

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 0169-01
Bill No.: HB 130
Subject: Health Care Professionals; Health Department; Drugs and Controlled Substances;
Pharmacy
Type: Original
Date: January 26, 2015

Bill Summary: This proposal establishes the Prescription Drug Monitoring Program Act.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2016	FY 2017	FY 2018
Total Estimated Net Effect on General Revenue	\$0	\$0	\$0

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 11 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
Total Estimated Net Effect on FTE	0	0	0

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

Officials from the **Department of Health and Senior Services (DHSS)** provide the following information:

§ 195.453.1 - Grants, Gifts and Donations:

This section of the proposal states, in part:

“...The department may apply for any available grants and shall accept any gifts, grants, or donations to develop and maintain the program. All funding for prescription drug monitoring program shall be provided exclusively by gifts, grants, and donations.”

The DHSS assumes none of the costs associated with a prescription drug monitoring system will be funded with General Revenue. Also, since the DHSS is not assured of any potential grant funding opportunities at this time, none of the prescription monitoring costs are assumed to be funded by grants. All costs of the prescription monitoring program (Sections 195.450 through 195.465 of the proposal) are, therefore, assumed to be funded solely by gifts and donations deposited into the Donated Fund. At this time, the DHSS is not aware of any potential gifts for donations for this purpose.

Further, the DHSS assumes costs related to a prescription monitoring program would commence in FY 2016. However, if gifts, grants, or donations sufficient to fund the prescription monitoring program on an ongoing basis are not received, it is assumed the program would not be implemented.

§§ 195.450 through 195.465 - Drug Monitoring Program Act:

One Health and Senior Services Manager (\$39,980 annually) will be needed to perform the following duties:

- Draft a Request for Proposal to solicit bids for the required database. Once the contract is awarded, this individual will be needed on an ongoing basis to monitor the database contract and program, maintain ongoing communication with professional organizations regarding compliance with reporting requirements, and other state and local agencies and the public regarding the program;
- Coordinate with investigative management of the Bureau of Narcotics and Dangerous Drugs (BNDD) for enforcement activities and with law enforcement and regulatory agencies of Missouri and other states for sharing data and tracking outcomes;
- Develop rules, policies, and procedures for reporting by dispensers and access to data by authorized parties;

ASSUMPTION (continued)

- Provide technical assistance to program participants on matters relating to the program;
- Supervise subordinate staff involved in program implementation;
- Design and prepare reports of program data and review data collected to determine trends;
- Provide required educational programs regarding the Prescription Drug Monitoring Program required in Section 195.468; and
- Develop reports to the General Assembly regarding the pilot project on prescription fraud (Section 195.477).

One Health Program Representative I (\$30,672 annually) will:

- Provide support to the program;
- Respond to inquiries and requests for database reports received;
- Perform coordination of communication with other agencies and the public, and maintenance of memoranda of understanding for data sharing;
- Assist practitioners in obtaining access to the reporting subsystem of the program;
- Generate and e-mail or generate, print, and fax reports as requested by authorized individuals and agencies that cannot access this information via the internet; and
- Respond to telephone inquiries regarding the program and answer the toll-free number established for reporting prescription fraud (Section 195.471).
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One Investigative Manager (\$39,980 annually) will:

- Review database information;
- Assign and supervise investigations;
- Assist the manager in operating the database and supervise investigative staff; and
- Assist the manager in providing the required educational courses (Section 195.468).

The above three positions will be hired as of September 1, 2015.

Three Investigator II positions will be needed to respond to complaints and conduct investigations. These positions are assumed to be telecommuters. These positions will be hired as of January 1, 2016.

Support from the Office of Administration (OA), Information Technology Services Division (ITSD) will be needed for DHSS to establish and maintain an application to monitor the prescribing and dispensing of schedule II, III and IV controlled substances by all professionals licensed to prescribe or dispense such substances in this state. Each dispenser will submit to DHSS, in electronic format, the required information in accordance with transmission standards established by the American Society for Automation in Pharmacy, or any successor organization, and shall report data within every seven days. A paper form alternative must be available for those provided a waiver for electronic submission by DHSS.

ASSUMPTION (continued)

Infrastructure costs have been calculated using the FY 2015 SDC (State Data Center) CAP (Cost Allocation Plan) document. ITSD costs assume the use of an application built for the State of Missouri and hosted in the SDC, as well as three servers to include development, testing and production of the application, with 100gb of disk storage for each. ITSD estimates total IT consultant costs, related expenditures, and on-going expenses to be \$736,201 for FY 2016; \$424,267 for FY 2017; and \$219,307 for FY 2018.

§195.453.5 - Dispenser reimbursements

Section 195.453.5 of the proposed legislation requires DHSS to reimburse dispensers for fees and other direct costs of transmitting the required information. For fiscal note purposes DHSS assumes that each of the 25,000 dispensers will invoice quarterly with each invoice averaging \$30. DHSS would, therefore, process 100,000 invoices annually. At \$30 each, total invoicing will equal \$750,000 each quarter.

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. DHSS estimates the number of invoices to be 100,000 for FY 2017 and FY 2018. DHSS estimates that each invoice will take 10 minutes to process in the DRL and 10 minutes to process in the DA. Three different job categories will work together as follows to pay an invoice: in DRL, an Office Support Assistant (\$22,932 annually) will take 2 ½ minutes to open the invoice, log it into the tracking system and forward it to the Account Clerk II; an Account Clerk II (\$25,572 annually) will take five minutes to enter the document into SAM II, confirm the account coding and forward to the Accountant I for approval; and the Accountant I (\$30,672 annually) will take 2 ½ minutes to verify the coding and funding availability and approve the document in SAM II. In the DA, an Office Support Assistant will take 2 ½ minutes to open the invoice, log it into the tracking system and forward it to the Account Clerk II; the Account Clerk II will verify the payment documents from DRL for coding and funding accuracy; and the Accountant I will take 2 ½ minutes to apply final approval to the payment. The additional FTE required for invoice processing is as follows:

100,000 invoices X 20 minutes per invoice = 2,000,000 minutes to process invoices. 2,000,000 minutes / 60 minutes per hour = 33,333 hours. 33,333 hours/2,080 = 16.00 FTE:

ASSUMPTION (continued)

Job Title	Percent of Time	DRL FTE	DA FTE	Salary	Total Annual Salaries
Office Support Assistant	25	2.00	2.00	22,932	\$91,728
Account Clerk II	50	4.00	4.00	25,572	\$204,576
Accountant I	25	2.00	2.00	30,672	\$122,688
Totals	100	8.00	8.00		\$418,992

It is assumed these positions will be hired on July 1, 2016.

§195.475 - Pilot Project

The proposed legislation requires DHSS to establish a pilot project by January 1, 2017; therefore, the first year of operations is assumed to be FY 2017 for fiscal note computation purposes. However, unless gifts or donations are received to fund the costs of the pilot project, the assumption is made that it will not be undertaken.

Section 195.475.1 of the proposed legislation requires DHSS to establish a toll-free hotline by January 1, 2017. The charge for a toll-free line is \$.0567 per minute. DHSS assumes the hotline will be established in FY 17 and there will be an estimated 1,000 calls per year at an average of five (5) minutes each, for a total estimated yearly cost of \$283.50 (1,000 x 5 = 5,000 x .0567 = \$283.50).

Section 195.475.5 of the proposed legislation states in part:

5. The department shall implement and provide all monitoring under the pilot project with existing department employees. Nothing in this section shall be construed as authorizing the hiring of additional employees to implement this pilot project and the department is required to implement this pilot project upon receipt of gifts, grants, and donations received for such purpose, without any additional state appropriations or department staff; except that, the department may enter into agreements with other state agencies or a private vendor, as necessary, to ensure the effective operations of the program if such agreements are funded solely from gifts, grants, and donations. Any agency or private vendor entering into an agreement with the department for the pilot project shall comply with the confidentiality provisions regarding the prescription information under section 195.456.

In summary, the DHSS assumes the proposal would have costs to Donated Funds of \$1,063,786 in FY 2016; \$4,915,522 in FY 2017; and \$4,626,359 in FY 2018.

ASSUMPTION (continued)

Oversight notes, per sections 195.453.1 and 195.475.5, that DHSS is not allowed to incur additional expenses that would be charged as an expense to the state or hire additional staff to implement the pilot project. All expenses have to be paid by gifts, grants and donated funds and DHSS is required to implement the pilot project using existing staff. Oversight assumes the DHSS would have to receive assurance of donated funds or grant monies prior to implementing the provisions of this proposal and the pilot project would be implemented using current staff.

For fiscal note purposes, the proposal would have no net fiscal impact because: 1) the Prescription Drug Monitoring Program does not receive sufficient funds to cover DHSS costs and is not implemented or 2) program donations and gifts are sufficient to cover the anticipated costs and income and expenditures net to \$0.

Oversight notes section 195.465 provides that the DHSS can assess administrative penalties on dispensers that knowingly fail to submit dispensation monitoring information or that knowingly submit incorrect information. It is assumed that the number and amount of administrative penalties is unknown. For fiscal note purposes, Oversight is not presenting these administrative penalties.

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 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 **Office of Attorney General** note that Section 195.465.1 provides that dispensers who knowingly fail to submit information or knowingly submit incorrect information shall be subject to an administrative penalty and may appeal the penalty to the Administrative Hearing Commission. The AGO assumes this will result in an increase in its caseload. Without knowing the number of resulting appeals, the AGO assumes any potential costs arising from this proposal can be absorbed with existing resources. If there is a significant increase in the number of referrals, or if multiple provisions pass, the AGO may seek additional appropriations.

Officials from the **Office of Administration (OA), Administrative Hearing Commission** anticipate this legislation will not significantly alter its caseload. However, if similar bills pass resulting in more cases, there could be a fiscal impact.

ASSUMPTION (continued)

Officials from the **Department of Corrections (DOC)** state penalty provisions for violations, the component of the proposal to have potential fiscal impact for the DOC, is for a class A misdemeanor. The DOC would not supervise these class A misdemeanor cases and so would not have a fiscal impact.

Officials from the **Office of the Secretary of State (SOS)** state 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 Mental Health**, the **Department of Public Safety, Missouri State Highway Patrol**, the **Department of Social Services**, the **Joint Committee on Administrative Rules**, the **Missouri Office of Prosecution Services**, the **Office of Administration, Division of Purchasing and Materials Management**, 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
	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>

<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

If this proposal is implemented, it will have an administrative impact on small business drug dispensers.

FISCAL DESCRIPTION

This proposal establishes the Prescription Drug Monitoring Program Act. In its main provisions, the proposal: (1) Requires the Department of Health and Senior Services 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. All funding for the program must be from gifts, grants, and donations; (2) Requires each dispenser to electronically submit specified information to the department for each prescription in accordance with transmission standards established by the American Society for Automation in Pharmacy, or any successor organization, and to report data within seven days; (3) Allows the department to 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 by paper form or other means if all the required information is submitted in the alternative format. The department may grant an extension to a dispenser who is temporarily unable to electronically submit the information due to unforeseen circumstances; (4) Requires the department to reimburse each dispenser for the fees and other direct costs of transmitting the required information; (5) Requires all submitted prescription information to be confidential and not subject to public disclosure under the Open Meetings and Records Law, commonly known as the Sunshine law, with specified exceptions. The department must review the dispensation information and, if there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, must notify the appropriate law enforcement or professional regulatory entity and provide dispensation information required for an investigation. A person authorized to have dispensation monitoring information who knowingly discloses the information or who uses the information in a manner and for a purpose in violation of these provisions will be guilty of a class A misdemeanor; (6) Requires the department to maintain a registry of persons who it has reasonable cause to believe may have violated the law or been in breach of professional standards. Any person identified must remain on the registry for a minimum of three years; (7) Allows the department to release non-personal, general information for statistical, educational, or research purposes after removing any identifying information; (8) Authorizes the department to contract with any other agency of this state or any other state with a private vendor or any state government that currently runs a prescription monitoring program;

FISCAL DESCRIPTION (continued)

(9) Specifies that a dispenser who knowingly fails to submit required dispensation monitoring information to the department or knowingly submits incorrect dispensation information will be subject to an administrative penalty in the amount of \$1,000 for each violation; (10) Requires the department to create and implement specified educational courses regarding the provisions of the proposal and, when appropriate, to work with associations for impaired professionals to ensure

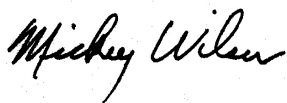
intervention, treatment, and ongoing monitoring and follow up and encourage individual patients who are identified and who have become addicted to substances monitored by the program to receive addiction treatment; and (11) Requires the Bureau of Narcotics and Dangerous Drugs within the department to establish by January 1, 2017, a two-year statewide pilot project for the reporting of fraudulently obtained prescription controlled substances. The bureau must submit by February 1, 2017, and February 1, 2018, a report to the General Assembly detailing specified information regarding the pilot project. Any person who in good faith reports to the bureau will be immune from any civil or criminal liability as a result of the reporting.

The provisions of the proposal regarding the pilot project by the Bureau of Narcotics and Dangerous Drugs will expire three years after the effective date and the remaining provisions will expire six years after the effective date.

This legislation is not federally mandated, would not duplicate any other program and would not 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
Department of Social Services
Joint Committee on Administrative Rules
Missouri Office of Prosecution Services
Office of Administration -
 Administrative Hearing Commission
 Division of Purchasing and Materials Management
 Office of State Courts Administrator
Office of Secretary of State
Office of State Public Defender



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