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 3, 2021
1:00 PM
Virtual Access Only
*****Refer to Page 2 of the Agenda for Meeting Access Information*****

Call to Order: Dr. Gofton

- Welcome
- Virtual Meeting Procedures
- Introductions
- Approval of agenda
- Approval of minutes

Department of Health Professions Report: David Brown, D.C., Barbara Allison-Bryan M.D.

Legislation and Regulation Update: Elaine Yeatts
18VAC76-20-40: Standards for the manner and format of reports and a schedule for reporting

Presentation:
Substance Use Disorder and Medication Assisted Treatment at Department of Corrections-Michael Fatula, Department of Corrections (DOC)
Discussion:

Program Reports:
Program Operations: Carolyn McKann
Website Utilization
Appriss Call Center Utilization

Program Analytics: Ashley Carter
Quarterly Statistics Update

Program Director Report: Ralph Orr
SUPPORT ACT of 2018, Section 5042—Requirements: Discussion
42 CFR Part 2 and PMP reporting exemption: Discussion
Additional Updates

Meeting Dates for 2021:

- October 1st at 9:00am

Election of Chair and Vice-Chair, Term September 2021-June 2022

Adjourn Dr. Gofton

Virginia Prescription Monitoring Program
Instructions for Accessing June 3, 2021 Virtual Advisory Committee Meeting

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Virginia Department of Health Professions

PMP Advisory Committee Meeting

June 3, 2021

Call to Order

- **Welcome**
- Virtual Meeting Procedures
- Introductions
- Approval of Agenda
- Approval of Minutes

Department of Health Professions Report

David Brown, D.C., Director, Department of Health Professions

Dr. Barbara Allison-Bryan, Chief Deputy Director, Department of Health Professions

Lisa Hahn, Chief Operating Officer, Department of Health Professions

Legislation and Regulation Update

Elaine Yeatts, Senior Policy Analyst

18VAC76-20-40. Standards for the manner and format of reports and a schedule for reporting.

- Current language
- A. Data shall be transmitted to the department or its agent within 24 hours of dispensing or the dispenser's next business day, whichever comes later, as provided in the Electronic Reporting Standard for Prescription Monitoring Programs, Version 4.2 (September 2011) of the American Society of Automation in Pharmacy (ASAP), which are hereby incorporated by reference into this chapter.
- B. Data shall be transmitted in a file layout provided by the department and shall be transmitted by a media acceptable to the vendor contracted by the director for the program. Such transmission shall begin on a date specified by the director, no less than 90 days from notification by the director to dispensers required to report.

DISCUSSION: 18VAC76-20-40

- Including specific ASAP standard in regulation is counterproductive
  - Data submitters cannot employ changes/updates to the ASAP standard designed to accommodate reporting issues such as field length
  - Data submitters must report in different standard formats to states
  - PMP vendor can accommodate reporting of data in ASAP Standard versions 4.2 and 4.2a today. Version 4.2b is used in one state and can be enabled later if necessary
  - The PMP cannot add a reporting element without legislative authority or regulatory process
  - DHP must provide a file layout which is based on the ASAP Standard and 90 days notification must be given prior to new requirements
  - If a reporting element is added that is not in version 4.2 the version would become unavailable. However, such a change to add a reporting element and remove availability of a specific standard version would have had stakeholder input during the legislative or regulatory process

18VAC76-20-40: *Proposed language:*

18VAC76-20-40. Standards for the manner and format of reports and a schedule for reporting.

A. Data shall be transmitted to the department or its agent within 24 hours of dispensing or the dispenser's next business day, whichever comes later.

B. Data shall be transmitted in a file layout provided by the department and shall be transmitted by a media acceptable to the vendor contracted by the director for the program. Such transmission shall begin on a date specified by the director, no less than 90 days from notification by the director to dispensers required to report.

Presentation:

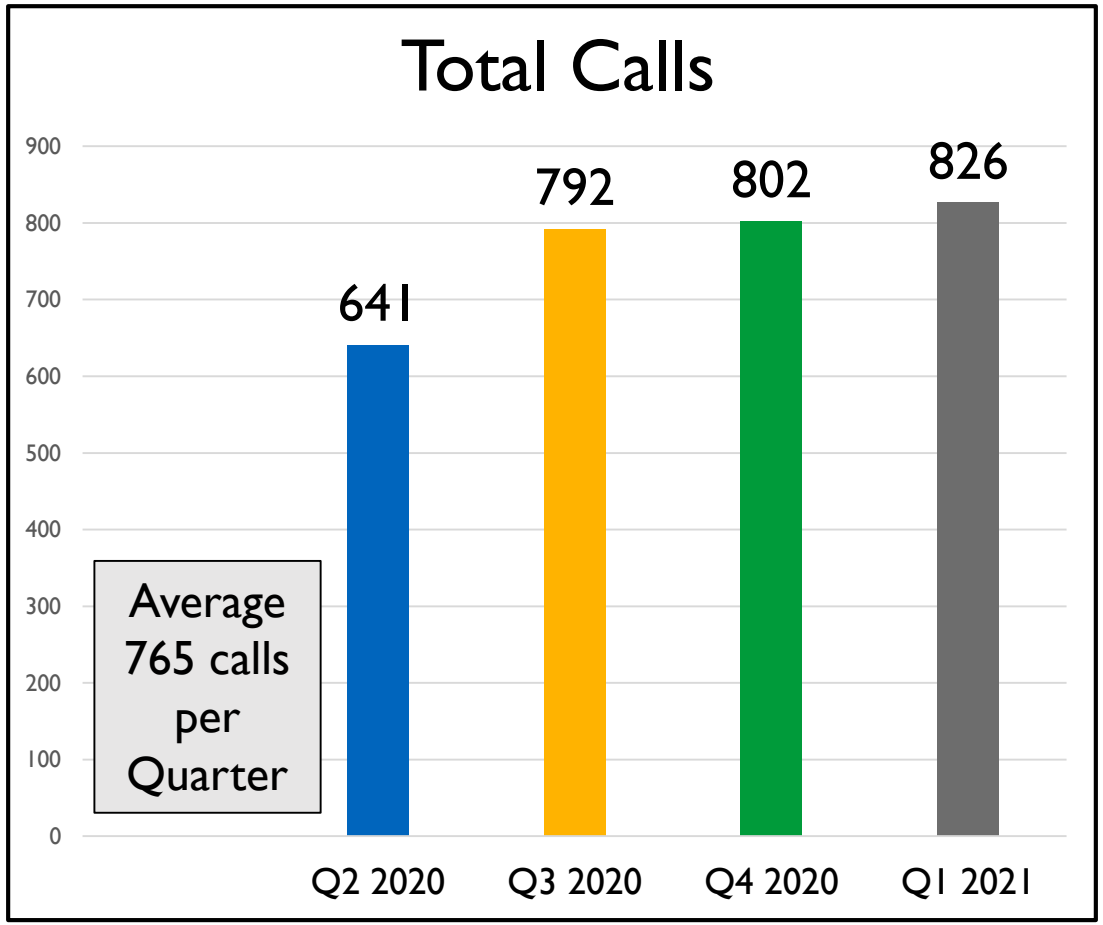
Substance Use Disorder and Medication Assisted Treatment at Department of Corrections:

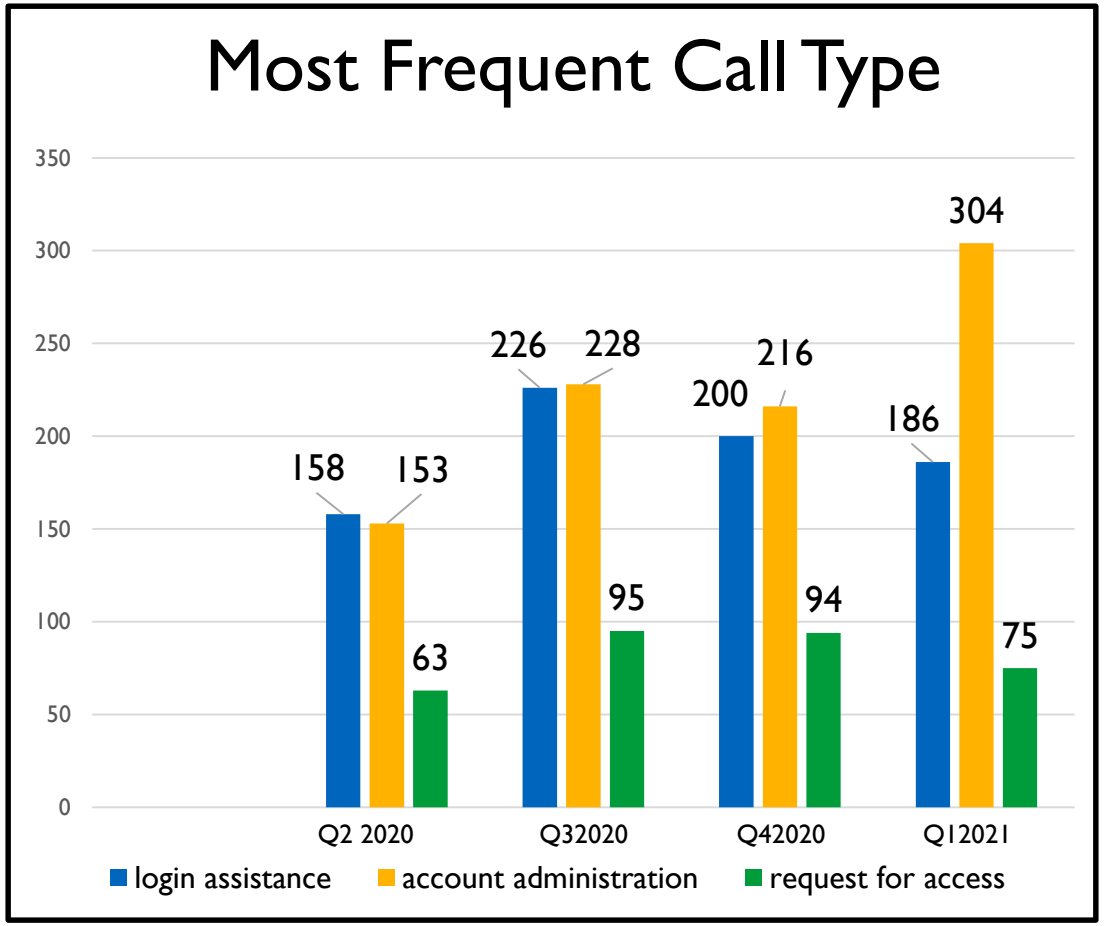
Michael Fatula, Department of Corrections (DOC)

Program Update: Operations

Carolyn McKann, Deputy Operations

Support Call Summary Q2 2020 – Q1 2021





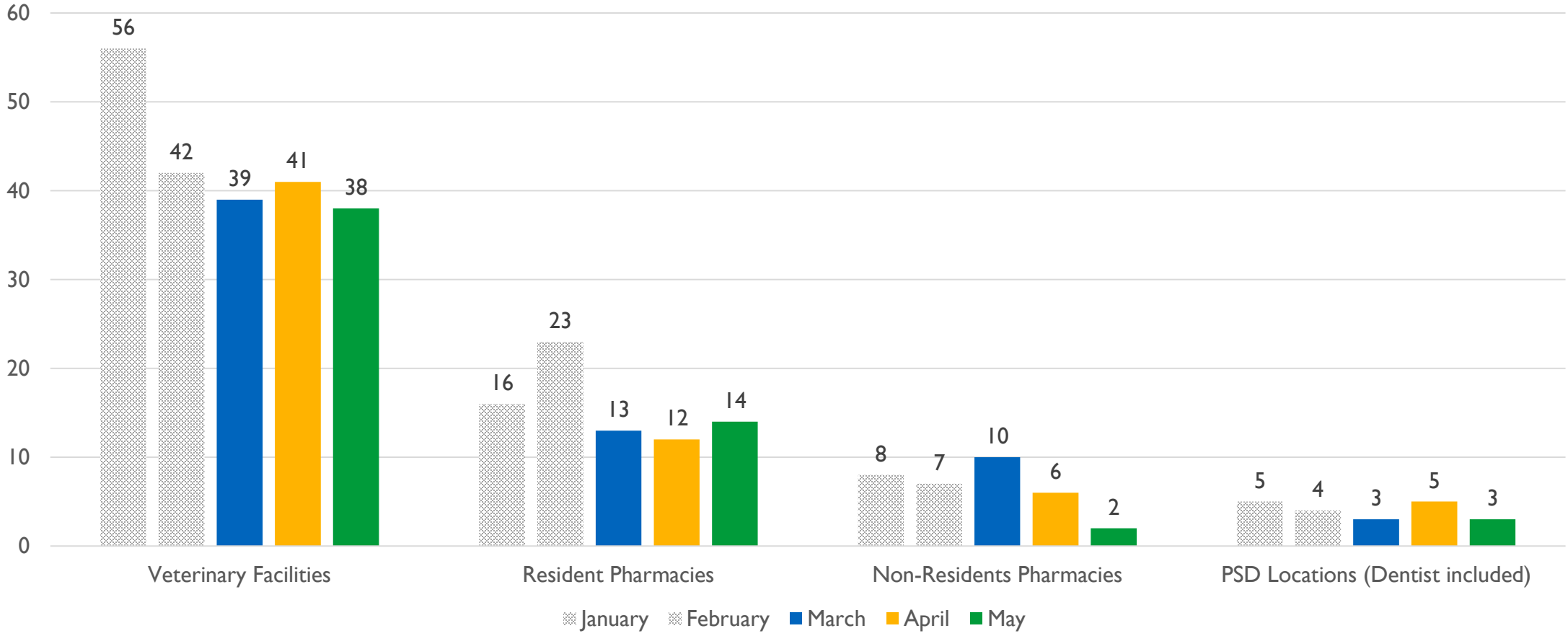
Website Utilization First Quarter 2021

Top Ten Visited PDF or Excel Files	
	Number of Hits
CDC Opioid Recommendations	372
Dr. Allison-Bryan's "PMP 101"	364
PMP Dispenser Guide	310
PMP AWARxE User Support Manual	263
2020 PMP Annual Report	206
PMP Regulations	193
2018 PMP Annual Report	134
Q4 2020 Quarterly Report	116
NarxCare Factsheet	104
Q12021 Newsletter (Reporting to the PMP)	100

During the first quarter of 2021, the PMP Website received 10,438 hits.

Virginia Department of Health Professions

Non-Compliant* Dispensers
by License Type



*Dispensers non-compliant for more than 7 days. Dispensers that have submitted missing data and now compliant may be included.

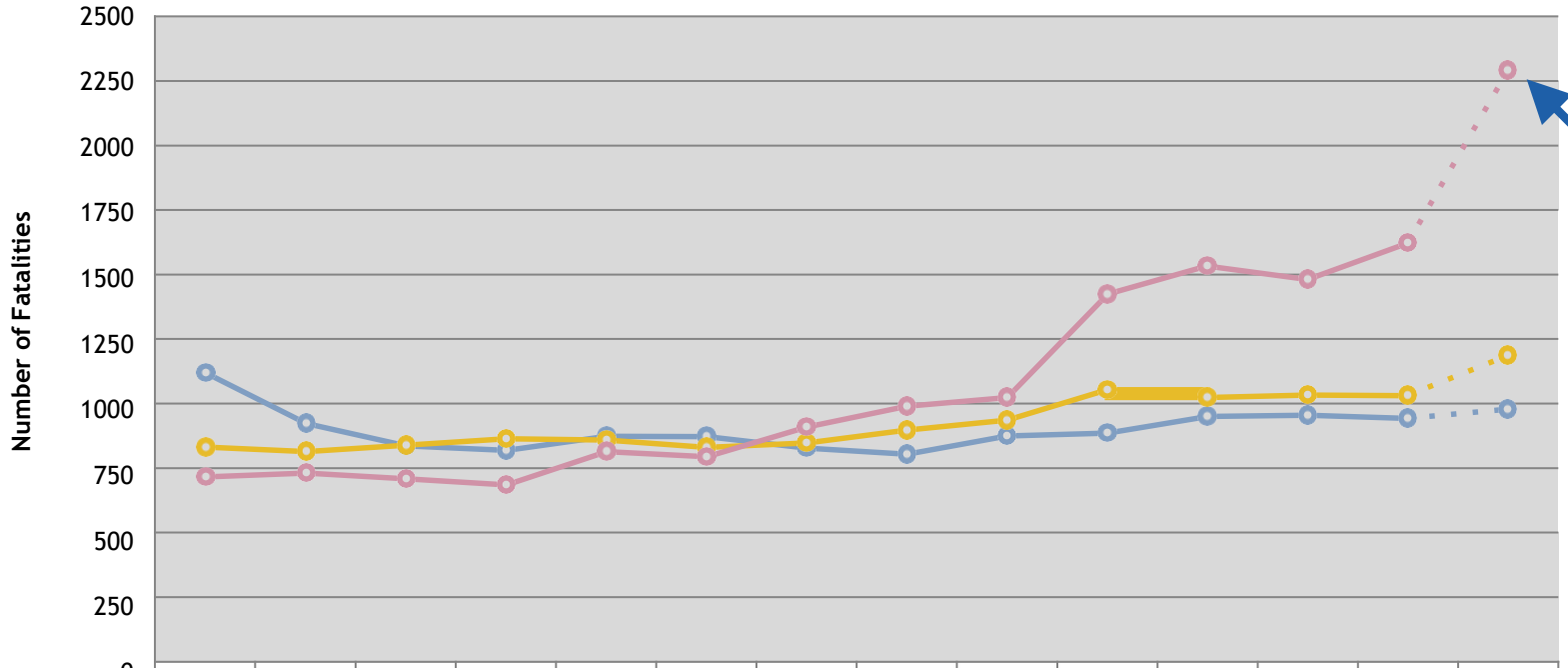
Program Update: Analytics

Ashley Carter, Senior Deputy

TOP 3 METHODS OF UNNATURAL DEATH

The leading methods of unnatural death in Virginia since 2007 have been motor vehicle collisions, gun-related deaths, and fatal drug overdoses (these methods of death include all manners of death: accident, homicide, suicide, and undetermined). In 2013, fatal drug overdose became the leading method of unnatural death in the Commonwealth. This trend has continued to worsen at a greater magnitude due mainly to illicit opioids (heroin, illicit fentanyl, and fentanyl analogs).

Total Number of Motor Vehicle, Gun, and Drug Related Fatalities by Year of Death, 2007-2020*



	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020*
Motor Vehicle Related	1124	928	841	823	878	877	832	808	879	890	955	960	947	982
Gun Related	836	818	843	868	863	835	852	901	940	1058	1028	1038	1036	1191
Fatal Drug Overdose	721	735	713	690	819	799	914	994	1028	1428	1537	1486	1627	2297

42% increase in 2020

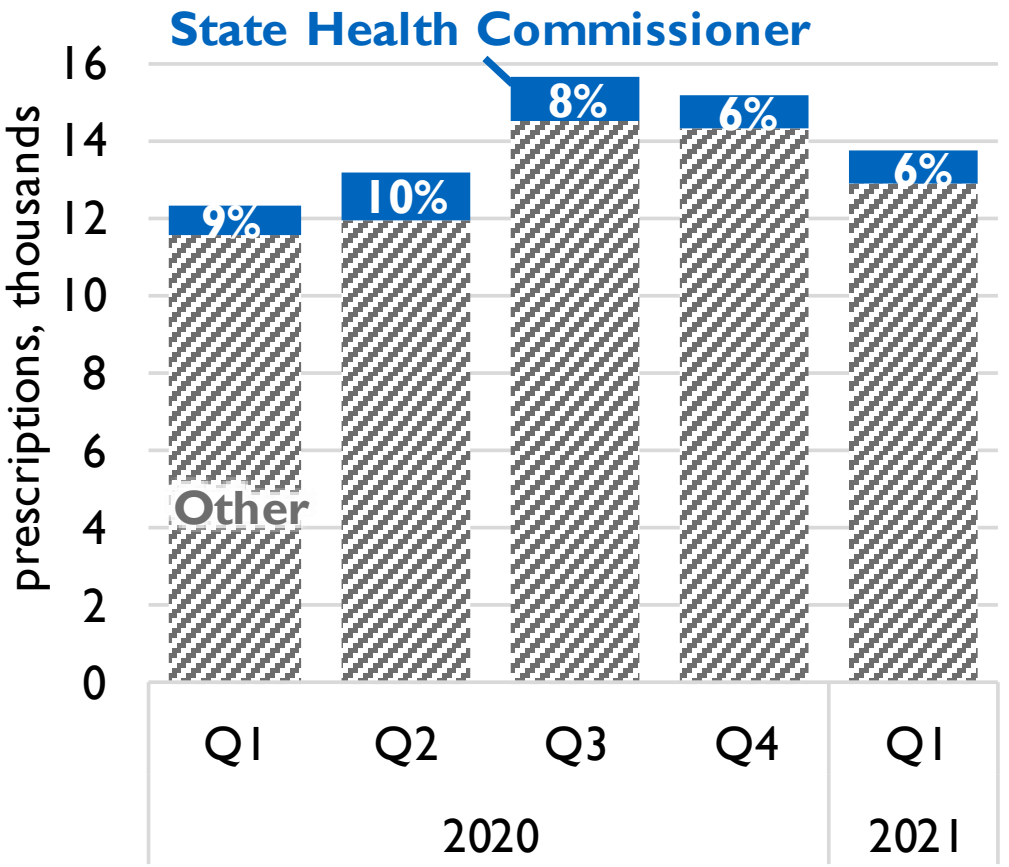
2020Q2: most overdoses ever recorded in Va.

[1] Top 3 methods of death (motor vehicles, guns, and drugs) include all manners of death (accident, homicide, suicide, and undetermined)

Naloxone

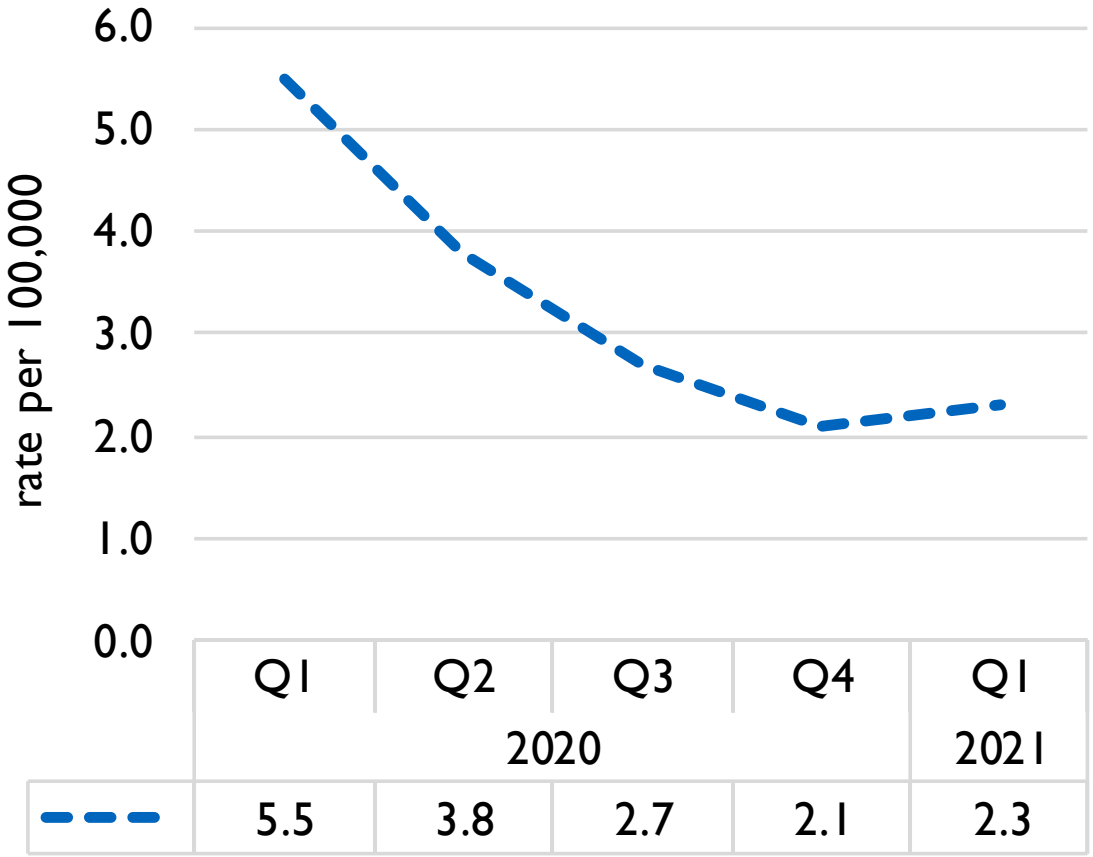
- State Health Commissioner's standing order authorizes Virginia pharmacies to dispense naloxone without a prescription
- 6% of total dispensations in 2021Q1 were dispensed using the standing order
- Naloxone became reportable to PMP as of July 1, 2018
  - Narcan® accounts for 99% of total naloxone dispensations

Naloxone prescriptions dispensed in pharmacies by prescriber, 2020Q1-2021Q1



Multiple provider episodes for opioids

- ≥5 prescribers and ≥5 pharmacies in a 6 month period
- Can be an indicator of doctor shopping and/or inadequate care coordination
- Between 2018Q1 and 2021Q1 dropped from 10.6 to 2.3 per 100,000

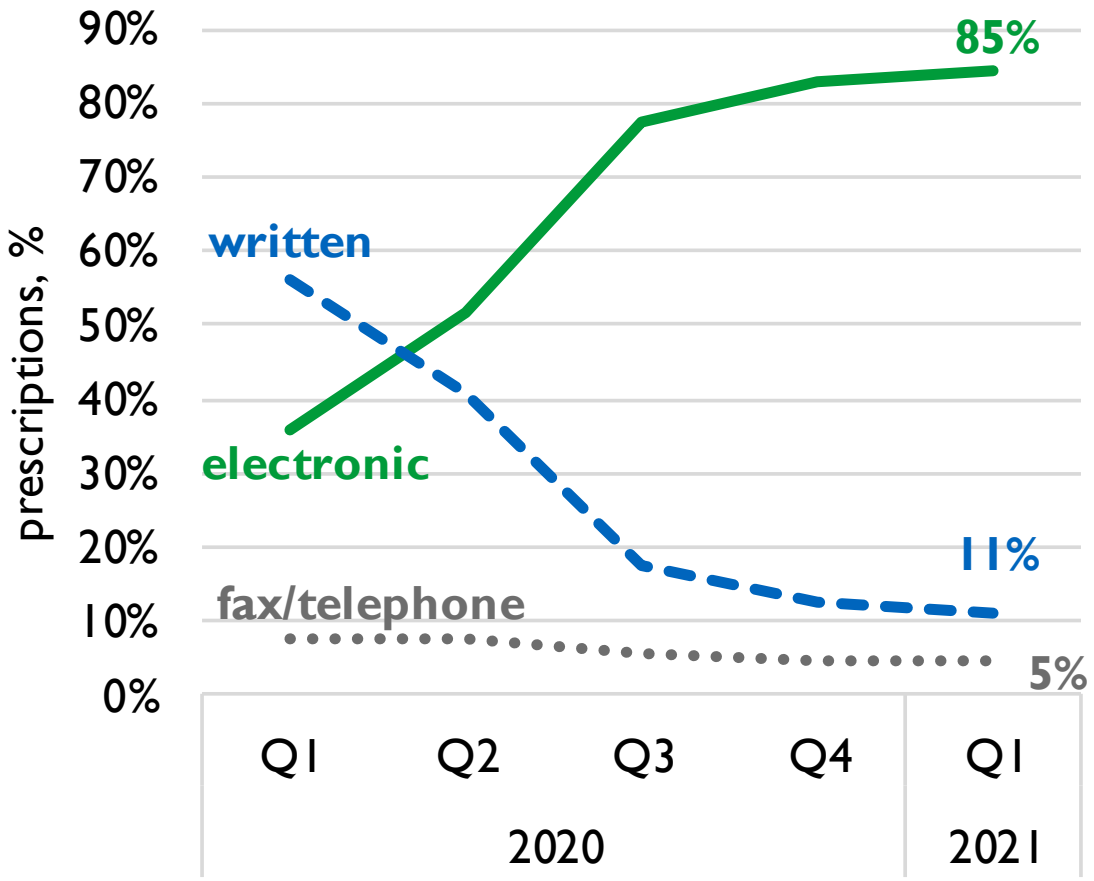


*CDC-defined opioids, excludes: 1) drugs not typically used in outpatient settings or otherwise not critical for calculating dosages in MME, such as cough and cold formulas including elixirs, and combination products containing antitussives. decongestants, antihistamines, and expectorants; 2) opiate partial agonists (e.g., buprenorphine)

Electronic prescribing for opioids

- As of 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)
- 85% of opioid prescriptions were electronic in 2021Q1

Opioid prescriptions by transmission type, 2020Q1-2021Q1



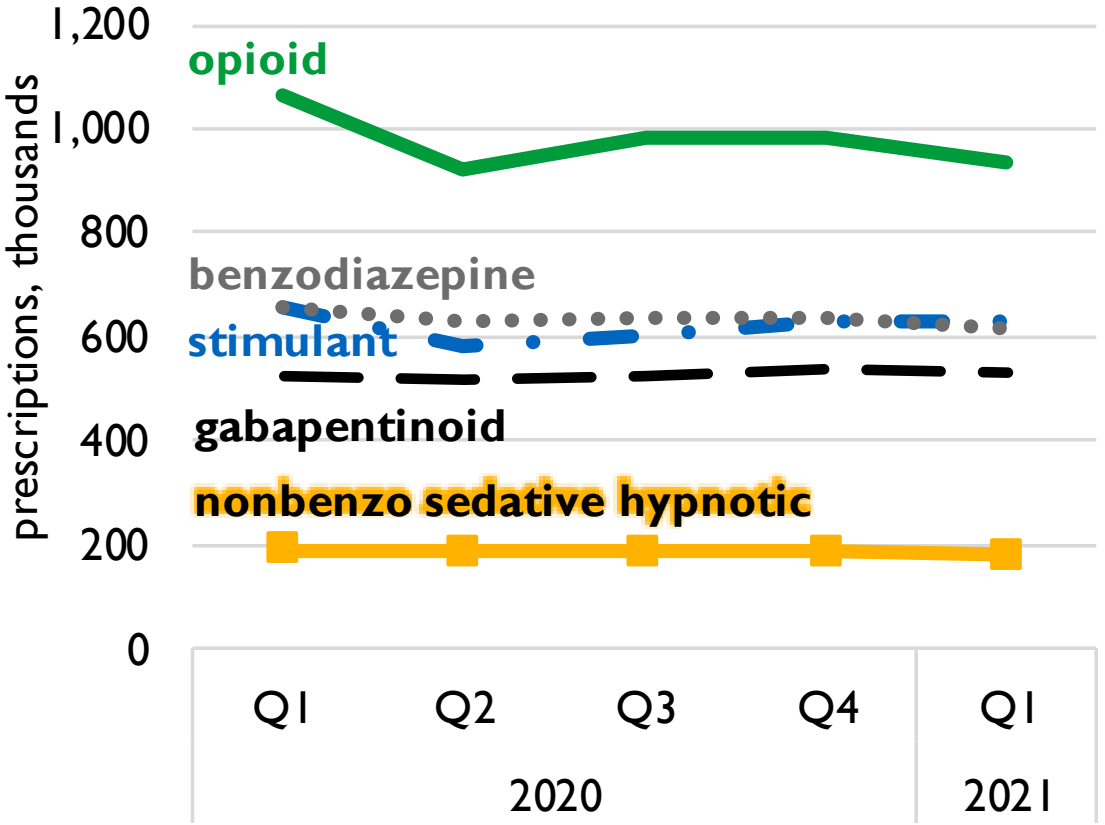
Analysis restricted to prescriptions reporting a mode of transmission
Code of Virginia § 54.1-3408.02 https://law.lis.virginia.gov/vacode/title54.1/chapter34/section54.1-3408.02/

Drug class

Percent change by drug class 2020Q1-2021Q1

- Opioid* ↓ 12%
- Benzodiazepine ↓ 6%
- Stimulant ↓ 4%
- Gabapentinoid ↑ 1%
- Nonbenzo sedative hypnotics ↓ 5%

Prescriptions dispensed by drug class, 2020Q1-2021Q1



*All opioids, including drugs not typically used in outpatient settings or otherwise not critical for calculating dosages in MME, such as cough and cold formulas including elixirs, and combination products containing antitussives. decongestants, antihistamines, and expectorants; opiate partial agonists (e.g., buprenorphine) is excluded

Program Director's Report

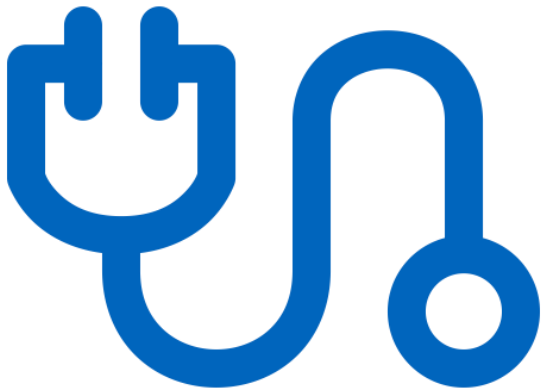
SUPPORT Act of 2018

What is a Qualified PDMP?

Sec 5042, Section 1944(b) of the Social Security Act, and CMS FAQs

SUPPORT Act requires PMP use

- Effective October 1, 2021, federal law requires a "covered provider" to the check the PMP before prescribing a controlled substance to a covered individual.
- This includes all drugs listed in Schedule II, not only opioids.
  - The state can also include drugs in Schedule III or IV.



PDMP 1: Covered providers have near real-time access

- Information regarding a covered individual's controlled substance prescription drug history
- The number and type of controlled substances prescribed to and filled for the covered individual during at least the most recent 12-month period
- The name, location, and contact information (or other identifying number selected by the state, such as a national provider identifier issued by the CMS National Plan and Provider Enumeration System) of each covered provider who prescribed a controlled substance to the covered individual during at least the most recent 12-month period

PDMP 2: Providers can easily use the PDMP information

- Through workflow integration
- May include electronic prescribing systems for controlled substances
- Current status
    - Integrated with over 5,300 facilities across Virginia
    - Integration supported for 455 EHR vendors, e-prescribing platforms and pharmacy software management systems
    - All 26 Veterans Health Administration facilities in Virginia are integrated

PDMP 3: Interoperability with other state PDMPs

- The state has data-sharing agreements with all contiguous states to track patients, prescribers, and prescriptions across state lines
  - Virginia's PMP is interoperable with all of its border states and the District of Columbia
  - Interoperable with 42 PMPs overall including the Department of Defense's Military Health System

PDMP 4: State Medicaid program access

- In accordance with state law, the state Medicaid program medical and pharmacy directors and their designees have access to the PDMP information in an electronic format based on data-sharing agreements in place
- In Code of Virginia today: 54.1-2523 Para C-9 and Para C-11

PDMP 5: Data for required reports

- The state produces data for the reports that are required to be submitted in the Annual Report to HHS in accordance with Section 1944 of the Act
    - Under Review with DMAS

PDMP 6: Utilization and quality reports

- The system produces reports to contribute to reports to HHS by the State Drug Utilization Review (DUR) Board and for program evaluation, continuous improvement in business operations, transparency and accountability, as well as identify patterns of fraud, abuse, gross overuse, excessive utilization related to limitations identified by the state, inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization among Medicaid physicians, pharmacists and enrollees associated with specific drugs or groups of drugs
- Reports that are specific to PDMP data and utilization may be generated by Virginia's PMP and its vendor within existing code and using data-sharing agreements

PDMP 7: Electronic case reporting

- The PDMP uses electronic case reporting to track opioid-related hospitalizations, emergency department visits, and/or urgent care visits
- Note: This requires clarification to determine what CMS is expecting

Current known status

- Ongoing conversations between CMS and Appriss Health
  - Review and discussion of examples of acceptable evidence for Operational Readiness Review
  - Development of metrics
  - Determine supporting data already available to CMS
  - Agreement between state and CMS

Virginia Department of Health Professions

42 CFR Part 2

PMP Reporting by Opioid Treatment Programs (OTPs)

Regulation Change to 42 CFR Part 2

- Appears to allow reporting by OTPs to state PMP
  - OTPs must be required to report to the PMP by state law
  - Patient consent must be given to the OTP to report
  - Some requirements raise questions
- Guidance suggests that OTP prescription information may not be provided for law enforcement or regulatory purposes
  - Unlike buprenorphine for MAT
  - PMP vendor does not currently have capability to restrict specific drugs to specific roles
- Some requirements cannot be accommodated using the ASAP standard used by PMPs and dispensers to standardize and facilitate reporting

Regulation Change to 42 CFR Part 2

- PMP currently has an exemption for reporting by OTPs in Code, legislation would be necessary to remove the exemption unless reporting by OTPs is specifically required in federal law (regulation?)
- OTPs generally dispense to patients on a daily basis, if these dispensations were reported to the PMP the report would become very cluttered, making it difficult for providers to identify overlapping or contraindicated prescription treatment received by the patient
- Unknown if PMP would have to track patient consent information
- More changes to the CFR are expected in the next year

Regulation Change to 42 CFR Part 2: Another Path to Inform Providers of OTP Participation?

- One state's PMP is currently considering an "ALERT" indicating that "Test Person is currently receiving substance use disorder treatment" or similar language
- The state uses one vendor to maintain a "Central Registry" of patients receiving SUD treatment at OTPs. The vendor would provide a file of patients to the PMP regularly. The specific OTPs would be responsible for patient consent.
- Legislative authority and SAMHSA review may be necessary
- Discussion

Quick Updates

Election of Chair and Vice-Chair

Term Begins September 2021

Meeting Dates and Adjournment

Next meeting date: October 1st, 9am

Adjourn