to the recipient in opioid overdose prevention, recognition, response, and administration. On average, 7% of all naloxone prescriptions are dispensed under the standing order quarterly (Fig. 9). Naloxone dispensed in pharmacies represents a portion of that distributed in Virginia; naloxone provided by other state agencies and nongovernmental organizations through community education and prevention programs is not reported to the PMP and therefore not included in this report. Among naloxone dispensations, Narcan® represents over 99% of the total.

Figure 9. Naloxone prescriptions dispensed in pharmacies by prescriber, January 2020-June 2021

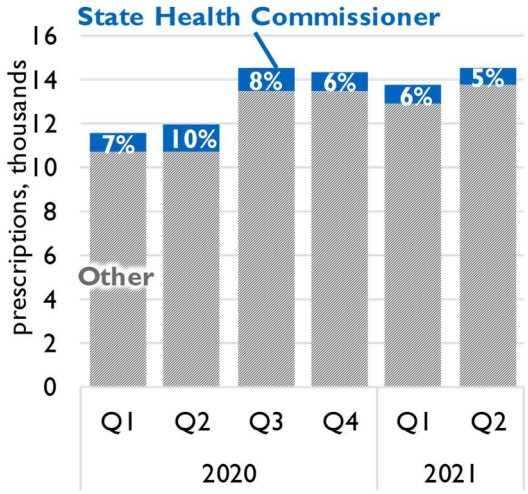

Fig. 9. State Health Commissioner's standing order used for 7% of quarterly prescriptions on average (solid blue); 93% prescribed by another practitioner (striped gray)

Identifying unusual patterns of prescribing and dispensing

Investigative findings by regulatory boards and analysis methodologies are regularly reviewed and, generally, indicators are prioritized for investigation and cases initiated on a quarterly basis. Due to pressure on the healthcare system resulting from Covid-19, this was suspended temporarily in March 2020 and resumed this year.

The following indicators were unanimously approved by the PMP Advisory Panel to identify aberrations:

- Highest ranked
  - prescribers/dispensers of all covered substances by prescription count
  - prescribers of opioids
  - prescribers of opioids with minimal PMP use

  - dispensers of opioids according to distance from patient, prescriber, and pharmacy
  - dispensers based on ratio of Schedule II to all Schedule II-V prescriptions
  - prescribers of ER/LA opioids to opioid naïve patients
  - prescribers of buprenorphine for opioid use disorder (OUD) dosing > 24 mg/day
- Prescribers/dispensers for patients meeting daily MME thresholds
  - One patient at 2,000 MME/day
  - One patient at 1,500 MME/day (prescribers only)
  - 10 patients at 1,000 MME/day (dispensers only)
  - 5 patients at 750 MME/day
  - 25 patients at 500 MME/day

Since receiving statutory authority to disclose PMP data indicative of unusual prescribing and dispensing to the Enforcement Division of DHP in July 2017, the Enforcement Division has conducted 91 reviews and initiated 60 case investigations of prescribers (n=37) and dispensers (n=23; Fig. 10 and 11).

Figure 10. Cases investigated by licensee type and indicator, 2016-September 2021

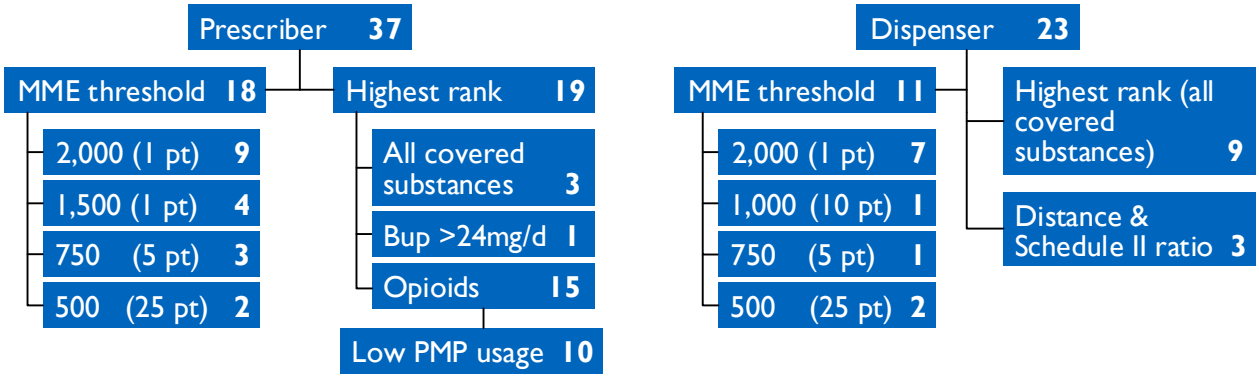

Fig. 10. Prescriber investigations almost equally distributed between MME threshold and highest rank indicators (left); dispenser investigations by indicator: MME threshold, 48%; highest rank, 39%; travel distance and ratio of Schedule II to total II-V prescriptions, 13%

Among the closed PMP-generated cases (n=60), 14% resulted in the finding of a violation and most also received a sanction from the applicable board (Fig. 11). Approximately the same number were issued an advisory letter (21%), pursuant to § 54.1-2400, or closed as undetermined (25%). Cases with an undetermined final disposition are those for which the relevant board concluded disciplinary proceedings would not be instituted at present but retain the ability to do so in the future. Only three cases continue to be active.

Figure 11. Findings of unusual prescribing and dispensing investigations, 2016-September 2021

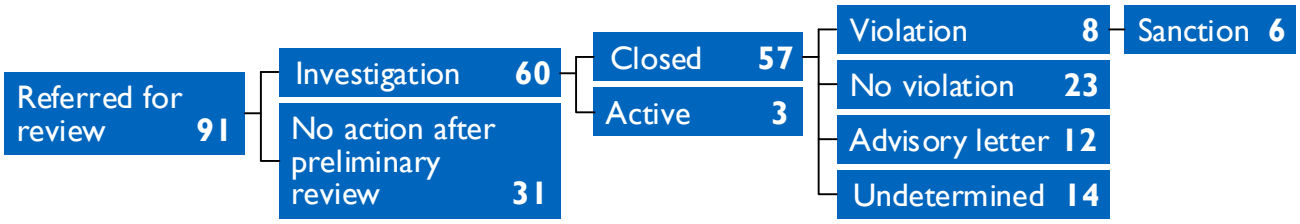

Fig. 11. 66% of prescribers/dispensers reviewed resulted in an investigation; 95% of investigations initiated were closed as of September 2021 with the following final dispositions: violation, 14%; no violation, 40%; advisory letter, 21%; undetermined, 25%

Conclusion

Virginia's PMP, interoperable with 41 other jurisdictions and integrated into the workflow of most prescribers and dispensers in the commonwealth, is an important tool in our state's response to the opioid epidemic. Data on patterns of controlled substance dispensing and database utilization can provide powerful insights on the impacts of federal and state policy changes and guide further action in stemming this public health crisis.

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[1] Dowell D, Haegerich TM, Chou R. *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*. MMWR Recomm Rep 2016;65(No. RR-1):1–49. Accessed September 30, 2019 from http://dx.doi.org/10.15585/mmwr.rr6501e1

[2] National Academies of Sciences, Engineering, and Medicine. 2019. *Medications for opioid use disorder save lives*. Washington, DC: The National Academies Press. Accessed September 30, 2019 from https://doi.org/10.17226/25310

[3] Buprenorphine used to treat opioid use disorder or addiction is excluded.

[4] Centers for Disease Control and Prevention. *U.S. State Opioid Dispensing Rate Maps*. National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. Accessed October 12, 2021 from https://www.cdc.gov/drugoverdose/rxrate-maps/state2020.html