Report of the Department of Health Professions

2018 Annual Report Virginia Prescription Monitoring Program

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



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COMMONWEALTH of VIRGINIA

David E. Brown, D.C. Director

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

www.dhp.virginia.gov TEL (804) 367- 4400 FAX (804) 527- 4475

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Michele L. Chesser, Ph.D. Executive Director Joint Commission on Health Care 600 East Main Street, Suite 301 Richmond, Virginia 23218

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 2018 Annual Report.

This report includes a summary of significant initiatives, recent operational changes, 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 and respond to unusual patterns of prescribing or dispensing of covered substances by prescribers or dispensers and misuse of covered substances by recipients is included. A new set of indicators for the upcoming year were established in consultation with the PMP Advisory Panel and description 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

Preface

Legislation passed during the 2018 General Assembly session (House Bill 313, Senate Bill 728) amended *Code of Virginia* § 54.1-2523.1 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.

The PMP Advisory Panel convened September 27, 2018 and unanimously recommended five indicators specific to prescribers and two to dispensers for use in the coming year. A description of these criteria is presented within the following report.

In addition to meeting requirements set forth legislatively, the following 2018 Annual Report provides a review of Virginia's Prescription Monitoring Program (PMP) activities, an analysis of prescription data collected, and statewide utilization of the database.

Prescription Monitoring Program, Virginia Department of Health Professions Staff

Ralph Orr, Director Ashley Carter, MPH, Deputy for Analytics Carolyn McKann, MHA, Deputy for Operations Desiré Brown, Administrative Specialist

Location

Perimeter Center 9960 Mayland Drive, Suite 300 Henrico, Virginia 23233

Contact

804.367.4514 | 804.367.4470 fax pmp@dhp.virginia.gov

Website: https://www.dhp.virginia.gov/dhp_programs/pmp

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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, gabapentin (a drug of concern), and naloxone. 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. The section entitled *Identifying unusual patterns of prescribing and dispensing*, beginning on page two, describes this process in depth.

As a result of legislation during the 2018 General Assembly session, two operational changes occurred on July 1, 2018: prescriptions dispensed for Schedule V medications and naloxone were added as covered substances and veterinarians must report covered substance dispensing for a course of treatment exceeding seven days.

Notable findings in the 2018 Annual Report (analyses based on January 2017-June 2018)

Medications that are most commonly abused can be grouped into four categories: pain relievers, stimulants, tranquilizers, and sedatives. The overall quantity of pain reliever, sedative, and tranquilizer doses dispensed decreased between 16% and 31%. Stimulant doses remained stable.

Prescribing of opioids is decreasing. The number of patients receiving and practitioners prescribing opioids declined by 25% and 10%, respectively.

Regulations Governing Prescribing of Opioids and Buprenorphine (18VAC85-21), 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. As a result, mono-product prescriptions decreased by 52%.

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. Though increasing incrementally, in June 2018, only 12% of opioids were submitted electronically and 78% written. The remaining 10% were transmitted via fax or by telephone.

Utilization of the PMP by prescribers, pharmacists, and their delegates has increased steadily over time. Specifically, quarterly use nearly quadrupled.

Initiatives and accomplishments

The Virginia PMP transitioned from the AWARXE platform to NarxCare Enterprise on July 30, 2018. NarxCare provides the same information on prescriptions, prescribers, and pharmacies as AWARXE with the addition of interactive, visual representations of that information 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. Virginia's purchase of the enterprise license for NarxCare provided this enhanced functionality to all PMP users.

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

Two notable operational changes occurred on July 1, 2018 as a result of legislation in the 2018 General Assembly session: requirement for veterinarians to report and expansion in the definition of covered substances. SB226 amended *Code of Virginia* § 54.1-2522 to require veterinarians dispensing covered substances to animals to report to PMP when the course of treatment exceeds seven days. In reporting the dispensation for an animal to PMP, the relevant information required in the report is specific to the owner of the animal. Veterinarians may request a waiver from the reporting requirement if they do not dispense covered substances exceeding a seven-day course of treatment. HB1556 and SB832 revised the definition of a covered substance in *Code of Virginia* § 54.1-2519 to include Schedule V medications for which a prescription is required, naloxone, and cannabidiol oil or THC-A oil dispensed by a pharmaceutical processor in Virginia.

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 that connects all hospital emergency departments facilitating 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 seven health systems and nearing implementation at another five. Beyond the EDCC program and the EDie platform, Virginia's PMP and their vendor, Appriss Health, is integrated with numerous electronic health record and pharmacy management systems to display PMP information within the clinical workflow.

Identifying unusual patterns of prescribing and dispensing

Prescribers and dispensers

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 62 reviews of prescribers (n=34) and dispensers (n=28) and initiated investigations as appropriate. The following indicators were used for both prescribers and dispensers:

- Top 10 prescribers/dispensers of all covered substances by prescription count
- Prescribers/dispensers for patients meeting certain daily MME thresholds
 - o One patient at 2,000 MME/day
 - o 10 patients at 1,000 MME/day
 - o 5 patients at 750 MME/day
 - o 25 patients at 500 MME/day

Based the collective experiences and knowledge gained by the Enforcement Division, the Boards of Medicine and Pharmacy, and PMP in conducting the reviews and investigations to date, opportunities to refine these indicators were identified. Specifically, maximizing resources and impact are primary in developing these indicators.

The PMP Advisory Panel met September 27, 2018 to review previous indicators used to identify unusual patterns of prescribing and dispensing of covered substances and make necessary changes to the indicators for use in the coming year. Prescribers and dispensers have indicators specific to their unique roles. The following indicators were unanimously adopted by the PMP Advisory Panel to guide PMP-initiated investigations for the coming year:

- Prescriber
 - o Top 10 prescribers of opioids
 - o Top 10 prescribers of opioids with minimal PMP use
 - o One or more patients prescribed 1,500 MME/day
 - Top 10 prescribers of ER/LA opioids to opioid naïve patients
 - Top 10 prescribers of buprenorphine for MAT dosing > 24mg/day
- Dispenser
 - o Top 10 dispensers of opioids from out of state prescribers
 - Top 10 dispensers based on ratio of Schedule II to all Schedule II-V prescriptions

Recipients

Unusual patterns of obtaining covered substances by recipients of covered substances is disclosed to prescribers via clinical alerts in the PMP application and provided to law enforcement personnel with the Drug Diversion unit of the Virginia State Police (VSP). Prescribers receive notification via the PMP alerting them when a recipient is obtaining covered substances from multiple prescribers and dispensers. Such behavior may be indicative of inadequate care coordination, misuse, or diversion. Alerts are presented daily within the PMP application.

PMP data indicative of possible diversion and forgery by a recipient are forwarded to VSP for further review and investigation, as necessary (Fig. 1). The following indicators, based on a 30-day time period, are used in identifying possible diversion and fraud:

- Multiple provider episodes: a minimum of seven prescribers and three pharmacies
- Prescription fraud/forgery: a maximum of two prescribers and minimum of five pharmacies

Multiple provider episodes, sometimes referred to as "doctor shopping," may represent drug diversion. Prescription fraud or forgery may be present when a recipient is obtaining multiple prescriptions from one or two prescribers.

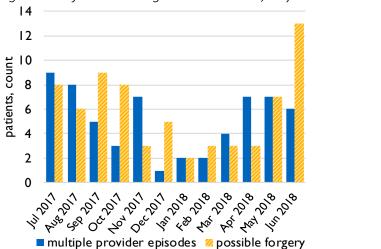


Figure 1. Referrals to Virginia State Police, July 2017-June 2018

Prescribing of covered substances

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

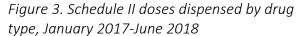
- 1. gabapentin
- 2. hydrocodone/acetaminophen
- 3. tramadol
- 4. dextroamphetamine/amphetamine (Adderall®)
- 5. alprazolam (Xanax®)
- 6. oxycodone
- 7. oxycodone/acetaminophen
- 8. clonazepam (Klonopin®)
- 9. lorazepam (Ativan®)
- 10. zolpidem (Ambien®)

Medications dispensed by drug type

Prescription psychotherapeutic medications that are most commonly abused can be grouped into four categories: pain relievers, stimulants, tranquilizers, and sedatives. Opioids are considered pain relievers. Stimulants are often prescribed to treat attention-deficit

hyperactivity disorder (ADHD). In general, tranquilizers include longer-acting benzodiazepines (e.g., diazepam) and muscle relaxants. Sleeping medications, shorter-acting benzodiazepines (e.g., temazepam), and barbiturates are classified as sedatives. Doses dispensed for three categories decreased between 16% and 31% between January 2017 and June 2018 (Fig. 2). The dispensing of stimulants remained stable. Opioids and stimulants are classified as Schedule II controlled substances. The overall reduction in prescribed doses of Schedule II medications is the result of changes in pain reliever prescribing (Fig. 3).

Figure 2. Doses dispensed by drug type, January 2017-June 2018



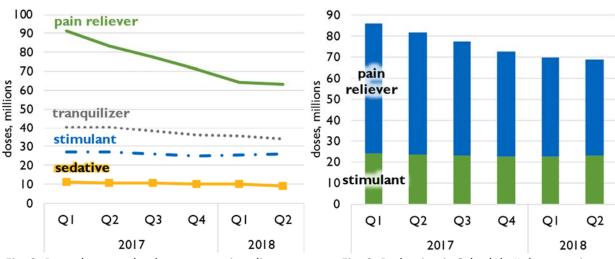


Fig. 2. Dose decrease by drug type: pain reliever, 31%; tranquilizer, 16%; stimulant, 4%; sedative, 18%

Fig. 3. Reduction in Schedule II doses: pain reliever, 26%; stimulant, 4%

Buprenorphine for medication-assisted treatment

Medication-assisted treatment (MAT) is the use of medications, like buprenorphine, in combination with counseling and behavioral therapies to treat opioid use disorders. While increasing numbers of buprenorphine prescriptions in general indicates increased treatment usage (19% 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), 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. 4). The overall decline of 52% in mono-product buprenorphine prescriptions as of June 2018 is indicative of progress toward improved prescribing practices.

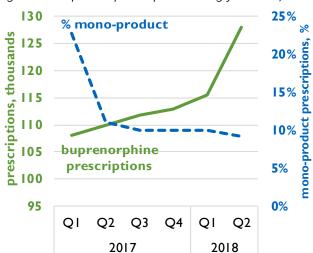


Figure 4. Buprenorphine prescribing for MAT, January 2017-June 2018

Fig. 4. Total buprenorphine prescriptions increased 19% (solid green); percentage of buprenorphine prescriptions for mono-product decreased from 23% to 9% (dashed blue)

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 a 30% decrease in the number of opioid doses dispensed between January 2017 and June 2018 (29 million to 20 million). Each opioid prescription provided an average of 17 days' supply of medications.

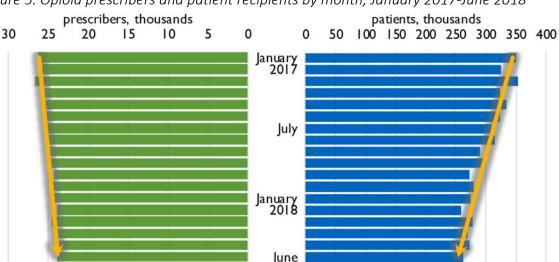


Figure 5. Opioid prescribers and patient recipients by month, January 2017-June 2018

Fig. 5. 10% decrease in prescribers of opioids (left); 25% decrease in patients receiving opioids (right)

An average of 300,000 Virginians per month received an opioid prescription between January 2017 and June 2018 from approximately 25,000 prescribers (Fig. 5). Throughout the 18-month period, there was a 25% reduction in patients receiving prescription opioids and 10% fewer

practitioners prescribing. In 2017, number of opioid prescriptions per capita was 0.6 or 61 prescriptions per 100 Virginians. This volume of opioid prescriptions is enough for nearly two of every three Virginians to receive one prescription over the course of a year. The rate in Virginia is consistent with that reported for the United States (58 per 100 Americans).²

Morphine milligram equivalent (MME) is a way to calculate the total amount 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) guidelines specify that dosages of 90 MME per day or greater should be avoided due to risk for fatal overdose.³ The MME per prescription decreased 4% between January 2017 and June 2018. Among Virginians receiving opioid prescriptions, the quarterly percentage of patients with an average dose at or above 90 MME per day decreased 37% (11% to 7%) (Fig. 6). Overlapping opioid prescriptions and concurrent opioid and benzodiazepine prescribing also increases the risk of overdose. Between January 2017 and June 2018, the percentage of days with overlapping opioid prescription remained relatively stable at an average of 15%. However, the percent of days with overlapping opioid and benzodiazepine prescriptions decreased from 19% to 16% (Fig. 7).

Figure 6. Patients receiving an average dose of 90 MME per day or greater, January 2017-June 2018

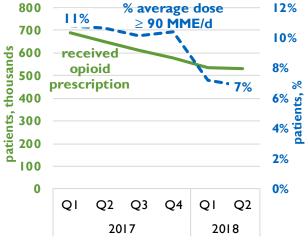


Fig. 5. 25% decrease in patients receiving an opioid prescription (solid green); percentage of patients receiving an average daily dose of \geq 90 MME decreased from 11% to 7% (dashed blue)

Figure 7. Percent of overlapping opioid and opioid-benzodiazepine prescription days, January 2017-June 2018

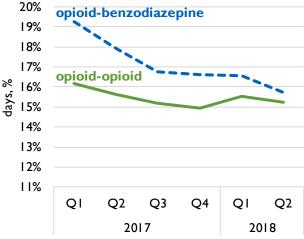


Fig. 6. % days with overlapping opioid prescriptions remained stable at an average of 15% (solid green); % days with overlapping opioid-benzodiazepine decreased from 19% to 16% (dashed blue)

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, has declined precipitously. The rate declined by two-thirds (63%), from 22 to 8 per 100,000 people, over an 18-month period (Fig. 7).

Figure 7. Multiple provider episodes for prescription opioids, January 2017-June 2018



Fig. 7. Multiple provider episodes decreased from 22 to 8 per 100,000 residents

Figure 8. Opioid prescriptions by transmission type, July 2017-June 2018

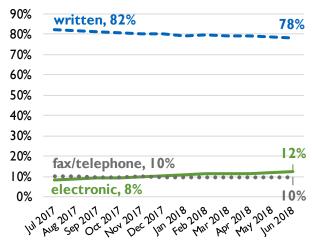


Fig. 8. Opioid prescriptions by transmission: written, decreased from 82% to 78% (dashed blue); fax/telephone, stable at 10% (dotted gray); electronic, increased 8% to 12% (solid green)

Electronic prescribing for opioids

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) must be written (§ 54.1-3410) or electronic. Though the percentage of opioid prescriptions transmitted electronically is gradually increasing, only 12% were electronic in June 2018. By comparison, 56% of gabapentin prescriptions are transmitted electronically (Fig. 8). Because gabapentin is not classified as a controlled substance, the electronic transmission of gabapentin is not subject to the same technological security standards applicable to opioids. While many practitioners are using e-prescribing, fewer are able to e-prescribe controlled substances.

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 (previously AWARXE), 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 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. 9). More specifically, quarterly use nearly quadrupled by mid-2018 compared to early 2017 (1.9 million to 7.8 million). This rapid rise in utilization of the PMP is primarily the result of expansions in integration within the electronic health record and pharmacy management systems. By the end of 2018, PMP requests are expected to nearly double compared to 2017 (18 million) and exceed 33 million.

Interoperability allows users of Virginia's PMP to access a patient's prescription history from 30 other states and the District of Columbia. Requests through a Gateway EHR connection in-state increased nine-fold by mid-2018 compared to early 2017 (Fig. 10). Additionally, Gateway integration requests by out of state users for Virginia residents' prescription history nearly tripled in the same period.

Figure 9. Prescription history requests, 2012-2018

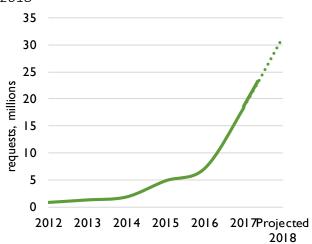


Fig. 9. Requests for a patient's prescription history increased 37x over six years

Figure 10. Prescription history requests by type, January 2017-June 2018

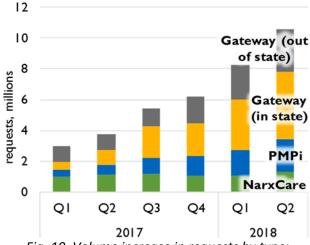


Fig. 10. Volume increase in requests by type: NarxCare, 37%; PMPi, 4.4x; Gateway (in-state), 9x; Gateway (out of state), 2.7x

¹ Buprenorphine used to treat opioid use disorder or addiction is excluded.

² 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 October 9, 2018 from https://www.cdc.gov/drugoverdose/pdf/pubs/2018-cdc-drug-surveillance-report.pdf

³ 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. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1

⁴ Requirements for Electronic Orders and Prescriptions, 21 C.F.R. § 1311 (2010).