

An Update to VHA's PDMP Reporting: Current and Future Perspectives

Rob Silverman, PharmD, ACHIP, FAMIA Danielle Kato, PharmD, MS, CUA Cindy Seburn, RPh

Veterans Health Administration, Patient Care Services, Pharmacy Benefits Management (PBM) Clinical Informatics

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Overview

- VHA pharmacy services: key concepts
- Regulatory impacts on data sharing to state prescription drug monitoring programs (PDMPs)
- Business rules for PDMP transmissions
- VistA pharmacy software development updates
- Operationalizing American Society for Automation in Pharmacy (ASAP) standards evolution and coordination with states for specific requirements
- Sustaining VistA PDMP support and associated challenges
- Future challenges
- Discussion and opportunities



VHA Pharmacy Services

- Federal pharmacists only required to hold a license in one state
- Two primary pathways for dispensing prescriptions
 - Local VA Medical Center (VAMC): patient pick-up or mail
 - Consolidated Mail Outpatient Pharmacy (CMOP)
 - Mail only
 - Fills >80% of prescriptions (includes controlled substances)
 - CMOPs filling controlled substances located in various states
- CMOP prescription (Rx) workflow
 - VAMC Rx data transmits to CMOP, RXs are filled, verified/released, and shipped to patients
 - CMOP fill data written back to local VAMC
 - The prescription remains "owned" by the VAMC
 - CMOP is a fulfillment process, not a full mail order pharmacy



VA Pharmacy Services continued

- Electronic health records (EHRs) for Rx dispensing
 - − VistA: ~130 separate instances
 - Oracle Health Federal EHR: Medication Manager Retail
 (MMR): single seamless instance, now covering 6 facilities
- Release Date: data field that signifies a patient's receipt of the prescription
 - May be prior to when patient has medication in hand due to shipping transit times
 - When populated, renders an RX eligible for transmission to PDMPs
- CHAMPVA Meds by Mail (MbM)
 - Rx processing for patient's nationwide
 - Unique challenges for PDMP transmissions



Legislative Authority for Sharing Data

- Public Law 115-86 (VA Prescription Data Accountability Act 2017)
 - (1) Under regulations the Secretary [of Veterans Affairs] shall prescribe, the Secretary shall disclose information about 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.



Data Sharing Constraints

- Federally defined Schedules of Controlled Substances only
 - 21 CFR Part 1308 Schedules of Controlled Substances
 - Transmitting prescriptions outside of these constraints amounts to an unauthorized disclosure
- VA pharmacies cannot honor state requests to share prescription data where:
 - Individual states define a medication as a controlled substance (e.g., gabapentin)
 - States define products of interest to share with PDMPs (e.g., naloxone)
- These constraints can only be changed through legislative pathways



Business Rules for PDMP transmissions

- VHA Directive 1108.21 Pharmacy Clinical Informatics
 - Signed June of 2023
 - Section 4. PARTICIPATION IN STATE PRESCRIPTION DRUG MONITORING PROGRAMS
- VA pharmacy PDMP enrollment and transmission
 - Determined by geographical location of the VAMC
 - Exception: MbM data sent to state of prescription delivery
- Data sharing limited to federally scheduled drugs
- Minimum data requirements outlined



Business Rules continued...

- Daily transmissions required
 - Automated job tasked nightly
 - Transmits shortly after midnight
- VA pharmacies and rejected prescription data
 - Must receive rejected prescription data
 - Reconciliation within 3 business days
- CMOPs do not transmit data to PDMPs (because dispensing data is written back to local facilities and then transmitted)
- As of 12/18/2023, all VA pharmacies transmitting to state PDMPs (Missouri)



VA Specific Considerations

- VA Internal Information Technology (IT) Security Rules expectations
 - Memorandum of Agreement / Interconnection Systems
 Agreement for any changes to network firewall protection
 - Can take months to update firewall configurations
- Firewall access granted at the Internet Protocol (IP) address / port level
 - An unchanged Domain Name Server (DNS) name will still impact access
 - Early notification decreases risk of lapse in transmissions
- Secure File Transfer Protocol (sFTP)
 - VA's standard for data transmissions
 - Other technologies not supported at this time

VA prescriptions from CPRS



VistA Development Updates and Timelines

- Drug Addiction Treatment Act of 2000:
 DATA-Waiver (i.e., X-Waiver) Elimination
 - 12/29/2022: Congress signed the Consolidated
 Appropriations Act of 2023
 - 1/12/2023: Drug Enforcement Administration (DEA) notified registrants
- Leveraged existing VistA functionality to support the legislation's intent for prescribing
 - Menu option for marking products exempt from requiring a Detox/Maintenance number (the X-number)
 - Guidance for configuring buprenorphine-containing products as exemptions sent 1/23/2023
 - Permitted prescribing while options for software enhancements were explored



VistA Development Updates and Timelines

Enhancements for DATA-Waiver elimination

- Development project enhancing VA systems' handling of DEA registration information was already underway
- Identified requirements to decommission functionality
- ASAP Standard coded into VistA is version 4.2
 - 4.2A and 4.2B manually coded and configured at each individual VistA instance if state had implemented
 - Notified potential for receiving transmissions in ASAP v5.0 as early as January 2024
- Requested enhancements to address 4.2A, 4.2B, 5.0, future standards, and features to propagate statespecific variations of each standard



VistA Development Updates and Timelines

- VA's multi-year planning for enhancements spans multiple fiscal years (FYs)
 - Request entered early 2023, earliest possible FY
 prioritization 2026, and currently in prioritization phases
 - Software development timelines lag behind
- X-Waiver elimination (a best-case scenario)
 - Had configurable workaround
 - Critical needs overlapped current work
 - Software changes decommissioning majority of the DATA-Waiver functionality installed nationwide January 2024
- First ASAP v5.0 implementation
 - Mid-January 2024 with effective date July 1, 2024
 - Aware of imminent implementation by field pharmacist



Multiple Versions, States, and VA Facilities

- ASAP versions active in VA pharmacies (estimates irrespective of EHR)
 - -4.1-5 states, 16 facilities
 - 4.2 19 states, 42 facilities
 - − 4.2A − 13 states, 30 facilities
 - − 4.2B − 13 states, 41 facilities
 - 5.0 (soon 1 state, 1 facility)
- Six facilities (across 4 states on version 4.2A) using the Oracle Health Federal Electronic Health Record (EHR)
- VHA's Pharmacy Benefits Management Clinical Informatics Program Office (PBM CI) and VA's Office of Information and Technology (OIT) product support personnel partner to support VistA facilities



ASAP Version by State

ASAP 4.1

AK CA IA ID MI ASAP 4.2

AR DC DE GA HI IN MN MO NC ND NJ NM PA PR SD UT WI WV WY ASAP 4.2A

CT
IL
MA
ME
MT
NH
NV
OH
OR
RI
TN
VA
WA

ASAP 4.2B

AL
AZ
CO
FL
KY
LA
MD
MS
NY
OK
SC
TX
VT

ASAP 5.0

NE

Future July 2024

Reference for versions 4.1 thru 4.2B: TTAC January 2024 Presentation

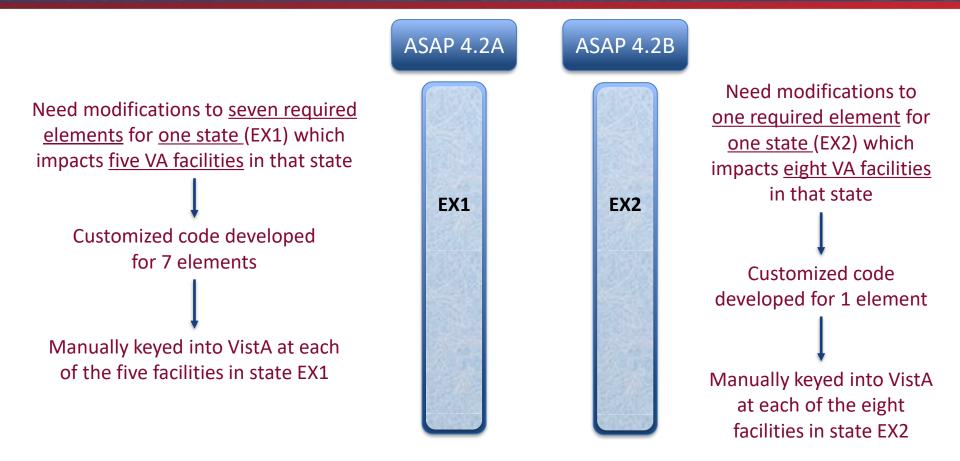


ASAP Version by State and VA Facilities

ASAP 4.1 ASAP 5.0 ASAP 4.2B **ASAP 4.2** ASAP 4.2A AR CT NE AK IL DC AZ CA DE MA CO 1 facility IA GA ME FL Future July 2024 ID HI MT KY MI IN NH LA MN NV MD 16 facilities MO OH MS NC OR NY ND RI OK NJ TN SC NM VA TX PA WA VT PR SD 30 facilities 41 facilities UT WI WV WY 42 facilities



State Customizations – VistA Use Case



Increasing number of versions in conjunction with state-specific differences for required elements and handling exceptions \rightarrow VA's standard must be customized for every state and version



Management and Operational Challenges

- Negotiating acceptable solutions and approaches to address variability and limitations in VA data
 - May require direct discussions between PBM clinical informatics and state PDMP administrators
 - Differences in acceptable ways of handling exceptions
- Limited situational awareness
 - National offices rely on communication from facilities
 - Often reactive and/or problem based
 - Cannot query into systems to ascertain configurations
 - Little-to-no visibility of planned PDMP changes communicated via dispenser accounts' email distributions



Supporting Individual VistA Facilities

Helpdesk tickets for unanticipated problems

- Example: transmission issues or other failures
- May be first indication of a change in expectations or configurations from the state

OIT does not have direct access to <u>all</u> VistA instances

- Support requires access of facility level informaticist
- Code for customized configurations manually keyed
 - Performed by the facility pharmacist
 - Observed by product support personnel via screen share
 - Time-consuming and potential for errors

General recommendations for site/PDMP communications

 Use of a group email (e.g., SiteNamePDMP@va.gov) over personal info (e.g., John.Doe@va.gov) so that updates and changes are entirely on the VA side and do not need vendor support for point-ofcontact changes



Supporting ASAP v5.0 Implementations

- Using dispensers' guides as primary resource
 - Reconciling VistA state configurations in new version against existing code for that state
 - Identifying new and/or consolidated fields that need generalized standard coding
- Addressing first state's specific requirements
 - Unique formatting (e.g., delimiters) and required elements
 - Negotiate exception handling for unavailable data → what's an acceptable alternative?
- What about next state that implements?
 - Process starts over with new state's dispensers guide



Persistent Challenges

- VA's reliance on dispensers' guides
 - VistA configured and coded based upon information within
 - If not included in dispensers' guides, likely VA is unaware
- Required data not available in VA systems
 - CMOP fills do not write back the filling pharmacists' name
 - State licensure information not housed within pharmacy application (pharmacy or prescriber)
 - Persons dropping off and picking up (AIR segments)
 - Diagnosis codes not connected to VA prescription data
 - VA does not "sell" prescriptions Release Date a common alternative but requires customization

- Treatment types not stored with prescription data



Persistent Challenges

- Managing multiple ASAP standard versions across multiple states and 130+ VA pharmacies
- Systems limitations
 - Difficulty accommodating condition-based transmissions
 - Cannot bulk change configurations remotely
- Different vendor processes (e.g., Secure Shell [SSH] public keys)
- Unexpected VA firewall access problems
 - VA security configures access at the IP address level
 - An unchanged DNS name does not equate to open firewall

 No national visibility into dispenser-level communications to individuals at VA facilities



Future Challenges

- Resources for software development to stay in compliance with evolving PDMP requirements
 - Extended timelines for funding
 - Availability of funding
- Unable (without significant lead time and development) to meet a real-time data transmission if it becomes a requirement
- Legislation that would change the scope of data sharing also inherently requires software development to modify the core functionality



Conclusions and Opportunities

- Advanced notification of planned changes to IP addresses and ports will avoid lapses in transmissions
- Dispensers' guides need to be comprehensive and updated regularly
 - Guide lists an element as optional, but it's required
 - Include reasons a transmission may be rejected
 - Address how extraneous segments are handled (i.e., ignored or rejected)
- Standardized nature of VA systems requires collaboration and communication with states to ensure seamless and successful transmissions



Questions may be directed to this email link:



PBM CI PDMP Points of Contact



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