COMMONWEALTH OF VIRGINIA
Meeting of the Virginia Prescription Drug Monitoring Advisory Committee

Perimeter Center, 9960 Mayland Drive, Suite 300 **804-367-4514(Tel)**
Henrico, Virginia 23233 **804-527-4470(Fax)**

Agenda of Meeting
June 2, 2022
10:00 AM
Board Room 1

Call to Order: Dr. Gofton

- Welcome
- Introductions
- Approval of agenda
- Approval of minutes

Department of Health Professions Report: David Brown, D.C.

Legislation and Regulation Update: Erin Barrett

Section 5042 SUPPORT Act reporting and CMS funding opportunity: Ashley Carter, MaryAnn McNeil (DMAS)

PMP Survey Discussion: Ashley Carter, Liz Zaunick (VDH)

Program Reports:
Program Operations: Carolyn McKann
PMP registration and integration update

Program Analytics: Ashley Carter
Annual report and quarterly statistics highlights
Prescriber penetration

Program Director Report: Ralph Orr
Twenty year anniversary of PMP legislation: A look back
Upcoming updates to NarxCare
Other announcements

Meeting Dates for 2022:

- September 7 at 10:00am

Election of Chair and Vice-Chair, Term September 2022-June 2023

Adjourn Dr. Gofton

Virginia Department of Health Professions

PMP Advisory Committee Meeting

June 2, 2022

Virginia Department of Health Professions

Call to Order

- **Welcome**
- Introductions
- Approval of Agenda
- Approval of Minutes

Virginia Department of Health Professions

Department of Health Professions Report

David Brown, D.C., Director, Department of Health Professions
Lisa Hahn, Chief Operating Office, Department of Health Professions

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Legislation and Regulation Update

Erin Barrett, Senior Policy Analyst

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Section 5042, 2018 SUPPORT ACT: Reporting and CMS Funding

Ashley Carter
MaryAnn McNeil (DMAS)

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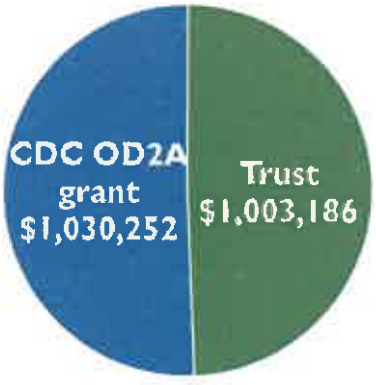
PMP funding snapshot

FY2021 Expenditures



- CDC Overdose Data to Action (OD2A) grant is a four-year award ending 08/31/2023
- Allocation for PMP *does* reduce funds VDH has to conduct grant activities

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PMP Survey Discussion

Ashley Carter
Liz Zaunick (VDH)

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PMP user survey

- Last survey conducted in 2004
- Will contract with VCU's Survey & Evaluation Research Lab (SERL) again, targeting October 2022
  - Sampling
- Purpose
  - Support need for continued funding, additional capabilities
  - Identify education gaps
- Topics?
  - Frequency of use
  - Decisions on treatment
  - Interstate requesting
  - Additional data: OTP, incarceration
  - All meds (not just CS)
  - Prescriber report

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Program Reports

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Program Operations: Registration and Integration Update

Carolyn McKann

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PMP Registration: Individual PMP Accounts

Registration Drives Everything!

FOR ALL USERS:

- Access to AWARxE application
- Provides means of communication from the Virginia PMP via the email address of record

FOR INTEGRATED USERS:

- Enables authentication for registered users in integrated facilities via these identifiers:
  - ✓ DEA number
  - ✓ NPI number
  - ✓ State license number
  - ✓ Email address

FOR PRESCRIBERS ONLY:

- Provides prescribers access to a peer comparison via the prescriber report
- Provides ability for prescribers to view their dispensing history via the MyRx Report

FOR PRESCRIBERS AND PHARMACISTS:

- Provides the means for prescribers and pharmacists to manage delegates

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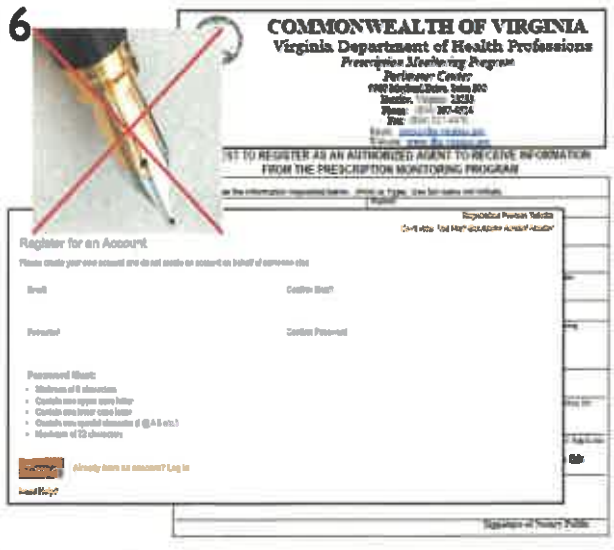
Transition to ALL Online Registration

Appriss Health Migration in 2016

- Online registration began for all health care roles in late 2016
- Law enforcement/regulatory roles continued on paper applications
- PMP Staff manually entered all account information for ALL law enforcement and regulatory users until Feb 2022
- First Group: DHP Investigators



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Simpler!!!

For Registered Users:

- Don't have to ask for the paper form because it is housed as a fillable pdf form in the AWARxE application
- Notarization of the pdf form is not required
- Can input their personal information themselves, avoiding typos
- Can set their own username and password at registration

For PMP Staff:

- Don't have to manually input each registration
- The affidavit is housed within the application as a fillable pdf form during the registration process
- The fillable form remains in the AWARxE application with the user's other account information and does not have to be saved to a PMP server

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Online Registrations

Roles Enabled

1. DHP Investigators 2/22
2. Medicaid Fraud Control Unit 2/22
3. Health Practitioners Monitoring Program 2/22
4. Virginia State Police Drug Diversion Unit 3/22
5. Office of the Chief Medical Examiner 3/22
6. DEA 5/22
7. FBI 5/22

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AFFIDAVIT ENDORSING A VIRGINIA STATE POLICE DRUG DIVERSION AGENT TO REGISTER AS AN AUTHORIZED AGENT TO RECEIVE INFORMATION FROM THE PRESCRIPTION MONITORING PROGRAM

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Biennial Renewal Update

Pursuant to:

18VAC76-20-50.

2. Registration as an agent authorized to receive reports shall expire on June 30 of each even-numbered year or at any such time as the agent leaves or alters his current employment or otherwise becomes ineligible to receive information from the program.

- Email requests for account renewals began on March 29, 2022
- As of Friday, May 20, 2022, 92% of the account holders had either sent in affidavits to renew their account through June 30, 2024 or had notified the Virginia PMP that the account was no longer needed
- Notices to remaining account holders are sent every 2 weeks
- PMP staff will deactivate all account holders who have not responded to any requests for renewal affidavits during the week beginning July 5, 2022

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Integration Update: Why is it Important?

Has resulted in an **exponential** increase in the utilization of the PMP by health practitioners, saving lives!

Simplifies Access to Data

Greater than **80%** of all **PMP reports** in Virginia are generated within an integrated solution

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Background

- Integration was initiated by the Virginia PMP in 2015
- Kroger Pharmacy (Ohio) is the first health care entity integrated with the Virginia PMP
- Currently there are 650+ software vendors that meet the Virginia PMP's requirements for integration
- Currently there are approximately 5,000 health care entities which integrate the Virginia PMP into their clinical workflow -- via their Electronic Medical Record (EMR), Pharmacy Dispensing System (PDS) or e-prescribing system

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Marketing Integration to AWARxE Users

1. Email campaign: 6 emails sent every 3-4 weeks beginning on November 3, 2021
2. Advertisement campaign on AWARxE dashboard
   - Began Monday, April 4, 2022
   - Will run through June 30, 2022
   - Bamboo Health will evaluate the direct impact of the dashboard campaign; results will determine possible continuation of the campaign

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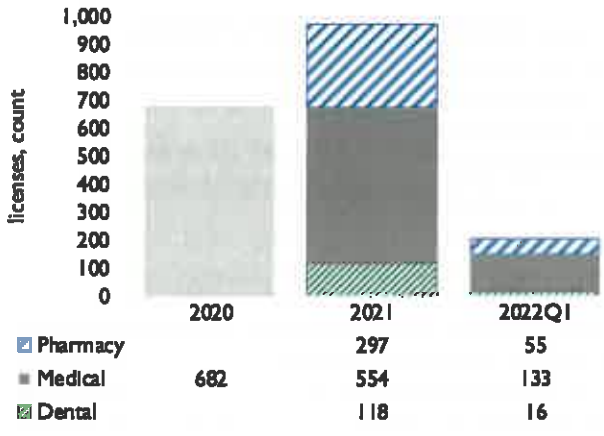
Integration License Approvals by Facility Type

- Approximately 40% of license requests for integration were approved since January of 2020 (integration was enabled in 2015)
- The vast majority of license approvals in the past 2 years are for medical establishments (60-65%)
- Some of the license approvals represent multiple locations regardless of facility type



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Program Analytics: Annual Report, Quarterly Statistics, Prescriber Penetration

Ashley Carter

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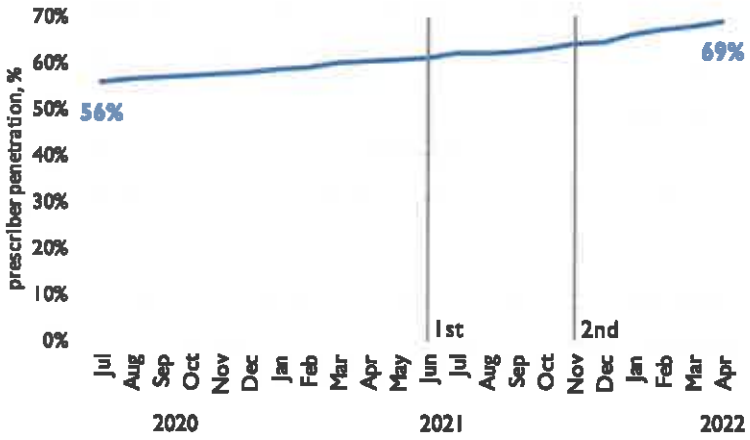
Prescriber penetration, July 2020-April 2022



- Prescriber penetration is defined as percent of prescribers accessing PMP via integrated EHR of the total prescribers actively prescribing controlled substances

$$\textit{prescriber penetration} = \frac{\textit{accessing PMP via EHR}}{\textit{actively prescribing CS}}$$

- Two email marketing campaigns (June and Nov 2021)

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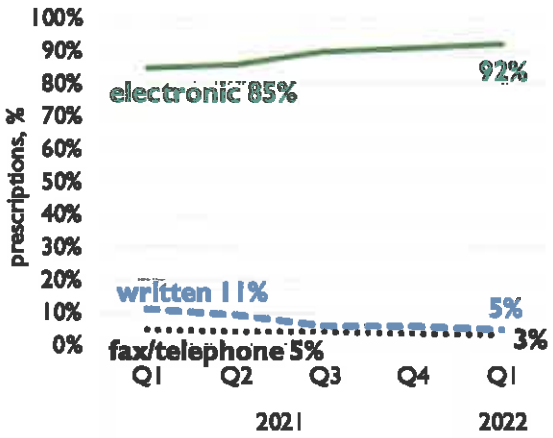
Electronic prescribing for opioids

- Beginning July 1, 2020 any prescription containing an opioid must be transmitted electronically from the prescriber to the dispenser (*Code of Virginia* § 54.1-3408.02)
- 92% of opioid prescriptions were electronic in 2022Q1

Opioid prescriptions by transmission type, 2021Q1-2022Q1



Analysis restricted to prescriptions reporting a mode of transmission
Code of Virginia § 54.1-3408.02 https://law.lis.virginia.gov/vacode/title54.1/chapter34/section54.1-3408.02/

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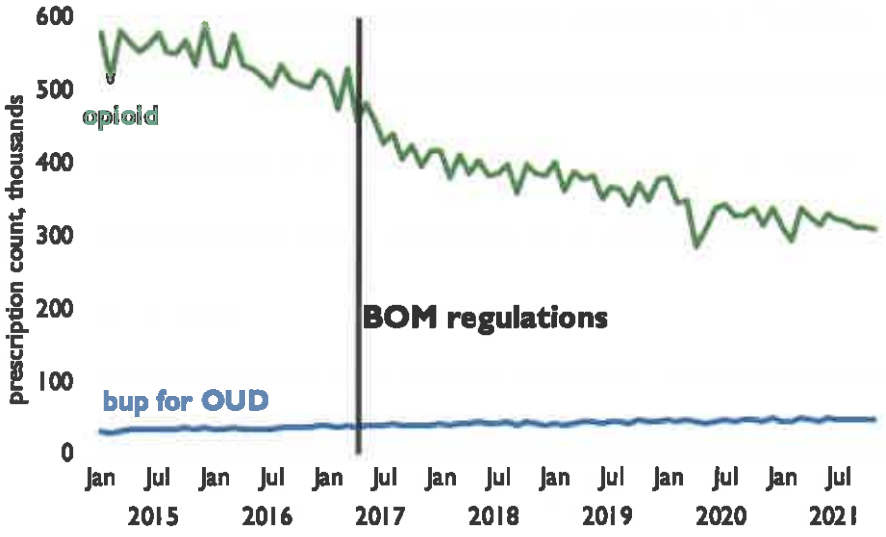
Opioid and Buprenorphine for OUD prescriptions, 2015-2021YTD



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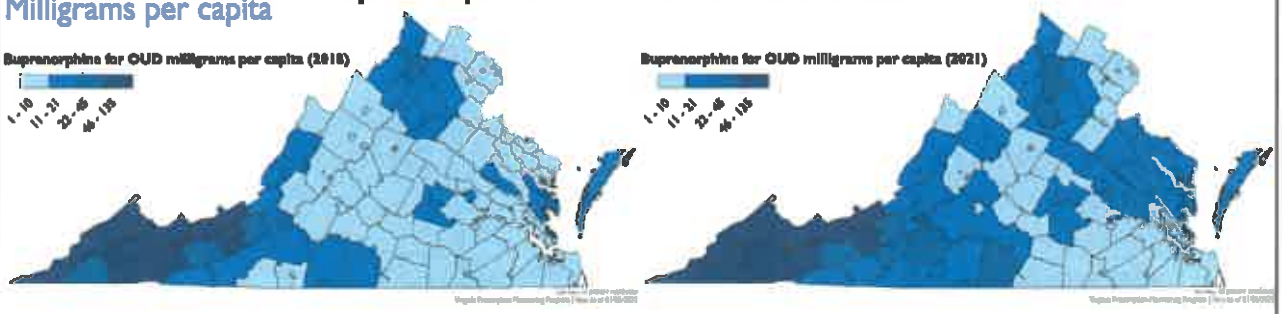
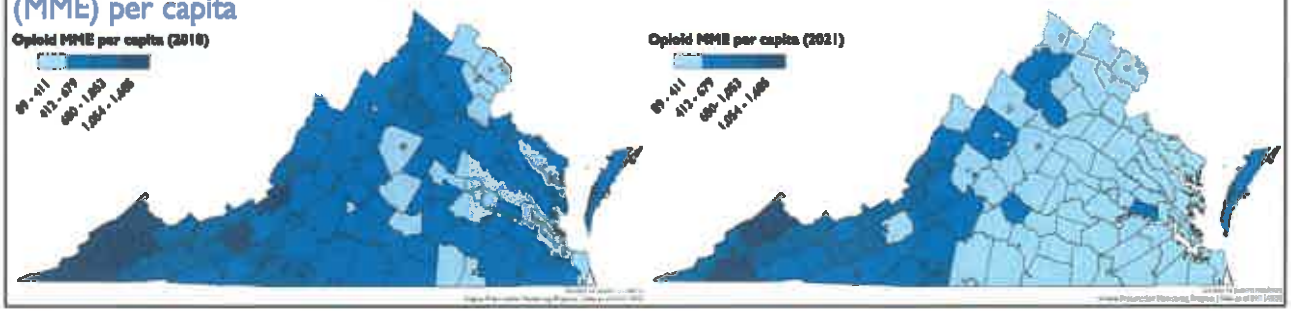
Buprenorphine for OUD, 2018 and 2021

Milligrams per capita



Opioids, 2018 and 2021

Morphine milligram equivalent (MME) per capita



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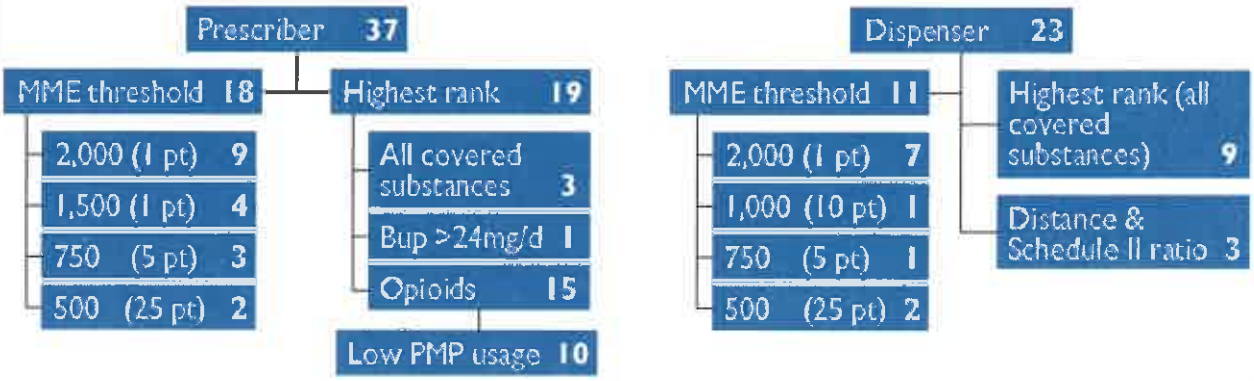
Cases investigated by licensee type and indicator, 2016-May 2022



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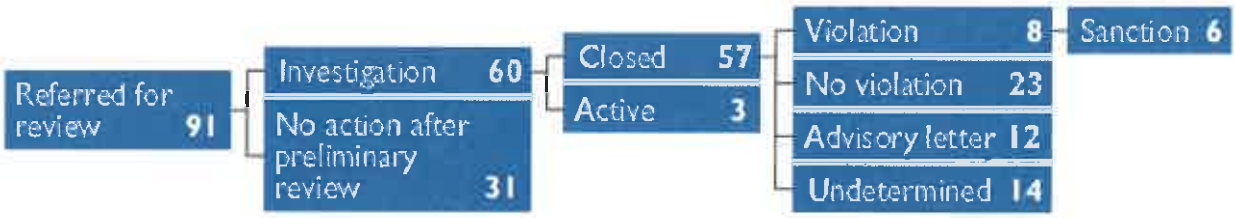
Findings of unusual prescribing and dispensing investigations, 2016-May 2022



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Meeting Dates

Next meeting: September 7, 2022

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Election of Chair and Vice-Chair: Term September 2022-June 2023

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Program Director Report

Ralph Orr

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Virginia's PMP

A Look Back And Forward

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A Perfect Storm?

- Pain is recognized as a Vital Sign (Joint Commission on Accreditation of Hospitals)
- Under treatment of pain becomes great concern
- The "paragraph"
- New drug formulation hits the market with a committed sales force
- Prescription drug abuse and crime explodes
- Overdose deaths increase at alarming rates

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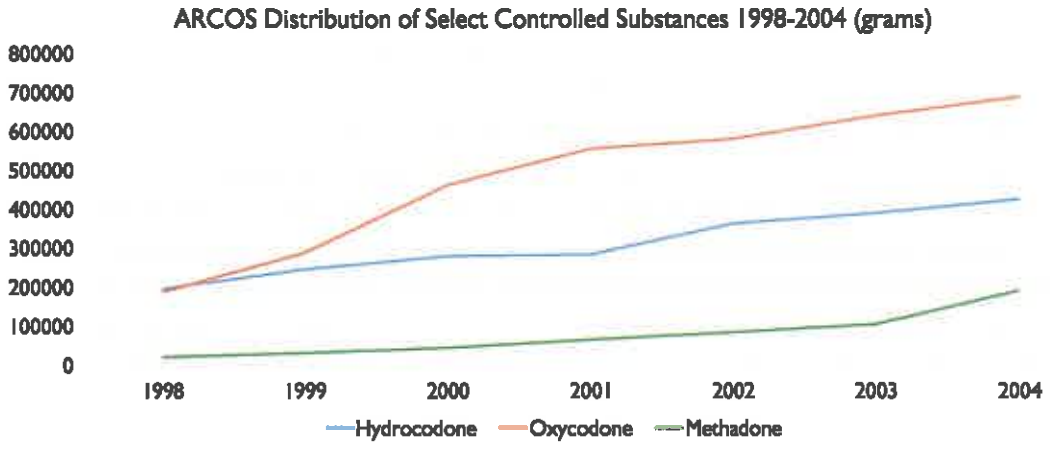
Total Virginia Distribution of Select Products



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2002 PMP Legislation

- Pilot Program for only SW Virginia (Health Planning Region III)
- Schedule II controlled substances only
- Access for Prescribers and State Police Drug Diversion
- Limited access for DHP Enforcement personnel
- Required a report with recommendations to be provided for the 2005 General Assembly

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Implementation and First Steps

- Agency Director directed the Board of Pharmacy to implement a pilot PMP, perform evaluation of that program and develop a report with recommendations to be completed by the fall of 2004
- Agency Director appointed an Advisory Committee to assist with implementation and evaluation of pilot
- First data collection began in September 2003 and the first meeting of the Advisory Committee was held in Roanoke
- PMP data was stored in an ACCESS database, requests had to be made by fax, queries were done manually and results returned by fax.
- Data was reported monthly and transmitted by mail on CDs

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Policy Issues Related to the PMP: June 9, 2004

- Limitations in coverage
- Access to data
- Analysis of data maintained by the program
- FUNDING
- Practitioner Education

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Access Issues

- Requirement that prescriber be licensed in Virginia
- Pharmacists did not have access
- No Access for federal law enforcement
- Other

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Funding Issues: June 2004

- License fees cannot be used for operation of program
- No general fund monies
- Use of select funds held by DHP Enforcement Division provided some seed money to get started
- Federal grant funding from BJA was only other funding available

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Utilization June 2004 and Program Evaluation

- 522 requests as of 6/2/04
- 463 prescriber requests
- 40 Drug Diversion requests
- 19 DHP requests
- 48 prescribers using the program
- 280,989 records in the database

- Federal Data Sources
- Literature Review
- Theft/Loss Reports
- Anthem Prescription Data
- Medicaid Prescription Data
- ARCOS Data
- 2004 PMP Conference

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Budget Update September 2004

- FY04 expenditures were $91,542
- Approximately $260,000 remained of original program budget
- Projected expenditures for FY05 were $253,000, including supplemental grant for fall conference

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Report of the Department of Health Professions and Virginia State Police: Nov04

- Recommendations:
  - Continue the program indefinitely
  - Expand data collection to include Schedule II-IV controlled substances
  - Expand the program to the entire Commonwealth
  - Allow pharmacists to access the program
  - Allow a prescriber in another state to request information
  - Allow access to DHP investigative personnel and HPIP personnel on a specific licensee when there is an open investigation
  - Allow Medical Examiners to access PMP for purpose of performing their duties

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Report of the Department of Health Professions and Virginia State Police: Nov04

- Recommendations Continued:
  - Allow access to DMAS for the purpose of investigating fraud
  - Allow access to the DEA when there is an open investigation on a prescriber or dispenser
  - Allow access to the program for research purposes where all identifying information is removed
  - Allow access for health/education purposes, providing information to prescribers on their patients who may be abusing, misusing or fraudulently obtaining controlled substances
  - Require non-resident pharmacies to report to the program
- 2005 General Assembly passed most of the recommendations made in the report

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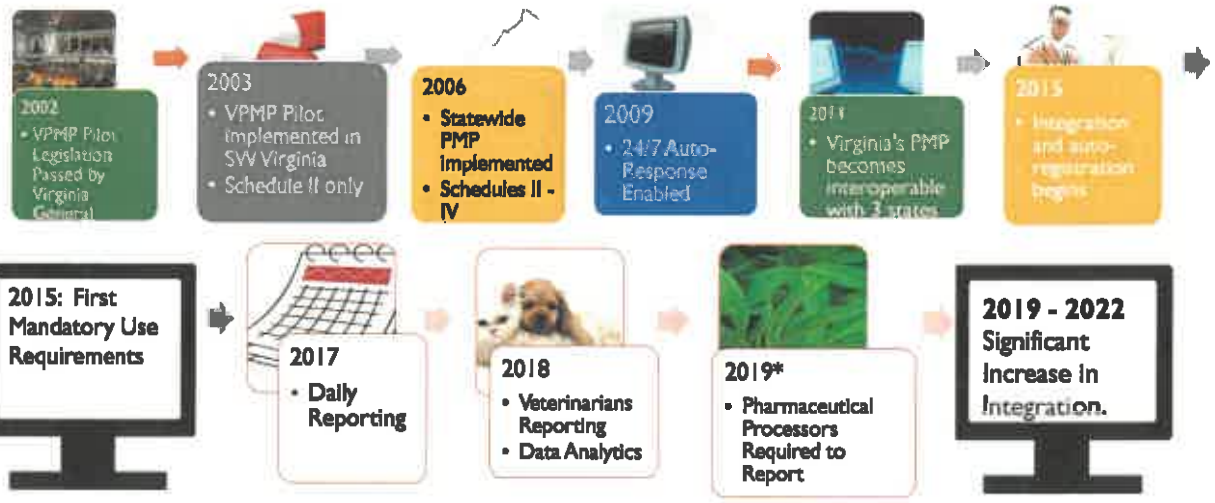
PMP TIMELINE: History



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Hot Topics from OD2A Conference in 2021

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Looking Forward

- Funding Sustainability

- Access-Who and How

- What information is to be provided

- Collaborations

- Data analysis and distribution

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ANNOUNCEMENTS

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Adjournment

Dr. Gofton

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HB 192 Opioids; repeals sunset provisions relating to prescriber requesting information about a patient.

An Act to repeal the second enactment of Chapter 113 and the second enactment of Chapter 406 of the Acts of Assembly of 2016, as amended by the second enactment of Chapter 249 of the Acts of Assembly of 2017, and the second and third enactments of Chapter 249 of the Acts of Assembly of 2017, relating to prescription of opioids; sunset.

Summary as introduced:

Prescription of opioids; sunset. Repeals sunset provisions for the requirement that a prescriber registered with the Prescription Monitoring Program request information about a patient from the Program upon initiating a new course of treatment that includes the prescribing of opioids anticipated, at the onset of treatment, to last more than seven consecutive days.

03/02/22 House: Signed by Speaker
03/03/22 House: Impact statement from DPB (HB192ER)
03/03/22 Senate: Signed by President
03/11/22 House: Enrolled Bill communicated to Governor on March 11, 2022
The Governor amended this legislation to reinstate the sunset provision to July 1, 2027. Accepted by the legislature April 27, 2022.

HB 193 Drug Control Act; adds certain chemicals to the Act.

An Act to amend and reenact §§ 54.1-3446, 54.1-3448, 54.1-3452, and 54.1-3454 of the Code of Virginia, relating to Drug Control Act; Schedule I; Schedule II; Schedule IV; Schedule V.

Summary as passed House:

Drug Control Act; Schedule I; Schedule II; Schedule IV; Schedule V. Adds certain chemicals to the Drug Control Act. The Board of Pharmacy has added these substances in an expedited regulatory process. A substance added via this process is removed from the schedule after 18 months unless a general law is enacted adding the substance to the schedule. This bill is identical to SB 759.

HB 264 Public health emergency; out-of-state licenses, deemed licensure.

An Act to amend and reenact §§ 54.1-2901, 54.1-2904, and 54.1-3011 of the Code of Virginia, relating to public health emergency; out-of-state licenses; deemed licensure.

Summary as passed House:

Public health emergency; out-of-state licenses; deemed licensure. Allows a practitioner of a profession regulated by the Board of Medicine who is licensed in another state or the District of Columbia and who is in good standing with the applicable regulatory agency in that state or the District of Columbia to engage in the practice of that profession in the Commonwealth with a patient located in the Commonwealth when (i) such practice is for the purpose of providing continuity of care through the use of telemedicine services and (ii) the patient is a current patient of the practitioner with whom the practitioner has previously established a practitioner-patient relationship and the practitioner has performed an in-person examination of the patient within the previous 12 months. The bill also provides that when the Board of Health has issued an emergency order, the Boards of Medicine and Nursing may waive (a) the requirement for submission of a fee for renewal or reinstatement of a license to practice medicine or osteopathic medicine or as a physician assistant or nurse practitioner and (b) the requirement for submission of evidence that a practitioner whose license was allowed to lapse for failure to meet professional activity requirements has satisfied such requirements and is prepared to resume practice in a competent manner for any person who held a valid, unrestricted, active license within the four-year period immediately prior to the application for renewal or reinstatement of such license. This bill is identical to SB 369.

HB 285 Clinical nurse specialist; practice agreements.

An Act to amend and reenact §§ 54.1-2957, as it is currently effective and as it shall become effective, and 54.1-2957.01 of the Code of Virginia, relating to clinical nurse specialist; practice agreement.

Summary as introduced:

Clinical nurse specialist; practice agreements. Provides that a nurse practitioner licensed by the Boards of Medicine and Nursing in the category of clinical nurse specialist who does not prescribe controlled substances or devices may practice in the practice category in which he is certified and licensed without a written or electronic practice agreement, provided that he (i) only

practice within the scope of his clinical and professional training and limits of his knowledge and experience and consistent with the applicable standards of care, (ii) consult and collaborate with other health care providers based on the clinical condition of the patient to whom health care is provided, and (iii) establish a plan for referral of complex medical cases and emergencies to physicians or other appropriate health care providers. The bill also provides that a nurse practitioner licensed by the Boards in the category of clinical nurse specialist who prescribes controlled substances or devices shall practice in consultation with a licensed physician in accordance with a practice agreement between the nurse practitioner and the licensed physician.

HB 444 Virginia Freedom of Information Act; meetings conducted through electronic meetings.

An Act to amend and reenact §§ 2.2-2455, 2.2-3701, 2.2-3707, 2.2-3707.01, 2.2-3708.2, 2.2-3714, 10.1-1322.01, 15.2-1627.4, 23.1-1301, 23.1-2425, 30-179, and 62.1-44.15:02 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 2.2-3708.3, relating to the Virginia Freedom of Information Act; meetings conducted by electronic communication means; situations other than declared states of emergency.

Summary as passed:

Virginia Freedom of Information Act; meetings conducted through electronic communication means. Amends existing provisions concerning electronic meetings by keeping the provisions for electronic meetings held in response to declared states of emergency, repealing the provisions that are specific to regional and state public bodies, and allowing certain public bodies to conduct all-virtual public meetings where all of the members who participate do so remotely and that the public may access through electronic communications means. The bill excepts local governing bodies, local school boards, planning commissions, architectural review boards, zoning appeals boards, and any board with the authority to deny, revoke, or suspend a professional or occupational license from the provisions that allow public bodies to conduct all-virtual public meetings. Definitions, procedural requirements, and limitations for all-virtual public meetings are set forth in the bill, along with technical amendments. The bill has a delayed effective date of September 1, 2022.

HB 537 Telemedicine; out-of-state providers, behavioral health services provided by practitioner.

An Act to amend and reenact §§ 54.1-2901, 54.1-3501, 54.1-3601, and 54.1-3701 of the Code of Virginia, relating to telemedicine; out of state providers; behavioral health services.

Summary as passed House:

Telemedicine; out of state providers; behavioral health services. Allows certain practitioners of professions regulated by the Boards of Medicine, Counseling, Psychology, and Social Work who provide behavioral health services and who are licensed in another state, the District of Columbia, or a United States territory or possession and in good standing with the applicable regulatory agency to engage in the practice of that profession in the Commonwealth with a patient located in the Commonwealth when (i) such practice is for the purpose of providing continuity of care through the use of telemedicine services and (ii) the practitioner has previously established a practitioner-patient relationship with the patient. The bill provides that a practitioner who provides behavioral health services to a patient located in the Commonwealth through use of telemedicine services may provide such services for a period of no more than one year from the date on which the practitioner began providing such services to such patient.

HB 933 Pharmaceutical processors; amends the definition of "cannabis oil."

An Act to amend and reenact §§ 54.1-3408.3, 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia, relating to pharmaceutical processors.

Summary as passed House:

Pharmaceutical processors. Amends the definition of "cannabis oil" by removing the requirement that only oil from industrial hemp be used in the formulation of cannabis oil. The bill removes the Board of Pharmacy patient registration requirement for medical cannabis but maintains the requirement that patients obtain written certification from a health care provider for medical cannabis. The bill directs the Board to promulgate numerous regulations related to pharmaceutical processors by September 15, 2022. This bill is identical to SB 671.

HB 939 Necessary drugs, devices, and vaccines; Comm. of Health to authorize administration and dispensing.

An Act to amend and reenact §§ 32.1-42.1 and 54.1-3408 of the Code of Virginia, relating to Commissioner of Health; administration and dispensing of necessary drugs, devices, and vaccines during public health emergency; emergency.

Summary as passed House:

Commissioner of Health; administration and dispensing of necessary drugs, devices, and vaccines during public health emergency; emergency. Allows the Commissioner of Health to authorize persons who are not authorized by law to administer or dispense drugs or devices to do so in accordance with protocols established by the Commissioner when the Board of Health has made an emergency order for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious, and infectious diseases and other dangers to the public life and health for the limited purpose of administering vaccines as an approved countermeasure for such communicable, contagious, and infectious diseases. Current law limits the Commissioner's ability to make such authorizations to circumstances when the Governor has declared a disaster or a state of emergency or the federal Secretary of Health and Human Services has issued a declaration of an actual or potential bioterrorism incident or other actual or potential public health emergency. The bill contains an emergency clause. This bill is identical to SB 647.

EMERGENCY

HB 1187 Out-of-state health care practitioners; temporary authorization to practice.

An Act to amend the Code of Virginia by adding a section numbered 54.1-2408.4, relating to out-of-state health care practitioners; temporary authorization to practice pending licensure; licensure by reciprocity for physicians; emergency.

Summary as passed:

Out-of-state health care practitioners; temporary authorization to practice; licensure by reciprocity for physicians; emergency. Allows a health care practitioner licensed in another state or the District of Columbia who has submitted an application for licensure to the appropriate

health regulatory board to temporarily practice for a period of 90 days pending licensure, provided that certain conditions are met. The bill directs the Board of Medicine to pursue reciprocity agreements with jurisdictions that surround the Commonwealth to streamline the application process in order to facilitate the practice of medicine. The bill requires the Department of Health Professions to annually report to the Chairmen of the Senate Committee on Education and Health and the House Committee on Health, Welfare and Institutions the number of out-of-state health care practitioners who have utilized the temporary authorization to practice pending licensure and have not subsequently been issued full licensure. The bill contains an emergency clause and is identical to SB 317.

EMERGENCY

HB 1323 Pharmacists; initiation of treatment with and dispensing and administration of vaccines.

An Act to amend and reenact §§ 32.1-325, 54.1-3303.1, and 54.1-3321 of the Code of Virginia, relating to pharmacists; initiation of treatment with and dispensing and administration of vaccines.

Summary as passed:

Pharmacists and pharmacy technicians; initiation of treatment with and dispensing and administration of vaccines. Allows pharmacists and pharmacy technicians acting under the supervision of a pharmacist to initiate treatment with and dispense and administer vaccines for COVID-19, nicotine replacement and other tobacco cessation therapies, and tests for COVID-19 and other coronaviruses to persons aged 18 years and older and vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19 and tests for COVID-19 and other coronaviruses to persons three years of age or older in accordance with a statewide protocol established by the Board of Medicine in collaboration with the Board of Pharmacy and the Department of Health. The bill also directs the Board of Medicine, in collaboration with the Board of Pharmacy and the Department of Health to develop such statewide protocol by November 1, 2022, and directs the Board of Pharmacy to adopt emergency regulations to implement the provisions of the bill. The bill also provides that when services related to the initiation of treatment with or dispensing or administration of a vaccination by a pharmacist, pharmacy technician, or pharmacy intern provided for by the state plan for medical assistance services are provided in accordance with the provisions of the bill, the Department of Medical Assistance Services shall provide reimbursement for such services.

Finally, the bill provides that provisions related to administration of COVID-19 vaccines to and testing for COVID-19 of minors shall become effective upon the expiration of the provisions of the federal Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 related to the administration of COVID-19 vaccines to and testing for COVID-19 of minors. This bill is identical to SB 672.

03/21/22 House: Impact statement from DPB (HB1323ER)
03/21/22 Senate: Signed by President
03/22/22 House: Signed by Speaker
03/22/22 House: Enrolled Bill communicated to Governor on March 22, 2022
Governor proposed amending bill to reinstate treatment for additional conditions which was stricken from the bill during committee.
Governor amendment was rejected.
Bill has been returned to the Governor with pharmacist permitted to initiate treatment for nicotine cessation and tests for COVID-19.
Governor action deadline: May 27, 2022.

HB 1324 Pharmacy, Board of; pharmacy work environment requirements.

An Act to direct the Board of Pharmacy to adopt regulations related to work environment requirements for pharmacy personnel; emergency.

Summary as passed House:

Board of Pharmacy; pharmacy work environment requirements. Directs the Board of Pharmacy to promulgate regulations related to work environment requirements for pharmacy personnel that protect the health, safety, and welfare of patients. The bill directs the Board of Pharmacy to adopt emergency regulations to implement the provisions of the bill.

EMERGENCY

SB 14 Prescription drug donation program; Bd. of Pharmacy shall convene a work group to evaluate.

An Act to direct the Board of Pharmacy to convene a work group related to increasing participation in the prescription drug donation program.

Summary as passed Senate:

Board of Pharmacy; prescription drug donation program; work group. Directs the Board of Pharmacy to convene a work group of interested stakeholders to evaluate any challenges and barriers to participation in the prescription drug donation program and ways to increase program participation, education, and outreach.

SB 480 Administrative Process Act; final orders, electronic retention.

An Act to amend and reenact § 2.2-4023 of the Code of Virginia, relating to the Administrative Process Act; final orders; electronic retention.

Summary as introduced:

Administrative Process Act; final orders; electronic retention. Clarifies that signed originals of final agency case decisions may be retained in an electronic medium. This bill is a recommendation of the Administrative Law Advisory Committee and the Virginia Code Commission.

SB 511 Opioid treatment program pharmacy; medication dispensing, registered/licensed practical nurses.

An Act to amend and reenact § 54.1-3321 of the Code of Virginia, relating to opioid treatment program pharmacy; medication dispensing; registered nurses and licensed practical nurses.

Summary as passed Senate:

Opioid treatment program pharmacy; medication dispensing; registered nurses and licensed practical nurses. Allows registered nurses and licensed practical nurses practicing at an opioid treatment program pharmacy to perform the duties of a pharmacy technician, provided that all take-home medication doses are verified for accuracy by a pharmacist prior to dispensing.

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).

Report Document No. RD677
Commonwealth of Virginia
November 1, 2021

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.

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, 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

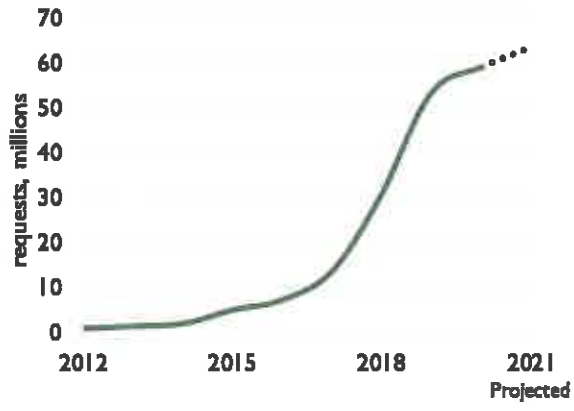

Fig. 1. Requests for a patient's prescription history increased 69x over nine years

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

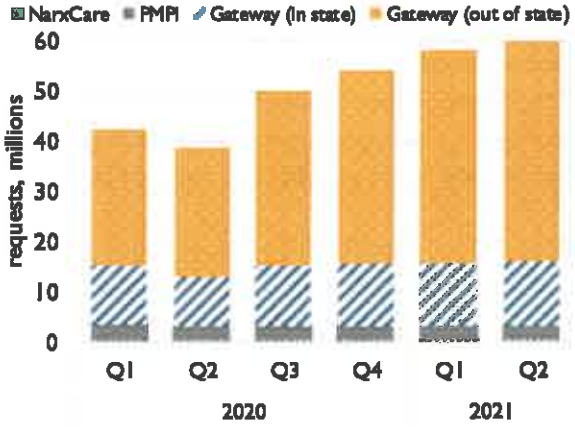

Fig. 2. Volume changes in requests by type: NarxCare, -13%; PMPi, -16%; Gateway (in state), 12%; Gateway (out of state), 63%

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

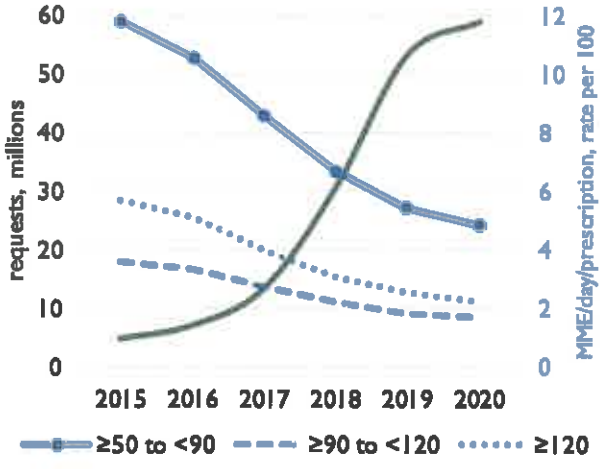

Fig. 4. Requests for a patient's prescription history increased 12x (solid green); percent change in rate of daily MME per prescription: ≥50 to <90, -59% (round marker blue); ≥90 to <120, -54% (dashed blue); ≥120, -61% (dotted blue)

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

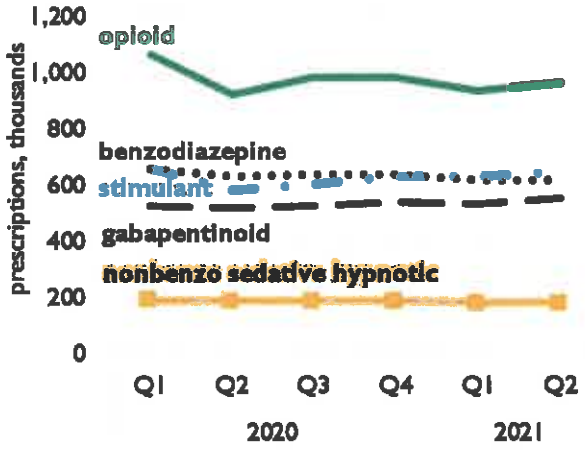

Fig. 5. Percent change by drug class: opioid, -10% (solid green); benzodiazepine, -6% (dotted gray); stimulant, -1% (dash-dot blue); gabapentinoid, 4% (dashed black); nonbenzo sedative hypnotic, -6% (square marker yellow)

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

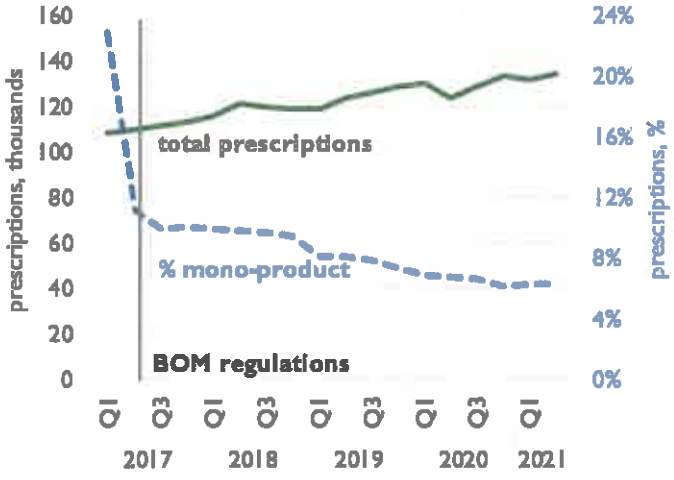

Fig. 6. Total buprenorphine prescriptions for OUD increased 24% (solid green); percentage of buprenorphine prescriptions for mono-product decreased from 23% to 6% (dashed blue); date Board of Medicine regulations promulgated (solid gray, March 2017)

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

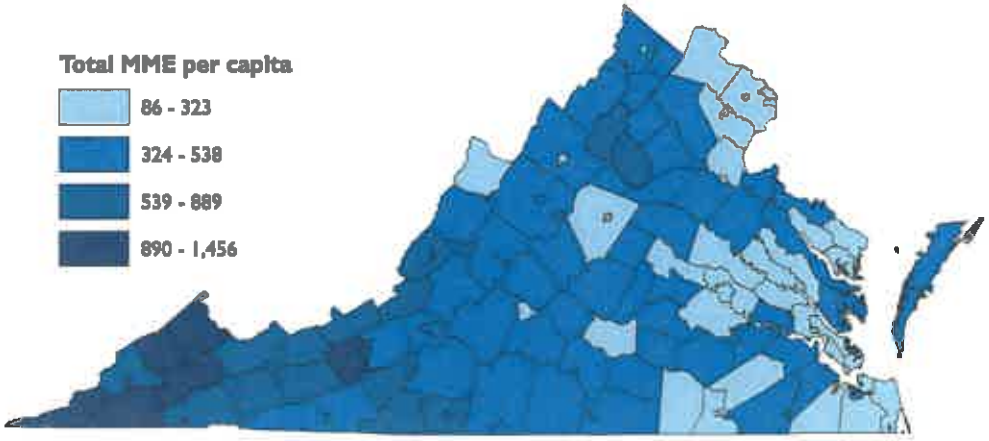

Fig. 7. MME per capita by patient residence

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

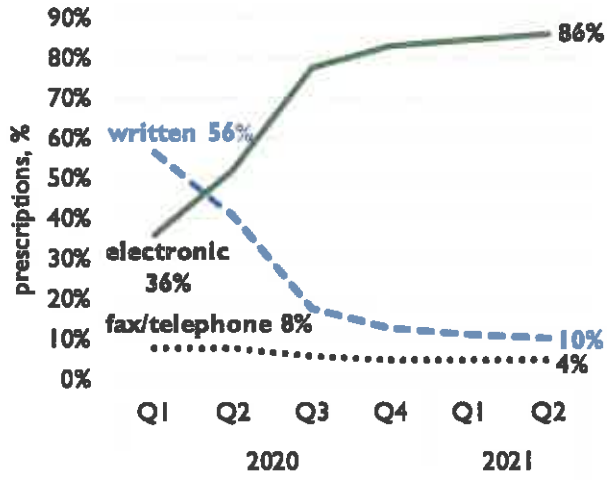

Fig. 8. Opioid prescriptions by transmission: written, decreased from 56% to 10% (dashed blue); fax/telephone, declined minimally from 8% to 4% (dotted gray); electronic, increased 36% to 86% (solid green)

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

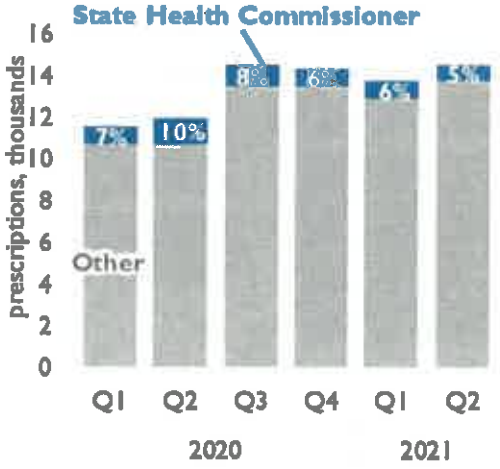

Fig. 9. State Health Commissioner's standing order used for 7% of quarterly prescriptions on average (solid blue); 93% prescribed by another practitioner (striped gray)

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

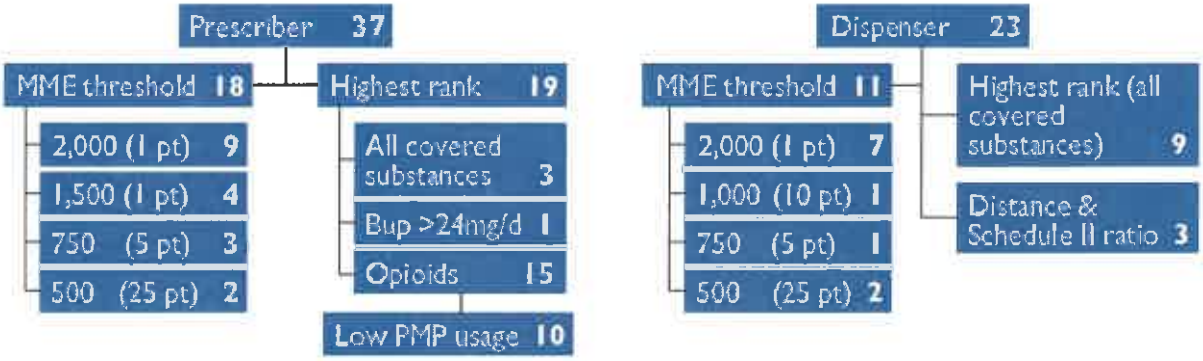

Fig. 10. Prescriber investigations almost equally distributed between MME threshold and highest rank indicators (left); dispenser investigations by indicator: MME threshold, 48%; highest rank, 39%; travel distance and ratio of Schedule II to total II-V prescriptions, 13%

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

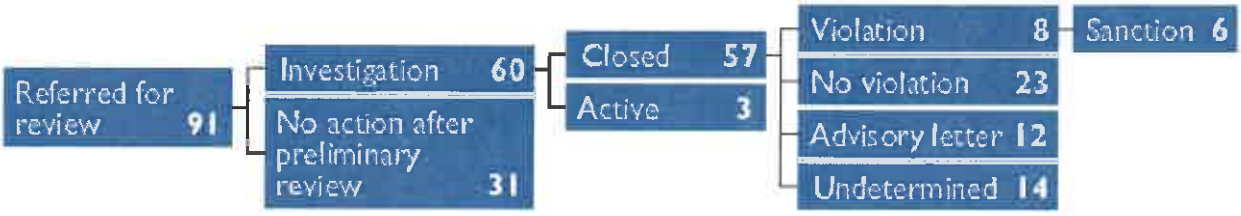

Fig. 11. 66% of prescribers/dispensers reviewed resulted in an investigation; 95% of investigations initiated were closed as of September 2021 with the following final dispositions: violation, 14%; no violation, 40%; advisory letter, 21%; undetermined, 25%

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