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# **Veterans Health Administration (VHA) Reporting to PDMPs**

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# Department of Veterans Affairs State Prescription Monitoring Programs

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# PDMP Data Transmissions from the Department of Veterans Affairs

Review of the legal history authorizing the VA to share data to Prescription Drug Monitoring Programs (PDMPs)

Status update on VA's current data sharing activities

Future plans and maintenance concerns with VA data transmissions





# **Initial Legislative Authority**

Under regulations the Secretary [of Veterans Affairs] shall prescribe, the Secretary may disclose information about a veteran or the dependent of a veteran to a State controlled substance monitoring program, including a program approved by the Secretary of Health and Human Services under section 399O of the Public Health Service Act (42 U.S.C. 280g–3), to the extent necessary to prevent misuse and diversion of prescription medicines.



# Revised Legislative Authority – MAY vs. SHALL

Under regulations the Secretary [of Veterans Affairs] shall prescribe, the Secretary shall disclose information about a veteran or the dependent of a veteran to a State controlled substance monitoring program, including a program approved by the Secretary of Health and Human Services under section 399O of the Public Health Service Act (42 U.S.C. 280g–3), to the extent necessary to prevent misuse and diversion of prescription medicines.



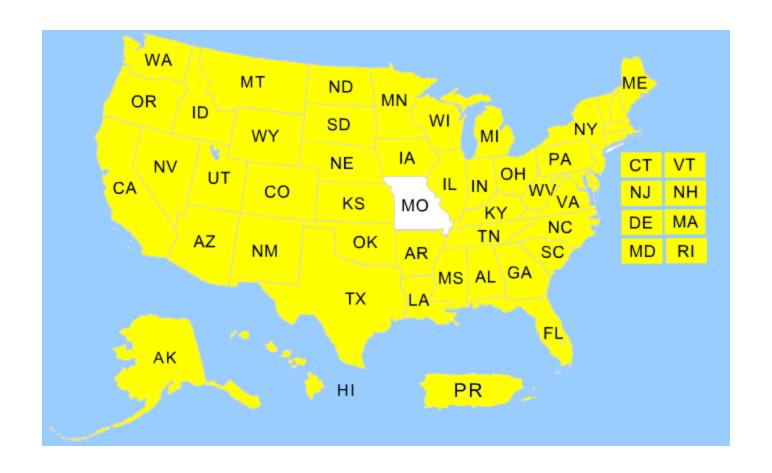
# **Current Legislative Authority**

- HR 1545 was signed by the President on 11/21/17 and became Public Law 115-86.
- The authority for VA to send data to State Prescription Monitoring Programs (SPMPs) now reads as follows:
- (1) Under regulations the Secretary shall prescribe, the Secretary shall disclose information about a veteran or the dependent of a veteran a covered individual to a State controlled substance monitoring program, including a program approved by the Secretary of Health and Human Services under section 3990 of the Public Health Service Act (42 U.S.C. 280g–3), to the extent necessary to prevent misuse and diversion of prescription medicines.
- (2) In this subsection, a 'covered individual' is an individual who is dispensed medication prescribed by an employee of the Department or by a non-Department provider authorized to prescribe such medication by the Department.





## **Transmission Status**







## **Exceptions**

- Missouri
  - Legislative/regulatory authority describes state-run programs
- Guam
  - All prescriptions dispensed to VA's Guam clinic are handled from the Honolulu HI VA Pharmacy (see ahead for discussion of business rules)
- CHAMPVA Meds by Mail (MbM)
  - Option A relates to internal VA enhancements
  - Option B for DoD-like approach
  - See ahead for additional discussion



# **VA Memorandum of Agreement**

- VA Internal IT Security Rules expect a Memorandum of Agreement / Interconnection Systems Agreement for any changes to the network firewall protection
- The authority (and requirement) to send data is in law and in regulation, but that doesn't completely remove the need for good communication between VA and states/vendors
- MOST HELPFUL -- Advance Notice for any IP Address changes
  - Takes weeks and sometimes months to request a new server URL to be enabled



### **Data Transmission Business Rules**

- VA sends data for all *federal* controlled substance prescriptions
- VA sends data to the SPMP of the state in which the pharmacy is geographically located
  - This is based on the computer setting of the pharmacy's "Mailing Frank Address/City/State/Zip"
- VA sends data shortly after midnight local time for prescriptions that were "released" yesterday
  - Release is a concept in the VistA EHR that incorporates pharmacist final check, prescription ready for window pickup, prescription entry to the postal delivery stream, etc.
  - Occasional automation workflows (e.g., ScriptPro) cause a prescription to be released twice ... VA has a workaround to address this





# **VOID Records**

- See previous slide re: VistA RELEASE Functionality
- VA is not a retail pharmacy; we do not "sell" prescriptions
- A VOID record is sent when a prescription that has been released is later RETURNED TO STOCK.
- Common scenarios
  - Prescription on shelf but never picked up
  - Prescription verified and filled but intercepted before dispensing due to change
- VA agrees that transmitting upon patient pick-up or mail delivery would be preferred but our EHR does not yet have a trigger at this point
- Enhancements to include a window pick up scan (proposed) and a manual VOID transmission in lieu of web site processes (original project interrupted) have been considered





# Comparison between VA model and DoD model

#### VA

- Transmissions similar to that of a National Network of Pharmacies
- Matches Process for neighboring retail pharmacies
- Community Prescribers access data through their existing EMR or State-based web portal in all locations

#### DoD

- Standalone Database similar to that of a "51st State"
- Provides DoD Operational Security
- Limited Access outside the Interstate Sharing Process



# **Future Development Plans**

### Distribution to State of Delivery

 VA recognizes that our Consolidated Mail Outpatient Pharmacy (CMOP) process is unique from traditional mail order pharmacies and that the business rules for transmission to the state in which the pharmacy resides does not offer insight for the state to which a CS prescription is delivered.

#### Centralized Connections

 Since the network firewall configuration changes are the VA's rate-limiting step, reducing the number of outbound connection points may improve the response time from the National Security Operations Center

# 2020 Development Project (Starting Soon...)

- 1. Transmit CMOP Prescriptions with delayed release ACK/acknowledgement to VistA
- (Re)Transmit by Date Range, Provider, Patient, Drug, Location, Rx #
- 3. Create system-generated Zero Reports
- 4. Send VOID Records from EHR instead of only via online portal
- 5. Address BUNAVAIL® buprenorphine/naloxone product
- Cancel batches that did not successfully transmit from VA to State/Vendor

...and a number of minor under-the-hood fixes.

This is clearly not everything that VA needs to enhance.





# **Meds by Mail / CHAMPVA**

- Establish 52<sup>nd</sup> State Approach?
- Develop additional capabilities to transmit to state of prescription delivery?
- Share DoD-like database?
- Other?



# **Data Sharing Constraints**

- Controlled Substance as defined by Federal Controlled Substance Act
- (b) *Definitions*. For the purposes of this section: Controlled substance means any substance identified in 21 CFR part 1308 as a schedule II, III, IV, or V controlled substance.

Interim Final Rule as originally published <a href="https://www.federalregister.gov/documents/2013/02/11/2013-03001/disclosures-to-participate-in-state-prescription-drug-monitoring-programs">https://www.federalregister.gov/documents/2013/02/11/2013-03001/disclosures-to-participate-in-state-prescription-drug-monitoring-programs</a>

Result – absence of authority or permission to share based on:

- State requests for state-level controlled substances (e.g., gabapentin)
- State requests for state-level products of interest (e.g., naloxone)





## Pharmacy and Provider – Two Directions of Data Flow

- VHA Pharmacy Benefits Management and VA Office of Information and Technology share responsibility for SPMP data OUTBOUND ... VA to State/Vendor
- VHA Primary Care Service holds responsibility for SPMP data INBOUND ... query via state website or (ideally) EHR integrated workflow approach
  - Documentation of provider query activities
  - Querying State Prescription Drug Monitoring Programs (PDMP)
    - https://www.va.gov/vhapublications/ViewPublication.asp?pub\_ID=32 83



# Department of Veterans Affairs Querying of State Prescription Drug Monitoring Programs

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Specialty Care Services, VHA





# **Topics**

Legal history

Current status

Future plans



# VA Has a Special Mission to Ensure Safe Prescribing and Prevent Drug Duplication or Diversion

- Veterans are at a high risk for adverse events and we take safety extremely seriously.
  - PDMP is just one of the risk/safety initiatives we have in place related to opioid usage and other controlled substances.
    - Urine Drug Screens
    - Informed Consent
    - Data tools to identify high risk patients and to have additional clinical reviews by specialized teams
- Not only are PDMP checks required by Federal law and recommended in Clinical Practice Guidelines, but it is clinically and administratively the right thing to do any time a clinician feels there may be a chance of adverse impacts caused by or related to a patient's medications.





## **Overdoses in Veterans**

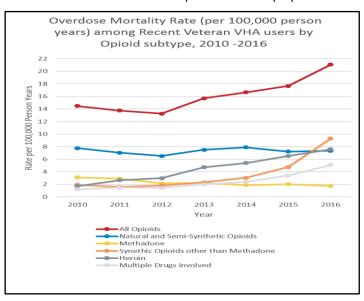
#### **VHA Veterans**

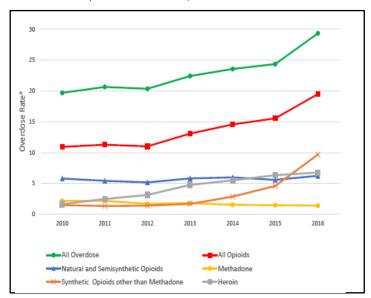
Opioid deaths 2016 Rate (per 100,000) 1,271 deaths; 3.5/day 21.1

#### **US Veterans**

2,775 deaths; 7.6/day 19.5

#### Comparison: US population rate 13.3/100,000 (in 2016, CDC)





Lin LA et al. Am J Prev Med. June 2019 Peltzman T et al. Am J Addict. 2020 Mar 29. [Epub ahead of print]





# **Legislative Mandates**

- Title IX: Jason Simcakoski Memorial Act Comprehensive Addictions Recovery Act of 2016 (CARA- Public Law 114-198) Section 911 – established requirement of VA clinicians to query state databases
- Maintaining Internal Systems and Strengthening Integrated Outside Networks
   Act (MISSION Act PL 115-251) Section 134 enhances VA clinicians and
   delegates authority to access all state databases
- Department of Veterans Affairs Expiring Authorities Act of 2018 (PL 115-251) expands the network of prescription drug monitoring programs available to VA health care providers to include state and regional programs not a part of the national network.
- Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Oct. 2018), H.R.6.
  - VA not mentioned specifically but support the requirements to enhance interoperability





# **Federal Mandates**

- Presidential Memorandum: Addressing Prescription Drug Abuse and Heroin Use (Oct. 2015)
- CDC Opioid Prescribing Guidelines (March 2016)
- Presidential Opioid Commission Report (November 2017)
- Nationwide Public Health Emergency to Address Opioid Crisis (Oct. 2017)
- President Donald J. Trump's Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand (March 2018)
- Office of National Drug Control Policy (ONDCP)
  - National Drug Control Strategy 2018, 2019, and 2020
  - Annual Performance Reporting System (PRS)





# Compulsory VHA PDMP Engagement

- GAO High Risk List 2021- in 2019, GAO highlighted "Federal Efforts to Prevent Drug Misuse which includes implementation of PMDPs
- OIG Audit Report #18-02830-164 VHA's Use of State Prescription Drug Monitoring Program Databases
- VHA Opioid Safety Initiative (OSI) guidelines issued as VA began opioid over prescribing in 2013
- GAO Report 18-380- Progress Made Towards Improving Opioid Safety, but Further Efforts to Assess Progress and Reduce Risk Are Needed
- OIG Report 17-01846-316 Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care
- VA has regular reports to Congress related to our PDMP work and other aspects of Opioid Safety
  - CTR 18-94- Report to Congress on Opioid Safety
  - CTR 18-112- Dependents and Prescription Drug Monitoring Program
  - CTR 18-202- Report to Congress on Prescription Drug Monitoring Program Utility
  - CTR 19- VA Participation in State Prescription Drug Monitoring Programs
  - CTR 19- Improvement of Opioid Safety Initiative
  - CTR 19- Opioid Therapy Clinical Practice Guidelines and Training
  - CMR 18-03- Tracking and Monitoring of Opioid Use
  - CMR 18-20- Report to Congress on Opioid Therapy and Prescription Rates
  - CMR 19- Progress Report on Actions Addressing Findings and Recommendations on VA Opioid Safety Initiatives





# VHA Specific

#### Opioid Safety Initiative and VHA Directive 1306:

- PDMP query rates have increased since the implementation of the PDMP Directive.
- 93.13% of Veterans on Long Term Opioid Therapy have a documented PDMP query within the last 365 days (as of August 5, 2020).
  VA providers documented over 7.3 million queries to PDMPS from June 2013
- VA providers documented over 7.3 million queries to PDMPS from June 2013 thru June 2020.
- Link to Directive:
   <a href="https://www.va.gov/vhapublications/ViewPublication.asp?pub\_ID=3283">https://www.va.gov/vhapublications/ViewPublication.asp?pub\_ID=3283</a>

#### Delegate Access:

Nationally, 35% of all VA PDMP queries are executed by delegates. Delegate access is critical to allow clinicians to maintain efficiency and effectiveness in their workflow while ensure this lifesaving practice is executed and within VHA's policy.

#### Oversight:

- Despite demonstrated VA progress, OIG issued a report in September 2019 with 8 recommendations related to VA PDMP utilization and compliance with VHA Directive 1306 and Clinical Practice Guidelines.
- Focus of the upcoming year will be improving compliance on ALL Controlled substances at all VA Hospitals (172) and VA Outpatient sites (1,241).





# VHA Specific

#### Current VHA policy:

- PDMP queried for all controlled substances on annual basis at a minimum.
- PDMP check prior to initiating therapy with a controlled substance.
- When clinical indications and patient safety concerns warrant <u>more frequently, at</u> the discretion of the prescriber.
- Prescribers must conform to the policies of the state of their licensure. This
  is key as VA Providers can work at any VA location if they have ANY state license
  - Relevant states: provider licensure, facility/practice location, Veteran residence
  - State policies vary greatly; several require PDMP check with each prescription.

Standard note title for documentation and monitoring policy compliance.

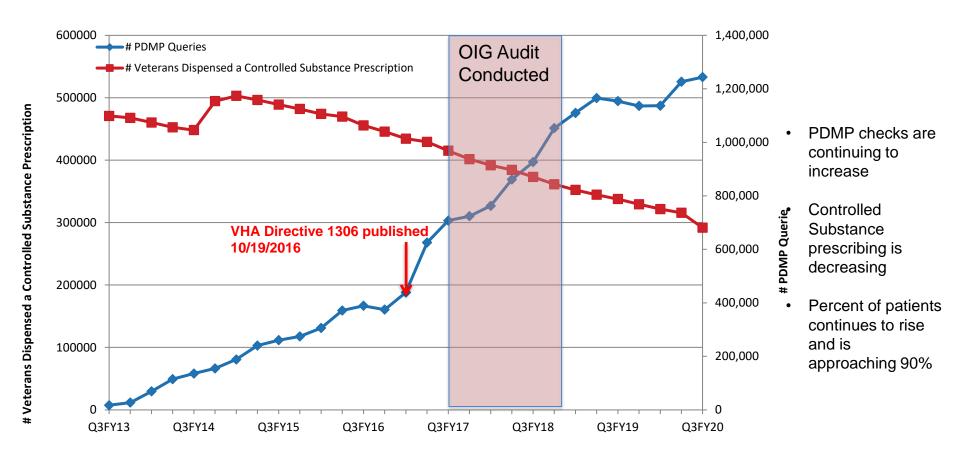
#### Exclusions

- Controlled substance prescription for ≤ 5-day supply without refills
- Any patient enrolled in Hospice care





# National: PDMP Queries and the Number of Veterans Dispensed a Controlled Substance Prescription







# **Current VA Compliance Rates**

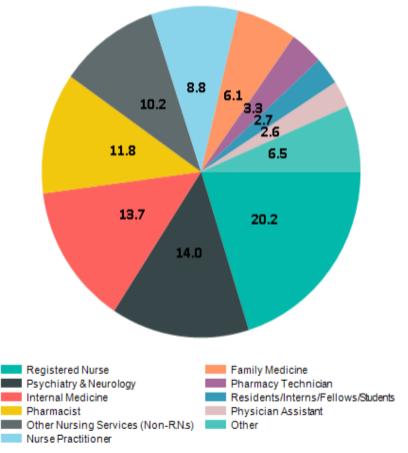
Quality Indicator	Location / Prescriber	Medications	Score (%)	Nat. Avg (%)	# Actionable Pats
Annual PDMP	National	All Controlled Substances (VA)	84.2	84.2	90,294
		Benzodiazepines (VA)	84.4	84.4	20,196
		Non-BZD Sed./Hypnotics (VA)	80.6	80.6	16,964
		Opioids (VA)	92.0	92.0	20,999
		Stimulants (VA)	86.3	86.3	7,673
		Other Controlled Substances (VA)	73.8	73.8	30,600
Quality Indicator	Location / Prescriber	Medications	Score (%)	Nat. Avg (%)	# Rxs w/o 90d PDMP
New Start PDMP (90 days)	National	All Controlled Substance Rxs (VA)	55.4	55.4	26,682
		Benzodiazepine Rxs (VA)	59.7	59.7	4,055
		Non-BZD Sed./Hypnotic Rxs (VA)	56.9	56.9	2,333
		Opioid Rxs (VA)	52.5	52.5	14,012
		Stimulant Rxs (VA)	65.7	65.7	2,146
		Other Controlled Substance Rxs (VA)	51.8	51.8	4,138





# National VHA PDMP Checks by Staff Type

National
% of PDMPs Checked in the last 90 Days by Staff Type



Source: VA Academic Detailing Dashboard

Staff Type	% PDMPs (90d)	
Registered Nurse	20.17	
Psychiatry & Neurology	14.01	
Internal Medicine	13.73	
Pharmacist	11.84	
Other Nursing Services (Non-R.N.s)	10.20	
Nurse Practitioner	8.81	
Family Medicine	6.12	
Pharmacy Technician	3.34	
Residents/Interns/Fellows/Students	2.72	
Physician Assistant	2.60	
MSA	1.12	
General Practice	1.07	
Emergency Medicine	0.66	
Clinical Nurse Specialist	0.50	
Nurse's Aide	0.44	
Physical Medicine & Rehabilitation	0.43	
Hospitalist	0.27	
Orthopaedic Surgery	0.24	
Pain Medicine	0.19	





# MISSION ACT – Section 134

MISSION Act Section 134 grants authority for VA clinicians and delegates to participate in all state-based prescription drug monitoring programs (PDMPs) regardless of state of licensure.

#### **Benefits:**

- Access to all state databases grants VA providers visibility into non-VA prescriptions, and other controlled substance prescriptions, Veterans have obtained, inside or outside the VA system in all 50 states.
- Requirement that all states allow VA prescriber and delegate access, means that VA clinicians can delegate a member of the team to conduct a query. This is critically important to an efficient, interdisciplinary workflow.
- Automated, not manual, solutions put in place for queries and data management surfacing the right information for clinical decision making – are imperative to improving care team/patient interactions.





# MISSION Act Section 134 – next steps

In order to fully codify the MISSION Act law and the subsequent Federal Code of Regulation updates, the VA must also publish a rule in the Federal Register regarding more specifics about how the law will be implemented. As of August 13, the subject matter experts are finalizing responses to internal Office of General Council (OGC) comments.

#### **Next steps:**

A stakeholder letter will be mailed to the states' PDMP administrators and other stakeholders for a 30-day comment period.

- 1. Any comments will need to be addressed and potentially included in the (final) draft rule.
- 2. OGC will review the final version of the regulation and the addendum which explains how the program office has addressed the comments.
- 3. VA will submit the proposed regulation to OMB for review targeted for fall.
- 4. The proposed draft regulation is targeted for release for public comment this winter.

Note: Although the regulation has not been published, many states are aware of the MISSION Act and are passing laws providing VA clinicians and delegates needed access. Florida passed state law to allow VA providers licensed out of state to access their database.





# **Security / HIPAA**

- As any PDMP data comes to the VA system, we treat it with the same security and privacy rules we treat our own data with:
  - Privacy Act of 1974, 5 USC 552a
  - Confidentiality of Certain Medical Records, 38 U.S.C
  - VHA Handbook 1605.1, Privacy and Release of Information
- National Association of Boards of Pharmacy (NABP)'s PMP Interconnect, Guidelines
- Every VA employee must take the following training annually:
  - VA Information Security and Privacy Awareness
  - HIPAA Action Refresher
  - Once the training is complete, we must sign a Rules of Behavior document stating that we understand the Rules of Behavior and the potential penalties of not following the rules.





# **On-going**

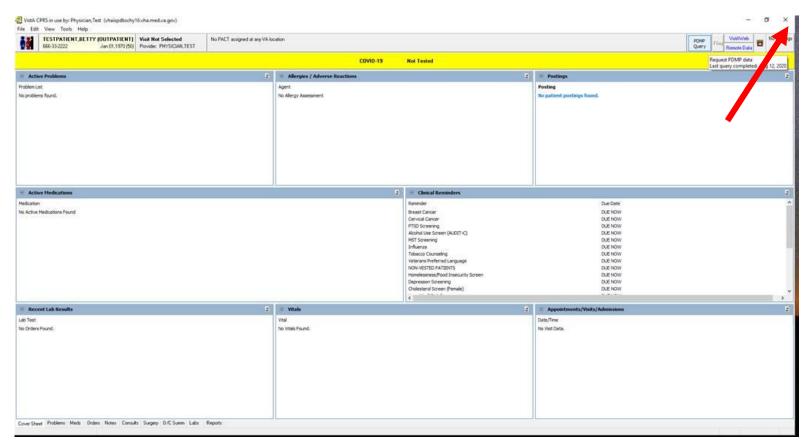
#### Technology Enhancement to our EHR

- One click access
- All available PDMP data (states and regions)
- Currently in test
- National role-out planned for October

#### Expectations of states:

- allow all VA providers and licensed delegates
- access regardless of physical location of Provider
- Work with VA and VA contractors to provide solutions to allow this access
- VA Directive 1306 is currently being revised to better align with compliance requirements from OIG, any updates in Clinical Practice Guideline recommendations and addressing new data available with greater access to states
- Queries conducted through NABP's PMP InterConnect will pull all medications of interest according to state requirements up to two years

# **VA EHR Software Screen**



- Integrated access within the EHR,
- Data displayed for review
- Provider will document as needed without any automated data storage,
- PDMP data will be reconciled with the medication list





# **Constraints**

- Need to finalize data access for states not in the VA solution using NABP's PMP InterConnect
- Change management
  - Training and integrated into the daily work and culture of VA clinicians, staff may still be apprehensive to change, despite our perceptions that this adds tremendous efficiency and value
- Timeframe required to publish final rule invoking federal supremacy
  - Rule making won't be complete until late 2021
- Parallel activities in two technology projects related to our EHRs to ensure equivalent solutions



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