

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 4607-02
Bill No.: SB 768
Subject: Health Care; Health Care Professionals; Health and Senior Services Department;
 Pharmacy; Physicians
Type: Original
Date: April 18, 2016

Bill Summary: This proposal establishes a Prescription Drug Monitoring Act.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
General Revenue	\$0 or (\$941,971)	\$0 or (\$5,997,046)	\$0 or (\$6,649,829)
Total Estimated Net Effect on General Revenue	\$0 or (\$941,971)	\$0 or (\$5,997,046)	\$0 or (\$6,649,829)

ESTIMATED NET EFFECT ON OTHER STATE FUNDS			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
Total Estimated Net Effect on <u>Other</u> State Funds	\$0	\$0	\$0

Numbers within parentheses: () indicate costs or losses.

This fiscal note contains 14 pages.

ESTIMATED NET EFFECT ON FEDERAL FUNDS			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
Total Estimated Net Effect on <u>All</u> Federal Funds	\$0	\$0	\$0

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
General Revenue	0 or 3	0 or 41	0 or 41
Total Estimated Net Effect on FTE	0 or 3	0 or 41	0 or 41

Estimated Net Effect (expenditures or reduced revenues) expected to exceed \$100,000 in any of the three fiscal years after implementation of the act.

ESTIMATED NET EFFECT ON LOCAL FUNDS			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
Local Government	\$0	\$0	\$0

FISCAL ANALYSIS

ASSUMPTION

Oversight notes Section B of this proposal provides that the proposal will be submitted to a vote of the people at the November 2016 election. Therefore, Oversight will not present election costs in the fiscal note. In addition, Oversight will range agency costs as \$0 or the amount presented since, if the proposal does not pass, the provisions of the proposal will not take effect. In addition, costs for FY 2017 are presented for 6 months since election results are not certified until 30 days after the election (December 8, 2016) and it is assumed that implementation of the program would generally not begin until January, 2017.

§195.453 - Prescription Drug Monitoring Program

Officials from the **Department of Health and Senior Services (DHSS)** state Section 195.453 requires DHSS to establish and maintain a program monitoring the dispensing of all Schedule II, III, or IV controlled substances by all professionals licensed to dispense such substances in this state. Further requirements in Sections 195.458.2, 195.459.2, and 195.460.1 would require real-time reporting at the time of prescribing and dispensing with an automated system review and response to the prescriber or dispenser based on algorithms included in the system. Responses will be either "no concern" or "concern with an explanation" and the prescriber or dispenser will use that information along with their professional judgment to make the determination whether it is appropriate to prescribe or fill the prescription. All the transmissions from dispensers and prescribers that resulted in a "concern with an explanation" will be reviewed by the DHSS as time and staff permits and appropriate investigations, referrals, etc. will be completed.

DHSS anticipates the need to hire the following staff on the dates indicated below:

One Program Manager, Broad Band 3, (\$76,416 annually) to provide overall direction and management of the program development and present educational programs; hired in November 2016.

One Broad Band 2 Manager (\$64,160 annually) to manage the Administrative Office Support Assistants (AOSAs) and Health Program Representatives in the daily operation of the program, and present educational programs; hired in September 2017.

Two Investigative Managers (\$45,120 each, annually) to develop and implement investigative standards and scope of investigative activities; one hired in November 2016 and one hired in September 2017.

Two Investigators III (\$39,984 each, annually) to supervise and train lower level investigative staff, coordinate and participate in inspections/investigations; hired in September 2017.

ASSUMPTION (continued)

Eighteen Investigators II (\$37,176 each, annually) whose duties will include investigation and inspections related to "concern with an explanation" prescriptions; review of submitted documents as they relate to such prescriptions, etc; hired in September 2017.

Two AOSAs (\$27,828 each, annually) to direct support functions for the program; plans, assigns, directs, and coordinates work schedules and activities of the staff; one hired in November 2016 and one hired in September 2017.

Two Senior Office Support Assistants (SOSAs, \$25,572 each, annually) whose duties will include providing overall clerical support for the program, tracking documents, preparing packets for law enforcement referrals, etc.; hired in November 2017.

Eight Health Program Representative I (\$30,672 each, annually) to generate and perform preliminary review and follow-up on "concern with an explanation" prescriptions; hired in September 2017.

The average pharmacy fills 250 prescriptions per day. DHSS, Bureau of Narcotics and Dangerous Drugs (BNDD) estimates that typically 10 percent of these are for Schedule II, III, or IV controlled substances. For fiscal note purposes, DHSS estimates 25 prescriptions /pharmacy x 1,348 pharmacies = 33,700 prescriptions to be submitted daily X 365 days or 12,300,500 prescriptions annually will be submitted to the system for review. It is further assumed that 101 licensed ambulatory surgery centers would dispense 10 times per day on 246 surgery days (no weekends and not on 15 holidays) for a total of 248,460 prescriptions dispensed annually (101 ASCs X 10 prescriptions daily X 246 days per year). It is further assumed that some individual practitioners may dispense from their offices. The BNDD has 24,067 registrants in practitioner categories. Assuming that 25 percent of them dispense schedule II, III, or IV drugs = 6,017 practitioner dispensers (24,067 registrants X 0.25). If they are assumed to dispense once a day only on 246 days, there would be 1,480,182 dispensings annually (6,017 dispensing registrants X 246 days). The grand total for all dispensers is assumed to be 14,029,142 prescriptions annually (12,300,500 pharmacy + 248,460 ASCs + 1,480,182 practitioners). Data is not available to estimate the number of the above estimated prescriptions that might relate to an ultimate user under 18 years of age.

Based on a study of 2010 and 2011 data by the federal Substance Abuse and Mental Health Services Administration (SAMHSA) and documented in the National Survey on Drug Use and Health (NSDUH) Report, 4.83 percent of prescription pain relievers are used for non-medical purposes in Missouri. <http://archive.samhsa.gov/data/2k12/NSDUH115/sr115-non-medical-use-pain-relievers.htm>

ASSUMPTION (continued)

Applying 4.83 percent to the 14,029,142 anticipated annual controlled substance prescriptions to be dispensed results in 677,608 "concern with an explanation" prescriptions annually that will need to be reviewed and potential follow-up actions taken. This is an average of 2,606 to be followed-up on each work day (52 weeks X 5 work days = 260; 677,608 "concern" /260 days). These will be reviewed and followed-up on by the Health Program Representative I and investigative staff. The level of initial review will depend on the type and severity of "concern with an explanation" generated by the prescription.

Category	FY 2018 (Sept - June)			-----FY 2018-----	
	Number Statewide	Annual Transmissions	Reimbursement	Annual Transmissions	Reimbursement
Pharmacies	1,348	10,250,417	\$2,562,604	12,669,515	\$3,167,379
ASCs	101	207,050	\$51,763	255,914	\$63,979
Individual Practitioners	6,017	1,233,485	\$308,371	1,524,587	\$381,147
Totals	7,466	11,690,952	\$2,922,738	14,450,146	\$3,612,505

Section 195.453.8

Section 195.453.8 of the proposed legislation requires DHSS to reimburse dispensers for fees of transmitting the required information. Based on recent discussions with the industries affected, the dispensers who will qualify for reimbursement will fall into three categories – pharmacies, ambulatory surgical centers and individual practitioners – each transmission is expected to cost \$0.25. The number of transmissions is expected to grow three percent annually and is reflected below:

Each dispenser is expected to invoice quarterly for a total of 29,864 (7,466 dispensers X 4 quarters) invoices in FY 2018 and FY 2019. DHSS would also be required to hire staff in both the Division of Administration (DA) and the Division of Regulation and Licensure (DRL) to process the invoices received from dispensers.

Based on current department practices, each invoice will take 10 minutes to process in DRL and 10 minutes to process in DA. Three different job categories will work together as follows to pay an invoice. In DRL, an Office Support Assistant will take 2½ minutes to open the invoice, log it into the tracking system and forward it to the Account Clerk II. In DRL, an Account Clerk II will

ASSUMPTION (continued)

take five minutes to determine and assign the account coding and forward to the Accounting Generalist II for review and approval. In DRL, the Accounting Generalist II will take 2½ minutes to verify the coding and funding availability and approve the document for central processing. In DA, an Office Support Assistant will take 2 ½ minutes to open the invoice and distribute it to the Account Clerk II. This position is also responsible for filing the documents after the payment processing is complete. In DA, the Account Clerk II will take five minutes to review, audit, and enter the payment documents from DRL into SAM II. In DA, the Accounting Generalist II will take 2½ minutes to apply final approval to the payment. The additional FTE required for invoice processing is as follows:

29,864 invoices X 20 minutes per invoice = 597,280 minutes to process invoices. 597,280 minutes / 60 minutes per hour = 9,954 hours. 9,954 hours/2,080 = 4.79 FTE (rounded to 5.00), broken down as follows:

Job Title	Percent of the Time to Process a Claim	DRL FTE	DA FTE	Salary	Total Annual Salaries
Office Support Assistant	25	0.625	0.625	\$23,160	\$28,950
Account Clerk II	50	1.25	1.25	\$25,824	\$64,560
Accounting Generalist II	25	0.625	0.625	\$36,204	\$45,255
Totals	100	2.5	2.5		\$138,765

It is assumed these positions will be hired on January 1, 2018.

Oversight assumes the DHSS would not hire partial FTEs. However, to keep the total number of new staff at the 5 FTE DHSS has indicated would be necessary to process the claims, Oversight assumes DHSS would hire 1 FTE OSA, 3 FTE Account Clerk II, and 1 FTE Accounting Generalist II.

Section 195.468

DHSS is required to create and implement three PDMP-related education courses. DHSS is currently required to provide education courses and information by Section 195.198, RSMo, and assumes the new requirements will be met with existing resources.

ASSUMPTION (continued)

DHSS provided the response for the **Office of Administration (OA), Information Technology Services Division (ITSD)/DHSS**. Infrastructure costs were calculated using the FY 2016 State Data Center (SDC) Cost Allocation Plan (CAP) document. ITSD is assuming the use of an application built for the State of Missouri and hosted in the SDC. Prescription data is to be maintained for a maximum of 180 days. Aggregated information from each prescriber and dispenser data source shall remain segregated from any other data source. Three servers to include development, test, and production with 100 gb of disk storage each are needed. Funding has been identified as General Revenue based on language in the bill that directs the department to establish and maintain this program subject to appropriation.

It is estimated that FY 2017 ITSD costs to the General Revenue (GR) Fund will total \$761,341; FY 2018 GR costs will total \$497,275; and FY 2019 GR costs will total \$163,659.

Officials from the **Office of Administration (OA), Division of Facilities Management, Design and Construction (FMDC)** indicated this proposal will have a cost to the General Revenue Fund of \$198,030 for FY 2017; \$202,982 for FY 2018; and \$208,055 for FY 2019. These costs are building lease costs, fuel and utilities, and janitorial services for the DHSS.

Oversight notes that the proposal is to be put to a vote of the people in November 2016. Oversight assumes, if the proposal passes, DHSS will not need rental space until the beginning of FY 2018 as it is anticipated that only 3 FTE will be hired at the onset to develop the program. Oversight will present FY 2018 and FY 2019 lease, fuel and utilities, and janitorial services costs as \$0 or the amount provided by FMDC.

Officials from the **Department of Corrections (DOC)** state this legislation would create a new D felony supervised by the Department of Corrections. There is no historical data upon which to base a more accurate estimate of the impact of this felony, thus the standard response for a new D felony is used.

It is estimated that a new nonviolent D felony will result in an increase of one prison and two probation sentences each year. The prison sentence will yield a total of 1.5 years in prison followed by 2 years on parole, while the probation sentences will each yield a total of three years on supervision. The total impact of an increase of 1.5 offenders in prison and 8 clients on supervision will not be felt until the third year after implementation.

The FY 2015 average cost of supervision is \$6.04 per offender per day or an annual cost of \$2,205 per offender. The DOC cost of incarceration is \$16.809 per day or an annual cost of \$6,135 per offender.

ASSUMPTION (continued)

The DOC would assume this legislation will result in long term cost as indicated below; a 2% inflation factor has been included:

Year 2017 (6 months)	\$ 5,273
Year 2018	\$19,508
Year 2019	\$26,780
Year 2020	\$28,485
Year 2021	\$29,055
Year 2022	\$29,636
Year 2023	\$30,229
Year 2024	\$30,834
Year 2025	\$31,450
Year 2026	\$32,079

Oversight assumes the DOC can absorb the minimal costs for FY 2017 and will present FY 2018 and FY 2019 costs as \$0 or the amount provided since this proposal may be put to a vote of the people in November 2016.

Officials from the **Office of Secretary of State (SOS)** state each year, a number of joint resolutions that would refer to a vote of the people a constitutional amendment and bills that would refer to a vote of the people the statutory issue in the legislation may be considered by the General Assembly.

Unless a special election is called for the purpose, a joint resolutions proposing a constitutional amendment is submitted to a vote of the people at the next general election. Article XII section 2(b) of the Missouri Constitution authorizes the governor to order a special election for constitutional amendments referred to the people. If a special election is called to submit a Joint Resolution to a vote of the people, section 115.063.2 RSMo requires the state to pay the costs. The cost of the special election has been estimated to be \$7.1 million based on the cost of the 2012 Presidential Preference Primary.

The Secretary of State's office is required to pay for publishing in local newspapers the full text of each statewide ballot measure as directed by Article XII, Section 2(b) of the Missouri Constitution and Section 116.230-116.290, RSMo. The Secretary of State's office is provided with core funding to handle a certain amount of normal activity resulting from each year's legislative session. Funding for this item is adjusted each year depending upon the election cycle with \$1.3 million historically appropriated in odd numbered fiscal years and \$100,000 appropriated in even numbered fiscal years to meet these requirements. Through FY 2013, the

ASSUMPTION (continued)

appropriation had historically been an estimated appropriation because the final cost is dependent upon the number of ballot measures approved by the General Assembly and the initiative petitions certified for the ballot. In FY 2013, at the August and November elections, there were 5 statewide Constitutional Amendments or ballot propositions that cost \$2.17 million to publish (an average of \$434,000 per issue). In FY 2015, the General Assembly changed the appropriation so that it was no longer an estimated appropriation and the Secretary of State's office was appropriated \$1.19 million to publish the full text of the measures. Due to this reduced funding, the Secretary of State's office reduced the scope of the publication of these measures. In FY 2015, at the August and November elections, there were 9 statewide Constitutional Amendments or ballot propositions that cost \$1.1 million to public (an average of \$122,000 per issue). Despite the FY 2015 reduction, the Secretary of State's office will continue to assumed, for the purposes of this fiscal note, that it should have the full appropriation authority it needs to meet the publishing requirements. Because these requirements are mandatory, the SOS reserves the right to request additional funding to meet the cost of its publishing requirements if the Governor and the General Assembly again change the amount or continue to not designate it as an estimated appropriation.

In addition, many bills considered by the General Assembly include provisions allowing or requiring agencies to submit rules and regulations to implement the act. The SOS is provided with core funding to handle a certain amount of normal activity resulting from each year's legislative session. The fiscal impact for this fiscal note to the SOS for Administrative Rules is less than \$2,500. The SOS recognizes that this is a small amount and does not expect that additional funding would be required to meet these costs. However, the SOS also recognizes that many such bills may be passed by the General Assembly in a given year and that collectively the costs may be in excess of what the office can sustain with the core budget. Therefore, the SOS reserves the right to request funding for the cost of supporting administrative rules requirements should the need arise based on a review of the finally approved bills signed by the governor.

Oversight assumes the SOS could absorb the costs of printing and distributing regulations related to this proposal. If multiple bills pass which require the printing and distribution of regulations at substantial costs, the SOS could request funding through the appropriation process.

For the purpose of this proposed legislation, officials from the **Office of State Public Defender (SPD)** cannot assume that existing staff will provide competent, effective representation for any new cases where indigent persons are charged with any of the proposed new crimes relating to dispensation of pharmaceuticals monitoring.

ASSUMPTION (continued)

While the number of new cases may be too few or uncertain to request additional funding for this specific bill, the SPD will continue to request sufficient appropriations to provide effective representation in all cases.

Oversight assumes the SPD can absorb the additional caseload that may result from this proposal.

Officials from the **Office of Attorney General (AGO)** state section 195.460 authorizes the bureau of narcotics and dangerous drugs to notify the appropriate professional licensing entity of violations of law or breaches of professional standards. This could result in an increase in caseload. Without knowing the number of resulting disciplines or appeals, the AGO assumes any potential costs arising from this proposal can be absorbed with existing resources. However, if there is a significant increase in the number of referrals, the AGO may seek additional appropriations.

Officials from the **Joint Committee on Administrative Rules (JCAR)** state the legislation is not anticipated to cause a fiscal impact to JCAR beyond its current appropriation.

Officials from the **Department of Insurance, Financial Institutions and Professional Registration, the Department of Mental Health, the Department of Public Safety, Missouri State Highway Patrol, the Missouri Office of Prosecution Services, the Office of Administration divisions of: Administrative Hearings Commission, Purchasing and Materials Management, and General Services, and the Office of State Courts Administrator** each assume the proposal would not fiscally impact their respective agencies.

<u>FISCAL IMPACT - State Government</u>	FY 2017 (6 Mo.)	FY 2018	FY 2019
GENERAL REVENUE FUND			
<u>Costs - DOC</u> (§195.465)	\$0 or...	\$0 or...	\$0 or...
Increase in incarceration and probation/parole costs	\$0	(\$19,508)	(\$26,780)
<u>Costs - DHSS</u> (§§195.450 - 195.462)	\$0 or...	\$0 or...	\$0 or...
Personal service	(\$99,576)	(\$1,215,453)	(\$1,498,491)
Fringe benefits	(\$52,434)	(\$665,098)	(\$823,160)
Equipment and expense	(\$28,620)	(\$473,992)	(\$317,179)
Rent and utilities	\$0	(\$202,982)	(\$208,055)
IT consultant costs & on-going expenses	(\$761,341)	(\$497,275)	(\$163,659)
Reimbursement to dispensers	<u>\$0</u>	<u>(\$2,922,738)</u>	<u>(\$3,612,505)</u>
Total <u>Costs</u> - DHSS	<u>\$0 or</u>	<u>\$0 or</u>	<u>\$0 or</u>
	<u>(\$941,971)</u>	<u>(\$5,977,538)</u>	<u>(\$6,623,049)</u>
FTE Change - DHSS	0 or 3 FTE	0 or 41 FTE	0 or 41 FTE
ESTIMATED NET EFFECT ON THE GENERAL REVENUE FUND	<u>\$0 or</u>	<u>\$0 or</u>	<u>\$0 or</u>
	<u>(\$941,971)</u>	<u>(\$5,997,046)</u>	<u>(\$6,649,829)</u>
Estimated Net FTE Change on the General Revenue Fund	0 or 3 FTE	0 or 41 FTE	0 or 41 FTE
 <u>FISCAL IMPACT - Local Government</u>	 FY 2017 (6 Mo.)	 FY 2018	 FY 2019
	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>

FISCAL IMPACT - Small Business

This proposal could have a negative fiscal impact on small business practitioners who dispense drugs from their offices as well as small business pharmacies and surgery centers.

FISCAL DESCRIPTION

This act establishes the Prescription Drug Monitoring Act. The Department of Health and Senior Services is required to establish and maintain a program to monitor the prescribing and dispensing of all Schedule II through Schedule IV controlled substances by all licensed professionals who prescribe or dispense these substances in Missouri. The Department shall use an existing data aggregation platform through the State Data Center within the Office of Administration to establish the Prescription Drug Monitoring Program (PDMP). The provisions of this act shall be subject to appropriations and may also be funded by federal or private moneys.

The Department shall ensure the privacy and security of personal information while only aggregating necessary and appropriate information related to the prescribing or dispensing of Schedule II through Schedule IV controlled substances. The aggregated information from each prescriber and dispenser data source shall remain segregated from any other data source. All submitted prescription and dispensation information shall be kept confidential with specified exceptions.

Most prescribers may, and all prescribers who hold themselves out to the public as pain management specialists and all dispensers shall, electronically submit to the Department information for each prescription or dispensation of a Schedule II through Schedule IV controlled substance. The Department may issue a waiver to a dispenser who is unable to submit the required information electronically. If a waiver is obtained, a dispenser can submit the required information in paper format or by other approved means. The Department shall reimburse each dispenser for the fees of transmitting the information required by this act.

This act delineates the duties of the prescribers, dispensers, and the Department for communicating when there is a prescription for or dispensation of a Schedule II through Schedule IV controlled substance. If the Department responds with a message that there was a concern detected and describes the nature of that concern, the prescriber or dispenser shall issue the prescription or the medication according to his or her professional judgment appropriate to the concern communicated. If the response is not timely, the prescriber or dispenser shall issue the prescription or the medication according to his or her professional judgment.

The Department shall review the prescription and dispensation information and, if there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the Department shall notify the appropriate law enforcement or professional regulatory entity and provide the prescription or dispensation information required for an investigation. If, after staff review, it appears that there is reasonable cause to believe that a person has obtained a prescription fraudulently from more than one prescriber, the Department shall contact the

FISCAL DESCRIPTION (continued)

prescribers, inform them of the potential problem and provide details, and request copies of medical records concerning the prescriptions of concern. The prescribers shall provide the records, if possible, by fax or electronically. If, after Department review of the provided records, it is clear that a person has obtained prescriptions under false pretenses, the entire matter shall be referred to the appropriate law enforcement agency or local prosecuting attorney for action. Nothing in the PDMP database shall be the sole basis for probable cause to obtain an arrest or search warrant as part of a criminal investigation.

Any person who unlawfully and knowingly accesses or discloses prescription and dispensation monitoring information or prescribers and dispensers who knowingly fail to submit the required information or who knowingly submit incorrect information shall be subject to penalties and shall be guilty of a Class A misdemeanor. Any persons authorized to have prescription or dispensation information who knowingly disclose such information or who use it in a manner and for a purpose in violation of the act shall be guilty of a Class D felony until December 31, 2016, and a Class E felony beginning January 1, 2017. Additionally, this act provides a private cause of action for persons whose data has been disclosed to an unauthorized person. Recovery under this cause of action for negligent disclosure shall include liquidated damages of \$25,000 and compensatory economic and non-economic damages, attorney fees, and court costs. Punitive damages are available for intentional and malicious unauthorized disclosure. Neither the sovereign nor the official immunity doctrines shall apply to a person or department authorized to have private medical information who discloses such information to unauthorized parties.

The Department shall annually provide to the General Assembly a report as to the number of controlled substances dispensed, broken down by drug, the number of incidents of fraudulent prescriptions identified and any other pertinent information requested by the General Assembly.

The Department shall create and implement an educational course regarding the provisions of this act and, when appropriate, shall work with associations for impaired professionals to ensure the intervention, treatment, and ongoing monitoring of patients who have been identified as being addicted to substances monitored by the act.

The provisions of this act shall not apply to Schedules II, III, and IV controlled substances prescribed or dispensed where the ultimate user is an individual under 18.

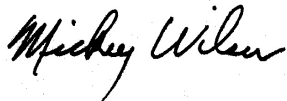
The provisions of this act shall expire on August 28, 2021.

This act contains a referendum clause.

This legislation is not federally mandated and would not duplicate any other program; however, this legislation would require additional capital improvements or rental space.

SOURCES OF INFORMATION

Office of Attorney General
Department of Health and Senior Services
Department of Insurance, Financial Institutions and Professional Registration
Department of Mental Health
Department of Corrections
Department of Public Safety -
 Missouri State Highway Patrol
Joint Committee on Administrative Rules
Missouri Office of Prosecution Services
Office of Administration -
 Administrative Hearing Commission
 Facilities Management, Design and Construction
 General Services Division
 Information Technology Services Division
Office of State Courts Administrator
Office of Secretary of State
Office of State Public Defender



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