Sustainability of the Prescription Monitoring Program

Joint Commission on Health Care
September 19, 2017 Meeting
Andrew Mitchell
Senior Health Policy Analyst
Outline

• Study Mandate
• Background
• Sustainable Funding Models
• Policy Options
Study Mandate

• In 2017, Senator Carrico, Sr. requested via SJR 285 that the JCHC study the sustainability of the Prescription Monitoring Program (PMP) and identify potential funding sources for its future operation.

• SJR 285 was left in the Senate Committee on Rules and agreed to by the Joint Commission on Health Care members at the May 23, 2017 work plan meeting.
Virginia PMP’s Goals

• Promote appropriate use of controlled substances for legitimate medical purposes, including deterrence of misuse, abuse and diversion of controlled substances, by:
  • Helping prescribers and pharmacists make safe prescribing and dispensing decisions
  • Identifying patients for risk of overdose
  • Monitoring patient compliance with treatment plan
  • Reducing illicit use of Controlled Substances

Virginia PMP – History/Evolution

• 2002: Authorized as a pilot project in Southwest Virginia to address prescription drug abuse
• 2006/7: Established as a statewide program based on $20M received from the federal court settlement agreement with The Purdue Frederick Company
• Selected current features
  • Database managed by the Department of Health Professions (DHP) collecting data on Schedule II – IV controlled substances and “drugs of concern” (currently tramadol, gabapentin)
  • PMP users:
    • Providers: Physicians, Nurse Practitioners, Physician Assistants, Optometrists, Podiatrists, Dentists
    • Dispensers: Pharmacists
    • Others: Law enforcement (for active investigations); Office of the Chief Medical Examiner
• Statutory Requirements:
  • Dispensers must report filled prescriptions within 24 hours
  • Prescribers must query PMP when initiating: opioid treatment anticipated to last more than seven days; opioid addiction therapy
Virginia PMP – Recent Programmatic Priorities

• User registration
  • DHP authorization of automatic user registration to PMP upon license renewal resulted in a 163% increase in registered users between October, 2015 and September, 2016

• Workflow integration
  • The current PMP user platform:
    • Requires users to step out of user workflow [e.g., Electronic Health Record (EHR) platform] and log into a stand-alone PMP platform
    • Does not provide patient-level analytics (e.g., patient risk scores)
  • Studies have found a lack of PMP integration with EHRs to be one of the most commonly cited barriers by providers to PMP use
  • Purdue Pharma L.P. is currently supporting integration with a 2-year $3.1M grant to integrate up to 18,000 users/400 pharmacies
  • DHP estimates the cost to integrate all PMP users to be $1.5M to $2.0M annually for the foreseeable future
Virginia PMP – Workflow Integration

- “Basic functionality”: Stand-alone/login-based platform; no analytics
Virginia PMP – Workflow Integration (2)

- “Enhanced functionality”: Integrated into provider/dispenser workflow with patient analytics

Source: Appriss
Virginia’s PMP Impact – Program Data*

- Available data routinely tracked by the Virginia PMP include:
  - Users (# registered to PMP, user characteristics, data requests)
  - Prescriptions (#/type of controlled substances entered into database)

- Virginia’s PMP program does not combine PMP data with other patient-level data to assess PMP implementation impact on outcomes

- Two analyses exist related to Virginia’s PMP:
  - 2016: between 2010-2015, there was a decrease in daily dose of opioids, while an increase in overdose deaths due to prescription opioids. No analysis was performed to determine what role the PMP/PMP requirements have played in trends.
  - 2011: Case study indicated Office of Medical Examiner used PMP data in multiple phases of death investigations (e.g., guiding tests/autopsies; finding evidence of diversion)

- More generally, few State Prescription Drug Monitoring Programs (PDMPs) conduct analyses linking PDMP implementation with outcomes (e.g., patient/provider behaviors; patient health outcomes)

* See Appendix for additional detail on the content of this slide
PDMP Impact – Research-based Evidence*

• Academic research on PDMPs has assessed provider/patient behaviors and health outcomes regarding:
  • Controlled substances prescriptions
  • “Doctor Shopping”
  • Non-medical use of prescription painkillers
  • Emergency Department visits
  • Drug overdose/mortality

• However, the evidence base on PDMP impact is limited in several ways:

  **Limitation:**
  • Randomized Control Trials’ gold standard methodologies not feasible
  • Wide variation in State-level PDMP implementation
  • Literature too nascent/diverse to combine data across individual studies

  **Consequences of Limitation:**
  • Difficulty establishing causality between PDMPs and outcomes
  • Reduction in generalizability across States
  • Uncertainty in expected magnitude of associations

* See Appendix for additional detail on the content of this slide
Virginia’s PMP in Comparison – Expenditures

- Across States, estimated annual operating expenditures range from $100,000 to $1.5 million

Sources: DHP; personal communications with State PDMPs
Virginia’s PMP in Comparison – Users

- Across States, the estimated number of registered users ranges from 1,700 to 150,000

Sources: DHP; personal communications with State PDMPs
Virginia’s PMP in Comparison – Activity

• Across States, the estimated annual number of controlled substances prescriptions filled (i.e., logged into the database) ranges from fewer than 1,000,000 to almost 47,000,000

Sources: DHP; personal communications with State PDMPs
Virginia’s PMP in Comparison – Activity

• Across States, the estimated number of annual inquiries ranges from around 100,000 to over 27,500,000

Sources: DHP; personal communications with State PDMPs
Virginia’s PMP Budget – Past Expenditures/Current Funding Sources

• Past Expenditures:

• Current Funding Sources: Source: DHP

<table>
<thead>
<tr>
<th>Basic functionality</th>
<th>Additional Initiatives</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>Source</td>
<td>Purpose/amount</td>
</tr>
<tr>
<td>PMP operational costs</td>
<td>Remaining funds in Purdue Frederick Company court settlement agreement</td>
<td>Prescriber reports ($50,000 for 2 years)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Advanced analytics ($30,000 for 2 years)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Strategic planning / resource allocation ($130,000 for 1 year)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Integration of up to 18,000 users/400 pharmacies ($3.1M for 2 years)</td>
</tr>
</tbody>
</table>
Virginia’s PMP Funding – Future Outlook

• For PMP basic functionality, court settlement agreement funds are anticipated to run out between FY2027 and FY2031 depending on future cost assumptions
  • Scenario 1: FY18 budget of $1.0M
  • Scenario 2: FY18 budget of $1.4M
  • Scenarios 1 & 2: annual 3% expenditure increase; 100% reinvestment of settlement interest

Source: DHP
Models of PDMP Financing

• Around 50% of States finance the majority of PDMP expenditures through fees assessed on:
  • Users (health professional and/or controlled substances registration fees); or
  • Authorities with oversight over PDMP users (regulatory Board funds)

• Around 20% of States finance the majority of PDMP expenditures through General Funds

• Less common models of State-level funding include:
  • Medicaid Fraud Unit revenue
  • Private donations / Foundation
  • Health insurance licensing fees

Source: PDMP TTAC
Suggested Models of Financing for Virginia’s PMP – Analytic Framework

• Overarching goal of sustainability is to maintain benefits of PMP use and potential benefits of increased PMP use to the Commonwealth

• Focus placed on options that do not incur additional costs to the Commonwealth

• The Commonwealth, PMP users and beneficiaries share interests, and potential responsibilities in, sustaining the PMP in terms of:
  • Basic functionality: stand-alone/login-based platform providing descriptive patient-level data
  • Enhanced functionality: platform integrated into provider/dispenser workflow (e.g., EHRs) providing patient-level analytics (e.g., patient risk scores)

• A transition period may be required to sustainably transition from the current model of financing to a longer-term solution
Suggested Models of Financing for Virginia’s PMP – Options Explored in Detail

<table>
<thead>
<tr>
<th>Model</th>
<th>Used by any PDMP?</th>
<th>Sustainability time horizon</th>
<th>Primary cost burden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Professional Licensing Fees</td>
<td>Yes</td>
<td>Long-term</td>
<td>Users</td>
</tr>
<tr>
<td>Health Insurance Premium Assessment</td>
<td>No</td>
<td>Long-term</td>
<td>Patients</td>
</tr>
<tr>
<td>Tax on Controlled Substances Sales</td>
<td>No</td>
<td>Long-term</td>
<td>Patients</td>
</tr>
</tbody>
</table>
## Suggested Models of Financing for Virginia’s PMP – Additional Options Reviewed

<table>
<thead>
<tr>
<th>Model</th>
<th>In use?</th>
<th>Sustainability time horizon</th>
<th>Primary cost burden</th>
<th>Reason(s) not recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider Controlled Substance registration fees</td>
<td>Yes</td>
<td>Long-term</td>
<td>PMP Users</td>
<td>Similar/identical in impact to professional licensing fees</td>
</tr>
<tr>
<td>General Funds (directly to PMP or via DHP)</td>
<td>Yes</td>
<td>Long-term</td>
<td>General Public</td>
<td>Incurs additional costs to Commonwealth</td>
</tr>
<tr>
<td>Medicaid Fraud Control Unit (MFCU) funds</td>
<td>Yes</td>
<td>Short-term / uncertain</td>
<td>Plan members</td>
<td>Variability in resource availability; MFCU funds already allocated to DMAS</td>
</tr>
<tr>
<td>State Police asset forfeiture funds</td>
<td>No</td>
<td>Short-term / uncertain</td>
<td>Incarcerated offenders</td>
<td>Variability in resource availability; funds already allocated by State Police</td>
</tr>
<tr>
<td>Medicaid drug rebate funds</td>
<td>No</td>
<td>Long-term</td>
<td>Industry</td>
<td>Funds already allocated by DMAS</td>
</tr>
</tbody>
</table>
Model 1: Professional Licensing Fee

- Where quantifiable, annual fees on professional licenses or controlled substances registration to support other States PDMPs range from $3 (CA) to $40 (NV)

<table>
<thead>
<tr>
<th>State(s)</th>
<th>Fee type</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA, KS, TX</td>
<td>Licensing</td>
<td>≤ $10</td>
</tr>
<tr>
<td>AL</td>
<td>Controlled Substances registration</td>
<td>$11-$20</td>
</tr>
<tr>
<td>CO</td>
<td>Licensing</td>
<td></td>
</tr>
<tr>
<td>NJ</td>
<td>Controlled Substances registration</td>
<td></td>
</tr>
<tr>
<td>AK</td>
<td>Licensing</td>
<td>&gt;$20</td>
</tr>
<tr>
<td>LA, NV</td>
<td>Controlled Substances registration</td>
<td></td>
</tr>
</tbody>
</table>

Source: personal communications with State PDMPs
Model 1: Professional Licensing Fee (2)

- A uniform fee increase of approximately $13 to $19 on health professions licensees required to register with the PMP would be anticipated to cover program costs of the PMP for basic functionality (projected to be $1.06M - $1.49M over the next five years)

<table>
<thead>
<tr>
<th>Health Profession</th>
<th># Required to Register With PMP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine</td>
<td>48,835</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>14,259</td>
</tr>
<tr>
<td>Dentistry</td>
<td>7,211</td>
</tr>
<tr>
<td>Nursing</td>
<td>6,748</td>
</tr>
<tr>
<td>Optometry</td>
<td>1,538</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>78,591</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Scenario</th>
<th>PMP Expenditures</th>
<th>Increased Annual Fee / Licensee</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY16 (actual)</td>
<td>$874,683</td>
<td>$11.13</td>
</tr>
<tr>
<td>FY18-FY22 average (low end)</td>
<td>$1.06M</td>
<td>$13.51</td>
</tr>
<tr>
<td>FY18-FY22 average (high end)</td>
<td>$1.49M</td>
<td>$19.09</td>
</tr>
</tbody>
</table>

Source: DHP
Model 1: Professional Licensing Fee (3)

- Compared to neighboring States, current license fee renewal levels for Virginia physicians and pharmacists – professions that make up 71% of required PMP registrants – are 3rd–lowest and at the median, respectively.

Sources: DHP; other State licensing agencies
Model 2: Controlled Substance Sales Tax

- 49 States (+ DC) exempt prescription medicines from sales tax
  - Illinois: taxes prescription medicines at a reduced rate (1%)
  - In 2014, Virginia’s Joint Subcommittee on Tax Preferences recommended continued exemption of sales and use tax on prescription medicines

- A Virginia Department of Taxation study estimated that sales tax exemptions for controlled substances resulted in approximately $32M in foregone revenue in 2011
  - Based on sales in 2011, a retail price sales tax of 0.013% to 0.026% on controlled substances sales would raise approximately $1M to $2M

- In CY2016, 13,847,223 controlled substances tracked by the PMP were dispensed
  - Based on controlled substances dispensed in 2016, a point-of-sale controlled substances tax of $0.08-$0.14 would raise approximately $1M to $2M

- The Virginia Department of Taxation estimates a one-time administrative cost of $83,400 in the first year and $21,620 thereafter to administer a new tax
Model 3: Health Insurance Premium Assessment

- Virginia’s State Corporation Commission’s (SCC) Bureau of Insurance currently assesses premiums on several types of insurers’ to support four funds

<table>
<thead>
<tr>
<th>Fund</th>
<th>Assessment as % total gross premium</th>
<th>Insurer type(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fire Program</td>
<td>1%</td>
<td>Fire, miscellaneous property and casualty, marine, homeowners, farmowners</td>
</tr>
<tr>
<td>Dam Safety, Flood Prevention and Protection Assistance</td>
<td>1%</td>
<td>Flood</td>
</tr>
<tr>
<td>Help Eliminate Automobile Theft</td>
<td>0.25%</td>
<td>Motor vehicle</td>
</tr>
<tr>
<td>Insurance Fraud</td>
<td>0.05%</td>
<td>Any</td>
</tr>
</tbody>
</table>

Source: Bureau of Insurance

- In considering a premium assessment on health insurers to support the PMP, it is important to note that:
  - An estimated 30% of health insurance policies in Virginia are fully-insured policies and regulated by the Virginia Bureau of Insurance across the individual, small employer, and large employer markets
  - The remaining 70% of health insurance policies are self-insured policies regulated by the US Department of Labor and would not be subject to an assessment by the Bureau of Insurance
Model 3: Health Insurance Premium Assessment (2)

• Based on premiums collected in 2016, an assessment of 0.01% - 0.02% on total health insurance premiums for policies regulated by the Virginia Bureau of Insurance would raise approximately $1M - $2M

• While the Bureau of Insurance does not assess insurance on a per policy basis, an assessment of 0.01% - 0.02% would equate to $0.95 - $1.78 per policy, on average

• The Bureau is not able to provide an estimate for an administrative cost for a premium assessment, but has indicated it would seek to minimize the cost

<table>
<thead>
<tr>
<th>Description</th>
<th>Individual</th>
<th>Small Employer</th>
<th>Large Employer</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Premium</td>
<td>$2,120,515,890</td>
<td>$1,854,759,912</td>
<td>$6,079,306,553</td>
<td>$10,054,582,355</td>
</tr>
<tr>
<td># certificates or policies</td>
<td>312,790</td>
<td>210,134</td>
<td>599,511</td>
<td>1,122,435</td>
</tr>
<tr>
<td># covered lives</td>
<td>468,593</td>
<td>374,977</td>
<td>1,134,959</td>
<td>1,978,529</td>
</tr>
</tbody>
</table>

Source: Bureau of Insurance
Comparison of Funding Models

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Amount needed to support PMP Functionality</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Basic alone*</td>
</tr>
<tr>
<td></td>
<td>Low end ($1.06M)</td>
</tr>
<tr>
<td>Licensing fee increase</td>
<td>$14</td>
</tr>
<tr>
<td>Controlled Substances sales tax</td>
<td></td>
</tr>
<tr>
<td>% retail price</td>
<td>0.014%</td>
</tr>
<tr>
<td>Flat point-of-sale</td>
<td>$0.08</td>
</tr>
<tr>
<td>Health insurance premium assessment</td>
<td></td>
</tr>
<tr>
<td>% total premium</td>
<td>0.011%</td>
</tr>
<tr>
<td>$ / policy***</td>
<td>$0.95</td>
</tr>
</tbody>
</table>

Example: Each of the following would generate enough revenue to support low-end estimates of basic PMP functionality expenditures (i.e., $1.06M):
- $14 increase in health professional license fee; OR
- Controlled Substances sales tax of 0.014% of retail price or $0.07 flat point-of-sale; OR
- Health insurance premium assessment of 0.011%

* Based on projected FY18-FY22 average ** Based on estimates for FY19 *** Informational only
# Virginia’s PMP – Sustainability Plan

The following outlines an illustrative transition plan – based on the 3 options for funding basic functionality – that is intended to maximize ongoing and future use/benefits of Virginia’s PMP while ensuring its long-term financing:

<table>
<thead>
<tr>
<th>Phase</th>
<th>Revenue source for PMP functionality</th>
<th># years</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Short-term | Basic: License fees AND/OR Tax on Controlled Substances AND/OR Health insurance premium assessment | 2-3 years | • Enhanced functionality supported by DHP using Purdue Frederick Company court settlement agreement funds  
  • Begins when Purdue Pharma LP $3.1M integration grant funds spent (anticipated end FY18) |
| Medium-term| Enhanced: DHP at 50%; health systems / hospitals / provider practices at 50% | 2-4 years | • 50% enhanced functionality supported by DHP using court settlement agreement funds  
  • Ends when court settlement agreement funds reach pre-determined floor (e.g., $5M) |
| Long-term  | Enhanced: Health systems / hospitals / provider practices at 100% | Indefinite | • Remaining court settlement agreement funds allocated by DHP to respond to program needs |
Policy Options

1. Take no action

2. Introduce legislation to amend the Code of Virginia authorizing the Department of Health Professions (DHP) to increase, by up to $30, licensing fees of health professions required to register with the Prescription Monitoring Program (PMP), provided that:
   • Annual fees/fee increases to support the PMP are deposited into a Virginia PMP fund, established by DHP and for the purpose of financing expenditures for basic PMP functionality
   • An enactment clause delays the effective date until the funds from the $3.1M Purdue Pharma integration grant have been distributed

3. Introduce legislation to amend the Code of Virginia authorizing the Virginia Department of Taxation to administer a retail sales or point-of-sale tax of 0.02% OR $0.10, respectively, on controlled substances, provided that:
   • Tax revenues to support the PMP are deposited into a Virginia PMP fund, established by the Department and for the purpose of financing expenditures for basic PMP functionality
   • An enactment clause delays the effective date until the funds from the $3.1M Purdue Pharma integration grant have been distributed
Policy Options

4. Introduce legislation to amend the Code of Virginia authorizing the Virginia Bureau of Insurance to assess health insurers 0.015% of the total premium of health plans in the individual, small employer and large employer markets, provided that:
   • Premium assessments to support the PMP are deposited into a Virginia PMP fund, established by DHP and for the purpose of financing expenditures for basic PMP functionality
   • An enactment clause delays the effective date until the funds from the $3.1M Purdue Pharma integration grant have been distributed

5. Introduce a budget amendment authorizing DHP to use, after funds from the $3.1M Purdue Pharma LP grant have been distributed, Purdue Frederick Company settlement agreement funds to support the integration of up to 100% of PMP users

6. Authorize a Non-General Fund appropriations increase of $110,000 for 1 Full-Time Equivalent position at the DHP to lead analyses drawing on PMP and other patient-level data sources that help the PMP meet its program goals of promoting appropriate use of controlled substances for legitimate medical purposes, including deterrence of misuse, abuse and diversion of controlled substances
Written public comments on the proposed options may be submitted to JCHC by close of business on October 12, 2017. Comments may be submitted via:

- E-mail: jchcpubliccomments@jchc.virginia.gov
- Fax: 804-786-5538
- Mail: Joint Commission on Health Care
  P.O. Box 1322
  Richmond, Virginia  23218

Comments will be provided to Commission members and summarized during the JCHC’s November 21st decision matrix meeting.

(All public comments are subject to FOIA release of records)
Citations
Citations

• Slide 4:

• Slide 6:

• Slide 9
  • Prescription Monitoring Program Center of Excellence at Brandeis, 2011. *Drug-Related Deaths in Virginia: Medical Examiner Use of PMP Data*,
  • Tennessee Health Licensure & Regulation Controlled Substance Monitoring Database Committee, 2017. *Controlled Substance Monitoring Database: 2017 Report to the 110th Tennessee General Assembly*
Citations


- Haegerich, T.M. et al., 2013. What we know, and don’t know, about the impact of state policy and systems-level interventions on prescription drug overdose. Drug and Alcohol Dependence, 145, pp.34–47.


Appendix: Additional Detail
Virginia’s PMP Impact – Program Data

• Across States that provide annual/routine PDMP reports, most produce descriptive reports with little analysis of the role that the PDMP may have in affecting outcomes or analysis of PDMP data with other data

• One State (Tennessee) performs epidemiological analyses that combine PDMP data with other patient-level data sources to identify markers of increased patient risk (e.g., mapping the natural history of addiction from prescription phase to identify “danger zones” when individuals are at higher risk for overdose/death).
PDMP Impact – Research-based Evidence

- Controlled substances prescribing
  - Several single-State studies have found associations between PDMP implementation and improved prescribing practices
  - Some multi-State studies have found associations between PDMPs and improved prescribing (e.g., among Medicaid populations; in the outpatient setting)
  - However:
    - Earlier studies generally unable to distinguish PDMP implementation from other policy changes
    - Magnitudes of associations in more recent studies have generally been modest

- Drug overdose/mortality
  - Multiple studies have found associations between PDMPs and decreased opioid-related mortality, although other studies have found no association with overall drug overdose mortality in most states

- “Doctor Shopping”
  - PDMPs associated with significant decrease in patients with 2 or more physicians sources of medications (one study)

- Non-medical use of painkillers
  - No association with PDMPs (one study)

- Emergency Department visits
  - No difference in ED visits involving opioid analgesics or benzodiazepine misuse in States with/without PDMP (two studies)