COMMONWEALTH of VIRGINIA

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December 19, 2019

Michele L. Chesser, Ph.D.
Executive Director
Joint Commission on Health Care
600 East Main Street, Suite 301
Richmond, Virginia 23219

Dear Dr. Chesser:

Pursuant to the provisions of the *Code of Virginia* Title 54.1 Chapter 25.2, I have the honor of submitting herewith the Prescription Monitoring Program's 2019 Annual Report.

This report includes a summary of significant initiatives, trends in covered substance prescribing, and utilization by prescribers, pharmacists, and their delegates of the Prescription Monitoring Program (PMP) database. Additionally, a review of efforts to identify, in consultation with the PMP Advisory Panel, and respond to unusual patterns of prescribing or dispensing of covered substances is included. Since receiving statutory authority to disclose PMP data indicative of unusual prescribing and dispensing to the Enforcement Division of DHP in 2016, 59 case investigations of prescribers and dispensers have been conducted and a summary of the licensing boards' findings is enclosed.

Please do not hesitate to contact me with any questions. I am available to provide additional information upon request.

Respectfully submitted,

Ralph Orr
Director
Prescription Monitoring Program

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December 19, 2019

Senator Stephen D. Newman
Chair, Senate Committee on Education and Health
Delegate Robert D. Orrock, Sr.
Chair, House Committee on Health, Welfare, and Institutions
Virginia General Assembly
900 East Main Street
Richmond, Virginia 23219

Dear Senator Newman and Delegate Orrock:

Pursuant to the provisions of Enactment Clause 3 of Chapters 113 and 406 (Regular Session, 2016), I have the honor of submitting herewith the Prescription Monitoring Program's 2019 Annual Report.

This report includes analyses on trends in prescribing of opioids and utilization of the Prescription Monitoring Program (PMP) database by prescribers, dispensers, and their delegates. Additionally, a summary of significant initiatives, trends in prescribing of other covered substances, and a review of efforts to identify and respond to unusual patterns of prescribing or dispensing is enclosed

Please do not hesitate to contact me with any questions. I am available to provide additional information upon request.

Respectfully submitted,

Ralph Orr
Director
Prescription Monitoring Program

Report of the Department of Health Professions

2019 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).

Report Document No. RD 702
Commonwealth of Virginia
November 1, 2019

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.

A description of these indicators and case findings is provided to that end.

In addition to meeting requirements set forth legislatively, the 2019 Annual Report provides a review of Virginia's PMP activities and an analysis of prescription data collected.

Prescription Monitoring Program, Virginia Department of Health Professions

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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, drugs of concern, and cannabidiol or THC-A oils 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. Approximately one million prescriptions are reported to PMP monthly and developing specific, meaningful criteria to detect aberrant behavior is challenging. Consequently, investigative findings by regulatory boards and analysis methodologies are regularly reviewed and refined. Notably, 13% of cases initiated through this process have been found in a violation; by comparison, only 8% of complaint-driven cases involving patient care were found in violation. The section entitled *Identifying unusual patterns of prescribing and dispensing*, beginning on page 8, describes this process and case findings in depth.

As a result of legislation during the 2019 General Assembly session gabapentin became a Schedule V controlled substance in Virginia on July 1, 2019. This did not result in any operational changes for PMP as gabapentin became reportable as a drug of concern in 2017.

Notable findings in the 2019 Annual Report (analyses based on January 2018-June 2019)

Prescribing of opioids is decreasing with the greatest decrease—46%—in very high-dose prescriptions. Specifically, prescriptions for daily dosages of 120 morphine milligram equivalents or greater decreased from 5.7 to 3.1 per 100 Virginians.

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. There was an immediate decline in mono-product prescriptions that has since stabilized.

Pursuant to *Code of Virginia* § 54.1-3408.02, beginning July 1, 2020 any prescription containing an opioid must be transmitted electronically (e-prescribing) from the prescriber to the dispenser. Although only 19% of opioids were submitted electronically in June 2019, this represents a 61% increase since January 2018.

Utilization of the PMP by prescribers, pharmacists, and their delegates has increased markedly in recent years. As of August 2019, year-to-date prescription history requests surpassed the annual total in 2018.

Initiatives and accomplishments

Last year, the Virginia PMP transitioned to NarxCare. NarxCare provides information on prescriptions, prescribers, and pharmacies with the addition of interactive, visual representations and risk scores. The patient risk scores are based on an algorithm which includes the number of prescribers, pharmacies, opioid daily dosage, and overlapping prescriptions. A higher score indicates a greater likelihood of misuse and risk of unintentional overdose or other adverse events.

In response to prescribers' interests in receiving information from the PMP on their own prescribing history and behavior, the PMP began providing this information directly to all opioid prescribers in April 2017. Each individualized Prescriber Report is created and electronically delivered on a quarterly basis. The report provides information regarding current prescribing volumes, behaviors, PMP use, and a comparison to peers within the same specialty.

Gabapentin became a Schedule V controlled substance in Virginia on July 1, 2019 as a result of HB2557 in the 2019 General Assembly session. Legislation to amend *Code of Virginia* § 54.1-3454 did not necessitate any operational change for the PMP since gabapentin became reportable as a drug of concern in 2017.

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. Work to integrate PMP with the EDCC program's platform, EDie, is ongoing. PMP data is currently integrated within EDie at nine health systems and nearing implementation at another three. At the time of this report, over 50% of ED encounters statewide were at health systems integrated with PMP.

Beyond the EDCC program and the EDie platform, Virginia's PMP and their vendor, Appriss Health, is integrated with numerous electronic health record (EHR) and 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 over 3,600 facilities statewide are currently accessing PMP within the clinical workflow.

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 and, as of August 2019, PMP requests in the current year exceeded the 2018 total. Requests through a Gateway EHR/PMS connection in-state increased twenty-fold by mid-2019 compared to early 2017 (Fig. 2). Additionally, Gateway integration requests by out of state users for Virginia residents' prescription history rose thirteen-fold in the same period.

Figure 1. Prescription history requests, 2012-2019

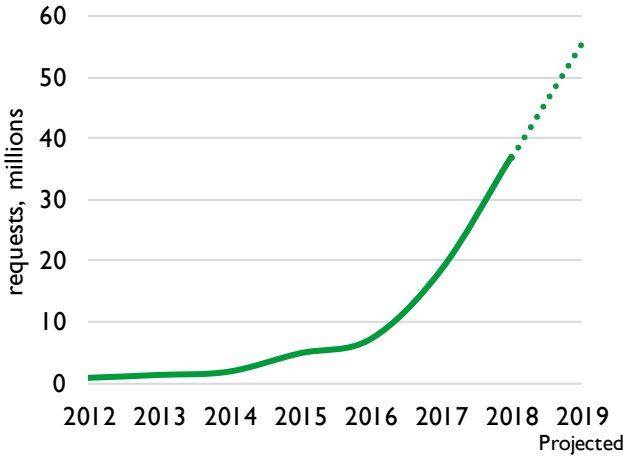

Fig. 1. Requests for a patient's prescription history increased 64x over seven years

Figure 2. Prescription history requests by type, January 2017-June 2019

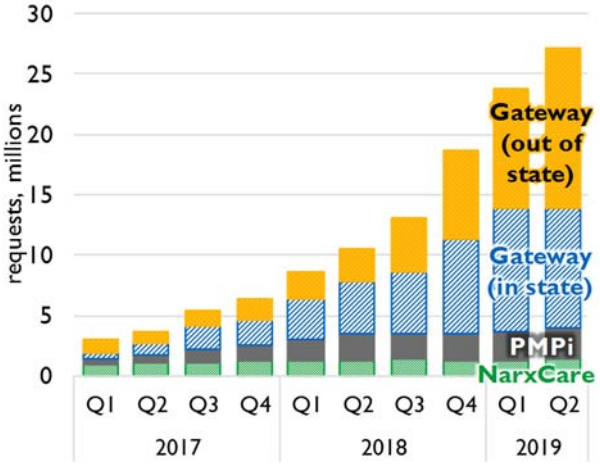

Fig. 2. Volume increase in requests by type: NarxCare, 38%; PMPi, 5x; Gateway (in state), 20x; Gateway (out of state), 13x

Interoperability allows users of Virginia's PMP to access a patient's prescription history from 38 other states, the District of Columbia, and Puerto Rico (Fig. 3). Additionally, in December 2018, the Military Health System PMP became interoperable with Virginia.

Figure 3. Virginia PMP interoperability, October 2019

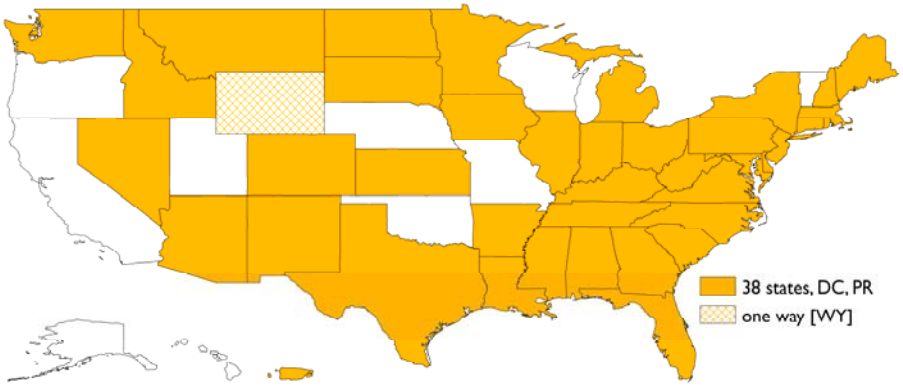

Fig. 3. Interoperable with 38 states, District of Columbia, Puerto Rico, and Military Health System

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 opioid 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 avoid dosages of 90 MME per day or greater due to risk for fatal overdose.[1] Further, Virginia imposes specific requirements of practitioners when prescribing for daily dosages exceeding the 50 and 120 MME thresholds (18VAC85-21-10, effective March 2017).

Between 2015 and 2018, daily MME per prescription decreased precipitously. Specifically, prescriptions for daily dosages of 50 to 90 MME (≥50 to <90) decreased by 43% from 11.8 to 6.7 per 100 Virginians and prescriptions for 90 to 120 MME (≥90 to <120) per day declined by 39% from 3.6 to 2.2 per 100 Virginians (Fig. 4). However, the greatest decrease—46%—was in prescriptions for daily dosages 120 MME or greater (≥120) from 5.7 to 3.1 per 100 Virginians.

Figure 4. Prescription history requests and opioid daily dosage by prescription, 2015-2018

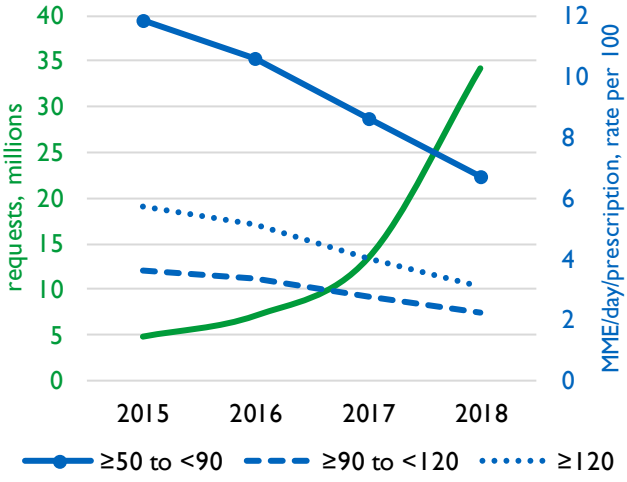

Fig. 4. Requests for a patient's prescription history increased 7x (solid green); percent change in rate of daily MME per prescription: ≥50 to <90, -43% (round marker blue); ≥90 to <120, -39% (dashed blue); ≥120, -46% (dotted blue)

Dispensing of covered substances

Gabapentin is the most frequently dispensed covered substance. The top 10 medications reported to PMP based on quantity of doses dispensed:

1. gabapentin
2. hydrocodone/acetaminophen
3. tramadol
4. dextroamphetamine/amphetamine (Adderall®)
5. alprazolam (Xanax®)
6. oxycodone
7. oxycodone/acetaminophen
8. clonazepam (Klonopin®)
9. lorazepam (Ativan®)
10. zolpidem (Ambien®)

Medications dispensed by drug class

Opioid, benzodiazepine, stimulant, gabapentinoid, and nonbenzodiazepine sedative hypnotics represent 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 and nonbenzodiazepine sedative hypnotics each decreased by 8% while benzodiazepines and stimulants remained relatively stable between January 2018 and June 2019 (Fig. 5). However, prescriptions for gabapentinoids increased by 22% during this time period.

Figure 5. Prescriptions dispensed by drug class, January 2018-June 2019

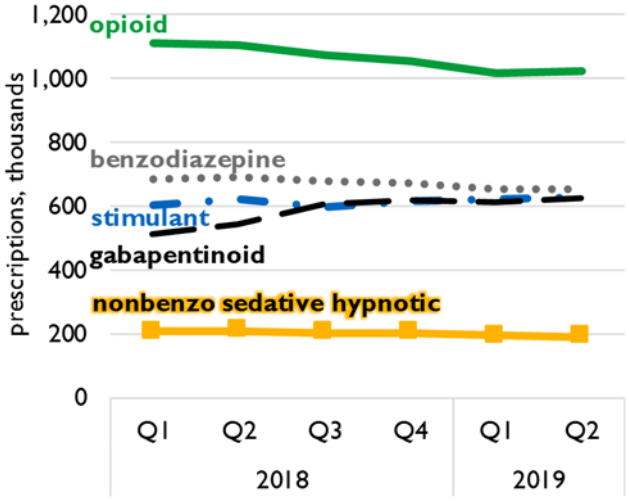

Fig. 5. Percent change by drug class: opioid, -8% (solid green); benzodiazepine, -5% (dotted gray); stimulant, 4% (dash-dot gray); gabapentinoid, 22% (dashed black); nonbenzo sedative hypnotic, -8% (square marker yellow)

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 (15% 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 limits on mono-product prescribing. An immediate decline in mono-product prescribing occurred between the first and second quarters of 2017 as a result but has since stabilized (Fig. 6). The overall decline of 60% in mono-product buprenorphine prescriptions as of June 2019 is indicative of progress toward improved prescribing practices.

Figure 6. Buprenorphine prescribing for OUD, January 2017-June 2019

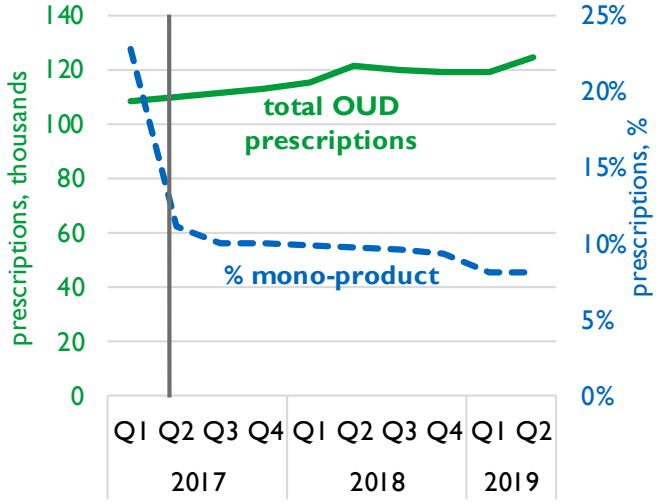

Fig. 6. Total buprenorphine prescriptions for OUD increased 15% (solid green); percentage of buprenorphine prescriptions for mono-product decreased from 23% to 8% (dashed blue); date Board of Medicine regulations promulgated (solid gray, March 2017)

Opioids

Prescription opioids are often used to treat acute and chronic pain and, when used appropriately, can be an important component of treatment. 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. Overall, there was an 18% decrease in the number of opioid doses dispensed between January 2018 and June 2019 (23 million to 19 million).[3] Each opioid prescription provided an average of 17 days' supply of medications. 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, remained constant at an average of 8.5 per 100,000 residents throughout the 18-month period.

An average of 270,000 Virginians per month received an opioid prescription between January 2018 and June 2019 from approximately 27,000 prescribers (Fig. 7). Throughout the 18-month period, there was a 12% reduction in patients receiving prescription opioids and 4% fewer practitioners prescribing. In 2018, the number of opioid prescriptions per capita was 0.5 or 49.3 prescriptions per 100 Virginians. This volume of opioid prescriptions is enough for over half of all Virginians to receive one prescription during the year. In the most recent year for which national data is available, 2017, Virginia was consistent with the United States overall (58.0 per 100 Virginians; 58.5 per 100 Americans).[4]

Figure 7. Opioid prescribers and patient recipients by month, January 2018-June 2019

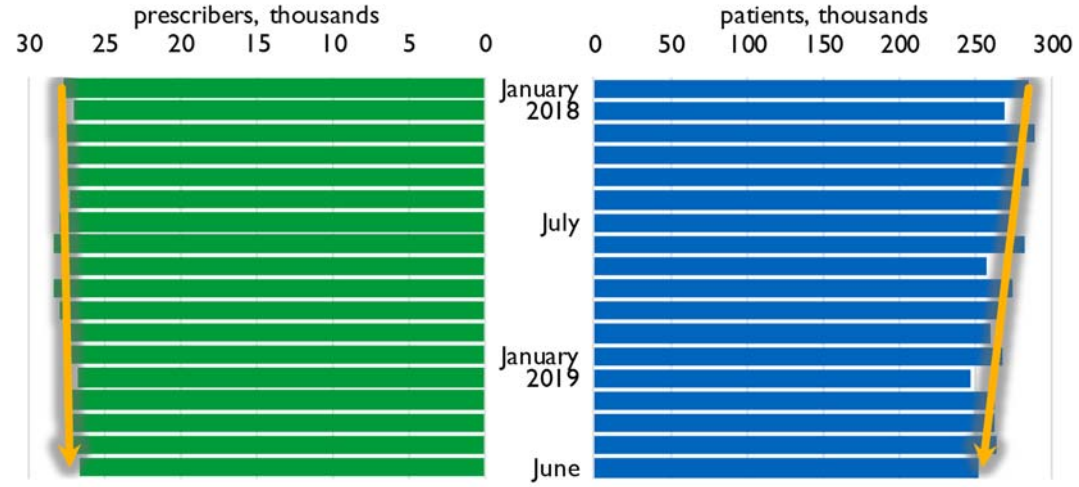

Fig. 7. 4% decrease in prescribers of opioids (left); 12% decrease in patients receiving opioids (right)

The MME per prescription decreased 4% between January 2018 and June 2019. Among Virginians receiving opioid prescriptions, the quarterly percentage of patients with an average dose at or above 90 MME per day remained stable (7%). Overlapping opioid prescriptions, which increase a patient's daily MME, and concurrent opioid and benzodiazepine prescribing both increase the risk of overdose. Between January 2018 and June 2019, the percentage of days with overlapping opioid prescriptions remained relatively stable at an average of 15%. However, the percent of days with overlapping opioid and benzodiazepine prescriptions decreased from 17% to 15%.

Opioid dispensing varies geographically across Virginia. Per capita, opioids are dispensed at greater strengths in southwest and more rural areas (Fig. 8). Dispensing was highest to patients in Dickenson and lowest in Arlington. The amount of opioids dispensed to Dickenson residents was 13 times higher than in Arlington and 4 times greater than in Virginia overall.

Figure 8. Opioid dispensing by county, 2018

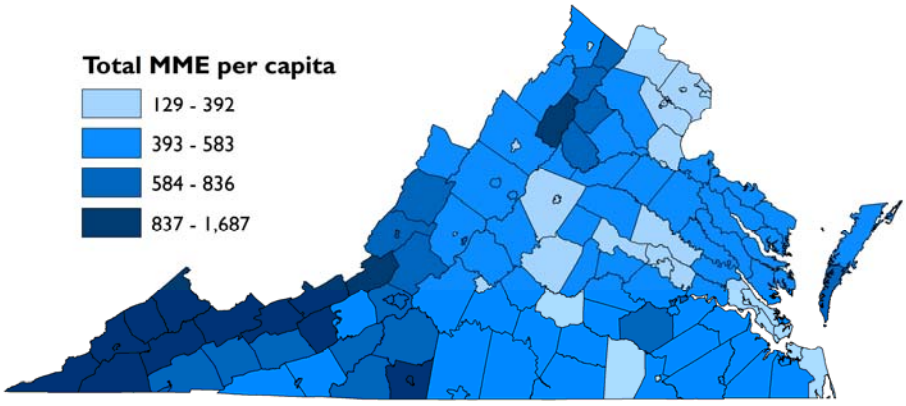

Fig. 8. MME per capita by patient residence

Electronic prescribing

Pursuant to *Code of Virginia* § 54.1-3408.02, beginning July 1, 2020 any prescription containing an opioid must be transmitted electronically (e-prescribing) from the prescriber to the

dispenser. Currently, prescriptions for Schedule II controlled substances (opioids, stimulants) may be written (§ 54.1-3410) or electronic. Although only 19% were electronic in June 2019 (among prescriptions with a mode of transmission reported), this represents a 61% increase since January 2018 (11%; Fig. 9). By comparison, 57% of gabapentin prescriptions were transmitted electronically. Because gabapentin is not classified as a federally controlled substance, the electronic transmission of gabapentin is not subject to the same technological security standards, promulgated by the Drug Enforcement Administration, applicable to opioids.[5] While many practitioners are using e-prescribing, fewer are able to e-prescribe controlled substances.

Figure 9. Opioid prescriptions by transmission type, January 2018-June 2019

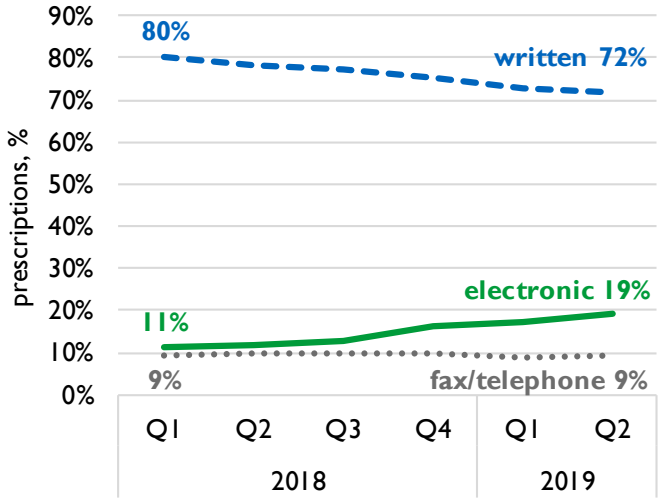

Fig. 9. Opioid prescriptions by transmission: written, decreased from 80% to 72% (dashed blue); fax/telephone, stable at 9% (dotted gray); electronic, increased 11% to 19% (solid green)

Overdose reversal medications

Naloxone is a medication designed to rapidly reverse opioid overdose. As an opioid antagonist, naloxone binds to opioid receptors and can block the effects of other opioids. Very quickly naloxone restores normal respiration to a person whose breathing has slowed or stopped as a result of overdosing with heroin or prescription opioid pain medications. Naloxone is administered as a nasal spray or injection and became reportable to PMP on July 1, 2018. The naloxone nasal spray is available under the brand name Narcan®. *Regulations Governing Prescribing of Opioids and Buprenorphine* (18VAC85-21-10) also require a practitioner to prescribe naloxone for patients receiving an opioid under certain circumstances. Specifically, patients with 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. In essence, 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, 10% of all naloxone prescriptions are dispensed under the standing order quarterly (Fig. 10). 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 included in this report.

Figure 10. Naloxone prescriptions dispensed in pharmacies by prescriber, July 2018-June 2019

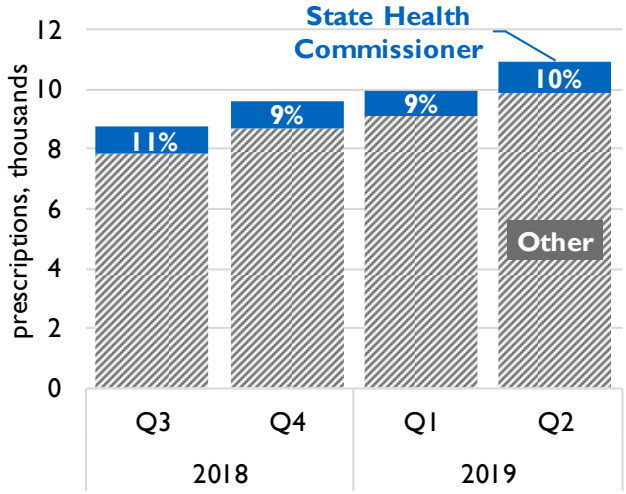

Fig. 10. State Health Commissioner's standing order used for 10% of quarterly prescriptions on average (solid blue); 90% prescribed by another practitioner (striped gray)

Identifying unusual patterns of prescribing and dispensing

Investigative findings by regulatory boards and analysis methodologies are regularly reviewed, and, to that end, the PMP Advisory Panel convened June 12, 2019. Indicators are prioritized for investigation and cases initiated on a quarterly basis. Upon completion of remaining indicators, the panel will reconvene.

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 MAT 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 87 reviews and initiated 59 case investigations of prescribers (n=36) and dispensers (n=23; Fig. 11 and 12).

Figure 11. Cases investigated by licensee type and indicator, 2016-August 2019

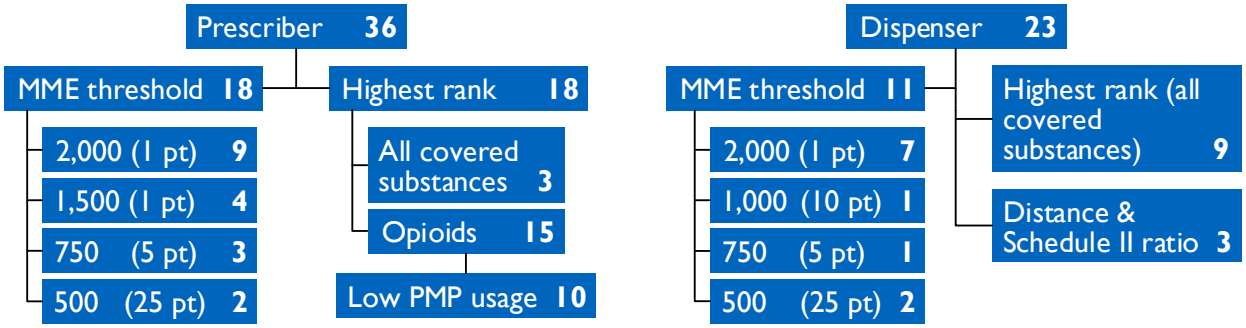

Fig. 11. Prescriber investigations equally distributed between MME threshold and highest rank indicators (left); dispenser investigations by indicator: MME threshold, 48%; highest rank, 39%; travel distance and ratio of Schedule II to total II-V prescriptions, 13%

Among the closed PMP-generated cases (n=40), 13% resulted in the finding of a violation and over half of them also received a sanction from the applicable board (Fig. 12). A comparable number were issued an advisory letter, pursuant to § 54.1-2400, and 28% were closed as undetermined. 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. By comparison, there were 3,887 complaint-driven cases involving patient care of which 8% were found in violation, 7% issued an advisory letter, and 46% were closed undetermined.

Figure 12. Findings of unusual prescribing and dispensing investigations, 2016-August 2019

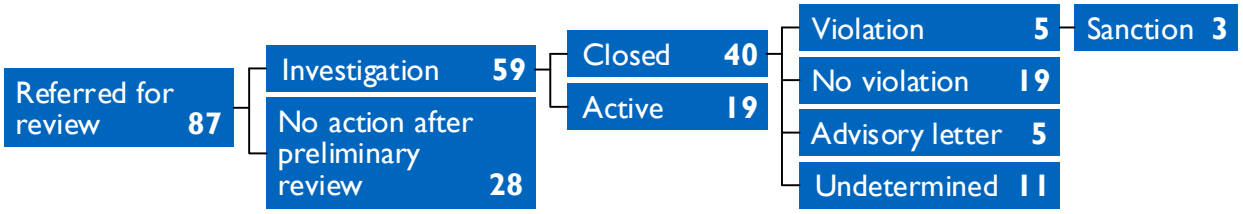

Fig. 12. 68% of prescribers/dispensers reviewed resulted in an investigation; 68% of investigations initiated were closed as of August 2019 with the following final dispositions: violation, 13%; no violation, 48%; advisory letter, 13%; undetermined, 28% (percentages do not sum to 100 due to rounding)

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.

[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. *2018 Annual Surveillance Report of Drug-Related Risks and Outcomes — United States*. Surveillance Special Report. Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. Published August 31, 2018. Accessed September 30, 2019 from https://www.cdc.gov/drugoverdose/pdf/pubs/2018-cdc-drug-surveillance-report.pdf

[5] Requirements for Electronic Orders and Prescriptions, 21 C.F.R. § 1311 (2010).