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

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Source: Appriss

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)

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

* See Appendix for additional detail on the content of this slide

Consequences of Limitation:

- Difficulty establishing causality between PDMPs and outcomes
- Reduction in generalizability
 across States
- Uncertainty in expected magnitude of associations

Virginia's PMP in Comparison – Expenditures

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



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

Basic f	unctionality	Additional Initiatives				
Purpose	Source	Purpose/amount	Source			
	Remaining funds in Purdue Frederick Company court settlement agreement	Prescriber reports (\$50,000 for 2 years)	VDH			
PMP		Advanced analytics (\$30,000 for 2 years)	VDH			
operational costs		Strategic planning / resource allocation (\$130,000 for 1 year)	DBHDS			
		Integration of up to 18,000 users/400 pharmacies (\$3.1M for 2 years)	Purdue Pharma LP			

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



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
 PDMP TTAC



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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 patientlevel 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

Model	Used by any PDMP?	Sustainability time horizon	Primary cost burden
Health Professional Licensing Fees	Yes	Long-term	Users
Health Insurance Premium Assessment	No	Long-term	Patients
Tax on Controlled Substances Sales	No	Long-term	Patients

Suggested Models of Financing for Virginia's PMP – Additional Options Reviewed

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

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)

State(s)		Fee type	Amount
•	CA, KS, TX	Licensing	< ¢10
•	AL	Controlled Substances registration	≤ \$10
•	СО	Licensing	¢11 ¢20
•	NJ	Controlled Substances registration	ŞTT-ŞZO
•	AK	Licensing	<u>∖¢20</u>
•	LA, NV	Controlled Substances registration	~320

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)

Health Profession	# Required to Register With PMP	Scenario	PMP Expenditures	Increased Annual Fee / Licensee
Medicine	48,835	FY16 (actual)	\$874,683	\$11.13
Pharmacy	14,259	FY18-FY22		
Dentistry	7,211	average (low end)	\$1.06M	\$13.51
Nursing	6,748	FY18-FY22		(() () () (() () ()
Optometry	1.538	average (high end)	\$1.49M	\$19.09
Total	78.591			

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



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

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

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 fullyinsured 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

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

Source: Bureau of Insurance

Comparison of Funding Models

	Amount needed to support PMP Functionality							
Funding Source	Basic alone*		Enhance	d alone**	Basic + Enhanced			
Funding Source	Low end (\$1.06M)	High end (\$1.49M)	Low end (\$1.5M)	High end (\$2M)	Low end (\$2.56M)	High end (\$3.49M)		
Licensing fee increase	\$14	\$19	\$19	\$25	\$33	\$44		
Controlled Substances sa	ales tax							
% retail price	0.014%	0.02%	0.02%	0.026%	0.036%	0.046%		
Flat point-of-sale	\$0.08	\$0.11	\$0.11	\$0.14	\$0.19	\$0.25		
Health insurance premiun	n assessr	nent						
% total premium	0.011%	0.015%	0.015%	0.02%	0.025%	0.035%		
\$ / policy***	\$0.95	\$1.32	\$1.34	\$1.78	\$2.29	\$3.10		

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:

Phase	Revenue s func	source for PMP ctionality	# years	Notes			
	Basic	Enhanced					
Short- term	 License fees AND/OR Tax on Controlled Substances AND/OR Health insurance premium assessment 	•License fees AND/OR	•DHP at 100% •2-3 years AND/OR •Tax on		•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		• 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) 			
pre ass Long- term		• 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 <u>increase</u>, by up to \$30, <u>licensing fees of health professions</u> 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 <u>retail sales or point-of-sale tax of 0.02% OR \$0.11, respectively, on controlled substances,</u> 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 <u>assess health insurers 0.015% of the total premium</u> 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
- 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

Public Comment

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

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 - Rasubala, L. et al., 2015. Impact of a Mandatory Prescription Drug Monitoring Program on Prescription of Opioid Analgesics by Dentists. *PLoS One*, 10(8), p.e0135957.
 - Yarbrough, C.R., 2017. Prescription Drug Monitoring Programs Produce a Limited Impact on Painkiller Prescribing in Medicare Part D. *Health Services Research*, p.n/a-n/a.

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 patientlevel 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 opioidrelated 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)