

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 0607-07
Bill No.: #Perfected SS for SCS for SB Nos. 63 and 111
Subject: Health Care Professionals; Health Department; Drugs and Controlled Substances;
 Pharmacy
Type: #Corrected
Date: March 31, 2015
 # To correct bill title.

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

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2016	FY 2017	FY 2018
General Revenue	Could exceed (\$966,393)	Less than (\$5,846,402)	Less than (\$6,536,227)
Total Estimated Net Effect on General Revenue	Could exceed (\$966,393)	Less than (\$5,846,402)	Less than (\$6,536,227)

ESTIMATED NET EFFECT ON OTHER STATE FUNDS			
FUND AFFECTED	FY 2016	FY 2017	FY 2018
Total Estimated Net Effect on <u>Other</u> State Funds	\$0	\$0	\$0

Numbers within parentheses: () indicate costs or losses.
 This fiscal note contains 13 pages.

ESTIMATED NET EFFECT ON FEDERAL FUNDS			
FUND AFFECTED	FY 2016	FY 2017	FY 2018
Total Estimated Net Effect on <u>All</u> Federal Funds	\$0	\$0	\$0

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)			
FUND AFFECTED	FY 2016	FY 2017	FY 2018
General Revenue	5	May be less than 41	May be less than 41
Total Estimated Net Effect on FTE	5	May be less than 41	May be less than 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 2016	FY 2017	FY 2018
Local Government	\$0	\$0	\$0

FISCAL ANALYSIS

ASSUMPTION

In response to the previous version of this proposal, officials from the **Department of Health and Senior Services (DHSS)** provides the following information:

For purposes of this fiscal note, it is assumed that the Prescription Drug Monitoring Program (PDMP) system will be functional in September 2016.

Section 195.453

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 and Section 195.459 would require real-time reporting at the time of dispensing with an automated system review and response to the dispenser based on algorithms included in the system. Responses will be either "no concern" or "concern with an explanation" and the dispenser will use that information along with their professional judgment to make the determination whether it is appropriate to fill the prescription. All the prescriptions that resulted in a "concern with an explanation" will be reviewed by the DHSS as time and staff permit 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 develop and present educational programs; hired in September 2015.

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 2016.

Two Investigative Managers (\$45,120 each, annually) to develop and implement investigative standards and scope of investigative activities; one hired in September 2015 and one hired in September 2016.

Two Investigators III (\$39,984 each, annually) to supervise and train lower level investigative staff, coordinate and participate in inspections/investigations; hired in September 2016.

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 2016.

ASSUMPTION (continued)

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 September 2015 and one hired in September 2016.

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 September 2016.

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 2016.

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 = 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).

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>

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.

ASSUMPTION (continued)

Section 195.453.6

Section 195.453.6 of the proposed legislation requires DHSS to reimburse dispensers for fees and other direct costs 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 2017 and FY 2018. 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.

Category	Number Statewide	-----FY 2017-----		-----FY 2018-----	
		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

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 take five minutes to determine and assign the account coding and forward to the Accountant I for review and approval. In DRL, the Accountant I 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 Accountant I 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:

ASSUMPTION (continued)

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	\$22,932	\$68,665
Account Clerk II	50	1.25	1.25	\$25,572	\$63,930
Accountant I	25	0.625	0.625	\$30,672	\$38,340
Totals	100	2.5	2.5		\$130,935

It is assumed these positions will be hired on January 1, 2017.

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 Accountant I.

For the previous version of this proposal, DHSS provided the response for the **Office of Administration (OA), Information Technology Services Division (ITSD)**. In that response, ITSD stated it is assumed that every new IT project/system will be bid out because all ITSD resources are at full capacity.

Infrastructure costs were calculated using the FY 2015 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. Three servers will be needed for development, test, and production with 100 gb of disk storage each.

It is estimated that FY 2016 ITSD costs to the General Revenue (GR) Fund will total \$736, 201; FY 2017 GR costs will total \$492,921; and FY 2018 GR costs will total \$159,196.

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)

Senate Amendments (SAs)

Oversight assumes SA No. 1, SA No. 2, SA No. 1 to SA No. 2, SA No. 3, SA No. 4, SA No. 5, SA No. 6, SA No. 7, SA No. 8, and SA No. 9 will have no fiscal impact.

SA No. 10, which provides that the provision of sections 195.450 to 195.468 shall not apply to schedule II, III, or IV controlled substances prescribed or dispensed where the ultimate user is an individual under eighteen years of age will have a fiscal impact.

Oversight assumes this amendment will reduce the number of prescriptions the DHSS would process through the Prescription Drug Monitoring Program (PDMP). A reduction in the number of prescriptions processed through the PDMP would result in a reduction in the reimbursements paid to dispensers for fees and other direct costs of transmitting the required information. In addition, a reduction in the number of prescriptions transmitted would result in a reduction in the number of FTE the DHSS would need to process dispenser invoices. It is unknown how many Schedule II, III or IV prescriptions are processed annually for persons under the age of 18, therefore, Oversight assumes the fiscal impact for this proposal will be less than costs provided by the DHSS.

In addition, it is unknown how the provisions of SA No. 10 will impact costs provided by the OA-ITSD. Adding additional restrictions to the system may result in additional IT contract costs. Therefore, Oversight assumes costs could exceed those provided by OA-ITSD.

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

While the number of new cases (or cases with increased penalties) 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 **Missouri Office of Prosecution Services (MOPS)** assume the proposal will have no measurable fiscal impact on MOPS.

ASSUMPTION (continued)

Officials from the **Department of Corrections (DOC)** state the DOC would not supervise the misdemeanor offenses stated in this proposed legislation; however, it would be responsible for administering corrections for the Class D felony committed by persons who knowingly disclose or use monitoring information in a manner that violates the rules under sections 195.450 to 195.468.

The figures are estimates based on a summary of current records that show 30% of new class D felonies are sentenced to prison and 70% are sentenced to probation and assigned to field supervision. The average sentence for a class D felony is 3.5 years. Offenders serving prison sentences for class D felonies spend on average 0.8 years in prison and serve the remainder of their sentences, 2.7 years, under field supervision. Offenders serving these sentences under field supervision are eligible for Earned Compliance Credit. Therefore, the length of field supervision for offenders released from prison is reduced by half in estimating the figures in the following tables. Offenders serving probation sentences for class D felonies serve on average three years under supervision.

The FY 2014 average cost of supervision is \$6.72 per offender per day or an annual cost of \$2,453 per offender. The DOC cost of incarceration is \$16.725 per day or an annual cost of \$6,105 per offender.

The DOC assumes the proposal would have the following long term costs. A 2% inflationary factor has been included.

FY 2016 (10 months)	\$2,775
FY 2017	\$7,800
FY 2018	\$10,278
FY 2019	\$10,487
FY 2020	\$10,701
FY 2021	\$10,919
FY 2022	\$11,141
FY 2023	\$11,368
FY 2024	\$11,599
FY 2025	\$11,835

Oversight assumes the DOC can absorb the minimal costs associated with this proposal.

ASSUMPTION (continued)

Officials from the **Department of Mental Health (DMH)** provide state operated hospitals' initial set-up of records, monthly maintenance, and logging of activity would be required to comply with the provisions of the Prescription Drug Monitoring Program Act. However, this cost should be minimal. It is assumed that existing resources are adequate to meet the requirements of the proposal.

Officials from the **Office of Attorney General** assume any potential costs arising from this proposal can be absorbed with existing resources.

In response to the previous version of this proposal, officials from the **Office of the Secretary of State (SOS)** stated 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.

Officials from the **Department of Insurance, Financial Institutions and Professional Registration**, the **Department of Public Safety - Missouri State Highway Patrol**, the **Joint Committee on Administrative Rules**, the **Office of Administration, General Services Division, Division of Purchasing and Materials Management** and the **Administrative Hearing Commission** 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 2016 (10 Mo.)	FY 2017	FY 2018
GENERAL REVENUE FUND			
<u>Costs - DHSS (§§195.450 - 195.465)</u>	Less than...	Less than...	Less than...
Personal service	(\$124,470)	(\$1,207,617)	(\$1,491,844)
Fringe benefits	(\$64,731)	(\$628,021)	(\$775,833)
Equipment and expense	(\$40,991)	(\$595,105)	(\$496,849)
Dispenser reimbursements (§195.453.6)	<u>\$0</u>	<u>(\$2,922,738)</u>	<u>(\$3,612,505)</u>
Total <u>Costs - DHSS</u>	<u>Less than</u> <u>(\$230,192)</u>	<u>Less than</u> <u>(\$5,353,481)</u>	<u>Less than</u> <u>(\$6,377,031)</u>
FTE Change - DHSS	5 FTE	May be less than 41 FTE	May be less than 41 FTE
 <u>Costs - OA-ITSD</u>	 Could exceed...	 Could exceed...	 Could exceed...
IT consultant fees and on-going support	(\$731,916)	(\$487,651)	(\$153,794)
Equipment and expense	(\$4,285)	(\$5,270)	(\$5,402)
Total <u>Costs - OA-ITSD</u>	<u>Could exceed</u> <u>(\$736,201)</u>	<u>Could exceed</u> <u>(\$492,921)</u>	<u>Could exceed</u> <u>(\$159,196)</u>
 ESTIMATED NET EFFECT ON THE GENERAL REVENUE FUND	 <u>Could exceed</u> <u>(\$966,393)</u>	 <u>Less than</u> <u>(\$5,846,402)</u>	 <u>Less than</u> <u>(\$6,536,227)</u>
 Estimated Net FTE Change on the General Revenue Fund	 5 FTE	 May be less than 41 FTE	 May be less than 41 FTE
 <u>FISCAL IMPACT - Local Government</u>	 FY 2016 (10 Mo.)	 FY 2017	 FY 2018
	 <u>\$0</u>	 <u>\$0</u>	 <u>\$0</u>

FISCAL IMPACT - Small Business

Small business pharmacies and dispensing individual practitioners may have an unknown impact resulting from obtaining computer hardware and software. In addition, these small businesses may have an unknown impact resulting from the time it takes to enter their dispensing

FISCAL IMPACT - Small Business (continued)

information and transmitting it to the data collection location. Although this information is currently maintained and documented by law, this proposal requires the information to be periodically submitted in an approved electronic format.

FISCAL DESCRIPTION

This proposal 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 using an existing data aggregation platform through the State Data Center within the Office of Administration. The provisions of this proposal shall be subject to appropriations and also may be funded with federal or private moneys.

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

A dispenser shall electronically submit to the Department information for each prescription. 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 proposal.

This proposal delineates the duties of both the dispenser and the Department for communicating in real-time when there is a prescription for 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 dispenser shall dispense or not dispense the medication according to his or her professional judgment appropriate to the concern communicated. If the response is not timely, the dispenser shall dispense or not dispense the medication according to his or her professional judgment.

The Department shall review the 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 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

FISCAL DESCRIPTION (continued)

than one prescriber, the Department shall contact the 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 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 dispensation monitoring information or 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 dispensation information who knowingly disclose such information or who use it in a manner and for a purpose in violation of the proposal shall be guilty of a Class D felony until December 31, 2016, and a Class E felony beginning January 1, 2017. Additionally, this proposal 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.

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 proposal 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 proposal.

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

The provisions of this proposal shall expire on August 28, 2020.

This legislation is not federally mandated, will not duplicate any other program, but will 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
 General Services Division
Office of State Courts Administrator
Office of Secretary of State
Office of State Public Defender

Mickey Wilson, CPA

Director
March 31, 2015



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