

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 3897-08
Bill No.: SS#2 for SCS for HCS for HB 1619
Subject: Drugs and Controlled Substances; Health Department
Type: Original
Date: April 29, 2008

Bill Summary: This legislation establishes a drug monitoring program and modifies existing record keeping for controlled substances and pseudoephedrine products. This legislation gives advanced practice registered nurses prescriptive authority for scheduled drugs. This legislation creates the Pharmacy Rebates Fund which will consist of all revenues received from pharmaceutical manufacturer rebates for use in the MO HealthNet Pharmacy Program.

This legislation for drug monitoring program will sunset six years from the effective date.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2009	FY 2010	FY 2011
General Revenue	(\$944,143)	(\$561,139)	(\$567,545)
Total Estimated Net Effect on General Revenue Fund	(\$944,143)	(\$561,139)	(\$567,545)

Numbers within parentheses: () indicate costs or losses.
This fiscal note contains 14 pages.

ESTIMATED NET EFFECT ON OTHER STATE FUNDS			
FUND AFFECTED	FY 2009	FY 2010	FY 2011
Total Estimated Net Effect on <u>Other</u> State Funds	\$0	\$0	\$0

ESTIMATED NET EFFECT ON FEDERAL FUNDS			
FUND AFFECTED	FY 2009	FY 2010	FY 2011
Total Estimated Net Effect on <u>All</u> Federal Funds	\$0	\$0	\$0

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)			
FUND AFFECTED	FY 2009	FY 2010	FY 2011
General Revenue	3 FTE	3 FTE	3 FTE
Total Estimated Net Effect on FTE	3 FTE	3 FTE	3 FTE

Estimated Total Net Effect on All funds expected to exceed \$100,000 savings or (cost).

Estimated Net Effect on General Revenue Fund expected to exceed \$100,000 (cost).

ESTIMATED NET EFFECT ON LOCAL FUNDS			
FUND AFFECTED	FY 2009	FY 2010	FY 2011
Local Government	\$0	\$0	\$0

FISCAL ANALYSIS

ASSUMPTION

Officials from the **Office of the State Public Defender, Office of the State Courts Administrator, Missouri State Highway Patrol, Department of Insurance, Financial Institutions & Professional Registration, Department of Agriculture, Department of Mental Health, Department of Revenue, Office of the State Treasurer** and the **Department of Public Safety** each assume the proposal would have no fiscal impact on their respective agencies.

Officials from the **Department of Social Services (DSS)** assume there is no fiscal impact to the DSS. The proposal does not give MO HealthNet Division (MHD) any new responsibility or authority. Responsibility to implement the program rests with the Department of Health and Senior Services (DHSS). The only role MHD plays is to facilitate meetings between the DHSS and the third-party agency to implement and administer the FN electronic logbook. MHD has a current contract with an outside agency that has the capability to provide the electronic logbook as an extension of the current contract with MHD.

DSS assumes the proposal would not affect the MO HealthNet Division. The scope of the Advance Practice Nurse's (APN) practice will not change because today if an APN's patient needs a controlled substance, the collaborating physician would sign the order. There would be no system changes required to allow APN to bill scheduled drugs to the MO HealthNet Division.

Amendment #2 (3897S06.02S):

DSS assumes the Pharmacy Rebates Fund is currently used as a funding source for four appropriations within the DSS Budget (HB 11). The four appropriations are MHD Administration, Pharmacy, SCHIP, and the Supplemental Pool. The majority of the rebates are designated as a funding source in the Pharmacy appropriation. Since SCHIP funds are used to support payments to providers, including pharmacists, for medical services for SCHIP eligibles, this would also be a permissible use under this legislation. (The amount currently appropriated to SCHIP from the Pharmacy Rebate Fund is \$225,430.)

ASSUMPTION (continued)

The current amounts appropriated to the other appropriations are:

MHD Administration	\$ 23,427
Supplemental Pool	\$ _____ 1(E)
Total	\$ 23,428

Therefore, if the legislation would pass, the fiscal impact would be that a GR replacement would be needed in those appropriations.

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. Any decisions to raise fees to defray costs would likely be made in subsequent fiscal years.

Officials from the **Office of the Attorney General (AGO)** assume that any costs associated with implementing the provisions of this proposal can be absorbed with existing resources. To the extent the implementation of the prescription monitoring program results in a significant number of new referrals to the AGO in the areas of Medicaid fraud or other possible criminal activity, AGO may seek necessary appropriations to handle the increase in workload.

In response to a previous version of this proposal, officials from the **Office of Prosecution Services (OPS)** assume any increase in the number of cases referred for criminal prosecution will have an additional fiscal impact on County Prosecutors. However, officials from the OPS are not aware of any estimates of the number of additional criminal cases that would be referred to County Prosecutors for charges because of this proposed legislation. Additionally, the OPS is

ASSUMPTION (continued)

not otherwise able to establish a workable estimate of the number of additional criminal cases that would be referred to County Prosecutors for charges. It is therefore, not possible to determine if this proposal would have a significant direct fiscal impact on county prosecutors or the OPS.

Oversight assumes the OPS could absorb the additional caseload that may result from this proposal within existing resources. Oversight assumes any significant increase in the workload of the OPS would be reflected in future budget request.

Officials from the **Department of Corrections (DOC)** state the DOC, cannot predict the number of new commitments which may result from the creation of the offense(s) outlined in this proposal. An increase in commitments depends on the utilization by prosecutors and the actual sentences imposed by the court.

If additional persons are sentenced to the custody of the DOC due to the provisions of this legislation, the DOC will incur a corresponding increase in operational cost through either incarceration (FY07 average of \$41.21 per inmate per day or an annual cost of \$15,040 per inmate) or through supervision provided by the Board of Probation and Parole (FY07 average of \$2.43 per offender, per day or an annual cost of \$887 per offender per year).

The following factors contribute to DOC's minimal assumption:

- DOC assumes the narrow scope of the crime will not encompass a large number of offenders.
- The low felony status of the crime enhances the possibility of plea-bargaining or imposition or a probation sentence.
- The probability exists that offenders would be charged with a similar but more serious offense or that sentences may run concurrent to one another.

In summary, supervision by the DOC through probation or incarceration would result in some additional costs, but it is assumed the impact would be \$0 or a minimal amount that could be absorbed within existing resources.

Officials from the **Department of Health and Senior Services** assume costs associated with the proposed bill relate to implementation of Sections 195.378 through 195.399, also referred to as the "Drug Monitoring Act", and Section 195.417.7, which requires the implementation of an electronic log of transactions involving the sale of ephedrine, phenylpropanolamine, or pseudoephedrine products.

ASSUMPTION (continued)

Information related to prescription monitoring program vendor contract information was sought and obtained related to other states with active prescription monitoring programs and electronic logs for methamphetamine sales tracking.

The U.S. Department of Justice, Bureau of Justice Assistance has announced the availability of implementation grants to assist states in implementing prescription monitoring programs. An application will be submitted for a maximum of \$400,000 in one time grant monies in response to this competitive grant announcement. Subsequent grant monies may be available for enhancements to the program. Since we are not assured of receiving these grant funds, this amount has not been included in the fiscal note worksheet.

Bureau of Narcotics and Dangerous Drugs (BNDD) Costs:

One Health and Senior Services Manager (1) will be needed to perform the following duties:

- Develop grant requests for DEA funds and prepare required reporting based on the conditions of any grant received;
- On an on-going basis monitor the program, maintain ongoing communication with the ITSD staff responsible for maintenance of the program applications, communicate with professional organizations regarding compliance with reporting requirements, and communicate with other state and local agencies and the public regarding the program;
- Coordinate with investigative management of the BNDD for enforcement activities and with law enforcement and regulatory agencies of this and other states for sharing data and tracking outcomes;
- Develop regulations, training materials and policies and procedures related to reporting by dispensers, access to data by authorized parties; provide technical assistance to program participants on matters relating to the program;
- Supervise subordinate staff involved in program implementation and administration; and
- Work with ITSD staff to design and prepare reports of program data; review data reports and report to administration trends identified.

One Office Support Assistant (keyboarding), would be necessary to provide clerical support to the program and to respond to inquiries and requests for database reports received. This individual will 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 and assist in the generation and distribution of reports as requested by authorized individuals and agencies that cannot access this information via the internet. This individual will also be responsible for responding to routine telephone inquiries regarding the program.

ASSUMPTION (continued)

Standard expense and equipment costs are included for the two BNDD positions identified above.

Office of Administration, Information Technology Services Division (ITSD) Costs:

Support from ITSD will be needed to assist DHSS in purchasing and customizing a data system to establish and maintain a program for the monitoring of prescribing and dispensing of all schedule II, III, IV, and V controlled substances except schedule V controlled substances containing any detectable amount of pseudoephedrine that do not require a prescription, by all professionals licensed to prescribe or dispense such substances in this state.

It is assumed that the application(s) will reside on servers at DHSS-ITSD and due to the large amount of data that will be collected and stored, a Storage Area Network (SAN) will need to be purchased. The hardware costs included in this response assumed the ongoing leasing of all hardware.

ITSD estimates that the following costs will apply:

Consultant cost for purchase and implementation of application. \$810,000 in FY 09, \$275,000 in FY10 and FY11.

The total amount for hardware and leasing requirements is \$97,091 annually.

ITSD Staffing:

1 FTE - Computer Information Technology Specialist II will be required to provide project management, development support and administration/maintenance of application.

1 FTE - Computer Information Technologist II will be required to provide on-going support of the application.

.50 FTE - Computer Information Technology Specialist I will be required to provide hardware server support installation and maintenance.

Standard expense and equipment costs related to each position are also included.

Oversight assumes the DHSS/BNDD could absorb one Office Support Assistant FTE and the DHSS/ITSD could absorb a one-half Computer Information Technology Specialist I FTE.

SEC:LR:OD (12/06)

ASSUMPTION (continued)

Oversight has, for fiscal note purposes only, changed the starting salary for the DHSS positions to correspond to the first step above minimum for comparable positions in the state's merit system pay grid. This decision reflects a study of actual starting salaries for new state employees for a six month period and the policy of the Oversight Subcommittee of the Joint Committee on Legislative Research. Oversight also adjusted the cost of the additional FTE to reflect six months in FY09.

DHSS assumes additional registration fees for advanced practice nurses will be generated by this legislation. This amount will be received primarily in a three-year cycle due to the three-year term of the registrations issued, except for individuals beginning practice in Missouri in intervening years.

The Division of Regulation and Licensure assumes that 80 percent of the total number of advanced practice nurses and physician assistants will apply for a three-year controlled substances registration in the first year. It is also assumed that the remaining eligible population, as well as additional individuals entering this line of work will apply of subsequent years. Revenue for the second and third years are therefore estimated using 15 percent of the total number eligible registrants.

Initial registrations (first year): $3,550 \times 0.80 \times \$90/3\text{-yr registration} = \$255,600$

New registrations and re-registrations for new sites (second and third year): $3,550 \times 0.15 \times \$90/3 \text{ yr registration} = \$47,925$

The Bureau of Narcotics and Dangerous Drugs (BNDD) expect that all individuals eligible to register to conduct activities with controlled substances will do so within the first six months of the enactment of this legislation, with the following effect:

- The increase in receipt of applications for registration will result in a delay in issuance of controlled substance registrations;
- There will be an increase in registrants from approximately 29,000 to 33,500;
- Newly registered individuals will have familiarity equal to or less than that of current registrants with regard to controlled substance laws and regulations;
- Of current registrants inspected, 43% are non-compliant with controlled substance requirements;
- The increase in registrants will result in an increase in complaints, investigations, violations identified and disciplinary actions taken, and

ASSUMPTION (continued)

- Each inspection or investigation of this new category of registrants will include the identification of collaborative practice agreements and their status as well as inspection/investigation of the advanced practice nurse registrant's collaborating physician(s) resulting in an increased complexity in inspections and investigations requiring more staff time per inspection or investigation.

The BNDD currently has four Investigator II positions and one Investigator III position to conduct inspections and investigations of the approximately 29,000 (as of 11-30-07) state controlled substance registrants. $29,000/5 = 5,800$ registrants per investigator.

As of December 17, 2007 there have been 3,552 advanced practice recognitions issued by the Missouri State Board of Nursing, excluding certified registered nurse anesthetists. It is assumed that all of these individuals will seek registration with DHSS, BNDD. This will result in an increase of approximately 3,550 registrants.

One additional Investigator II will be needed to respond to the increased workload in performing enforcement activities for the increased number of registrants. Standard expense and equipment costs are included for this FTE.

Support from Information Technology Services Division (ITSD) will be needed to modify and maintain the existing database used by the DHSS, BNDD. The modifications will include the addition of data fields to capture information about advanced practice registered nurses that have a controlled substance prescribing authority delegated in a collaborative practice agreement. Additional reports will also be required to meet the needs of the Bureau.

ITSD assumes one-time consultant cost for analysis, design development, testing and implementation of the needed medications to collect and store the data will cost \$143,000. ITSD also assumes the project will require the need for one Computer Information Technology Specialists I to provide project management, development support and administration maintenance of the application. This position would require one full time staff the first year, and then reduced to half of a full time position in subsequent years.

Oversight assumes since this version of the proposal has DHSS handling approximately 1,500 less initial registrations the DHSS/BNDD could absorb one Investigator II FTE. Oversight assumes if DHSS does see a significant increase in the workload and a fiscal impact were to result, the DHSS may request additional funding through the appropriations process. Oversight assumes the DHSS/ITSD could absorb one Computer Information Technology Specialists I FTE.

<u>FISCAL IMPACT - State Government</u>	FY 2009 (10 Mo.)	FY 2010	FY 2011
GENERAL REVENUE FUND			
<u>Income</u> - Department of Health and Senior Services			
Registration Fees	\$255,600	\$47,925	\$47,925
<u>Costs</u> - Department of Health and Senior Services			
Personal Services	(\$65,897)	(\$135,749)	(\$139,821)
Fringe Benefits	(\$29,140)	(\$60,028)	(\$61,829)
Equipment and Expense	(\$31,187)	(\$17,768)	(\$18,301)
Consultant Costs	(\$143,000)	\$0	\$0
Consultant & Purchase of Application	(\$810,000)	(\$275,000)	(\$275,000)
Specialized Computer Equipment	(\$97,091)	(\$97,091)	(\$97,091)
<u>Total Costs</u> - DHSS	<u>(\$1,176,315)</u>	<u>(\$585,636)</u>	<u>(\$592,042)</u>
FTE Change - DHSS	3 FTE	3 FTE	3 FTE
<u>Costs</u> - Department of Social Services			
MHD Admin & Supplemental Costs	<u>(\$23,428)</u>	<u>(\$23,428)</u>	<u>(\$23,428)</u>
ESTIMATED NET EFFECT ON GENERAL REVENUE FUND	<u>(\$944,143)</u>	<u>(\$561,139)</u>	<u>(\$567,545)</u>
Estimated Net FTE Change for General Revenue Fund	3 FTE	3 FTE	3 FTE
 <u>FISCAL IMPACT - Local Government</u>			
	FY 2009 (10 Mo.)	FY 2010	FY 2011
	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>

FISCAL IMPACT - Small Business

Licensed pharmacies and dispensing practitioners may incur an indeterminate fiscal impact for purchasing electronic equipment, software and related man-hours required in entering and transmitting data to the electronic log for methamphetamine purchases. Tracking this information is already required, but allowed to be kept in a paper log. Also, licensed pharmacies may incur an indeterminate fiscal impact for purchasing electronic equipment, software and related man-hours required in entering and transmitting data to the controlled substance prescription monitoring program in the Department of Health and Senior Services. Any cost incurred may be offset somewhat by the benefits provided by being able to access controlled substance prescription data from the program.

Small hospitals and clinics that currently pay fees to the Department of Health and Senior Services for controlled substance registrations for their practitioners will incur an additional cost in paying for the Missouri state controlled substance registrations at \$90 per three-year registration for each of their advanced practice nurses. An additional \$551 per three-year registration for each federal registration from the U.S. Drug Enforcement Administration would also be incurred. These businesses may choose to require the individual advanced practice nurse to submit payment for their own registrations.

FISCAL DESCRIPTION

Current law requires certain documentation relating to the sale of products containing pseudoephedrine. For non-prescription pseudoephedrine products, this legislation requires that the photo identification that must currently be provided to the pharmacist must be issued by a state or the federal government, or another acceptable document and that such identification must be furnished prior to purchase. The log currently maintained by pharmacists is modified to now include the signature of the purchaser, the name of the product and the time of the purchase. The legislation also requires that the log be electronic, rather than written. The seller is required to deliver the product directly into the custody of the purchaser.

The legislation modifies the current gram limits for the sale of pseudoephedrine products. The legislation provides that the limits do not apply to quantities that must be sold, dispensed or distributed in a pharmacy under a valid prescription or to any purchase by an individual of a single package containing not more than 60 mg of pseudoephedrine. The current 30 day period limit of 9 grams to a person applies without regard to the number of transactions. For mail order or mobile retail sales within a 30 day period, the limit on pseudoephedrine products shall be 7.5 grams without regard to the number of transactions. Within a twenty-four hour period, no person may obtain 3.6 grams without regard to the number of transactions.

FISCAL DESCRIPTION (continued)

The legislation provides that liquid or liquid-filled gel capsule forms of pseudoephedrine must be in a place where customers do not have direct access to them. The legislation repeals provisions that exempted the liquid and liquid-filled gel capsule forms of pseudoephedrine from recordkeeping and log maintenance requirements.

The person selling the pseudoephedrine products shall maintain an electronic log of each transaction, including the name and signature of the purchaser, the name of the drug, the date and time of purchase and the name or initials of the person selling the drugs. Pharmacies must submit information regarding sales of certain pseudoephedrine products in accordance with transmission methods and frequencies established by the department of health and senior services. All logs, records and other documents maintained for the dispensing of pseudoephedrine products shall be open for inspection and copying by law enforcement officers whose duty it is to enforce state or federal controlled substance laws.

The legislation establishes a drug monitoring program in the Department of Health and Senior Services. The program will monitor the prescribing and dispensing of all Schedule II through Schedule V controlled substances by all licensed professionals who prescribe or dispense these substances in Missouri. The dispenser must electronically submit to the Department information for each prescription or dispensing. The legislation specifies the frequency of the submissions. 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 may submit the required information in paper format or by other approved means. With certain listed exceptions, all submitted prescription information shall be confidential.

The legislation authorizes the release of non-personal, general information for statistical, educational, and research purposes. The Department may contract with other state agencies or private vendors to implement the provisions of this legislation. Any person, contractor or entity that knowingly releases information access from the program shall be guilty of a class A misdemeanor for a first violation and a class D felony for subsequent violations as well as a civil monetary penalty of up to \$25,000. The Department is required to implement certain education courses regarding the prescription monitoring program. The Department shall, when appropriate, work with associations for impaired professionals to ensure ongoing monitoring and treatment.

Nothing in the drug monitoring program shall be construed to require a dispenser or prescriber to access or check information from the program prior to dispensing, prescribing or administering medications. Dispensers and prescribers are immune from liability based on any claim of damages as a result of accessing or failing to access the information in the drug monitoring program.

FISCAL DESCRIPTION (continued)

The provisions of this legislation shall be effective on January 1, 2009 and the drug monitoring program shall sunset in six years.

Currently, advanced practice registered nurses have the authority to administer, dispense and prescribe certain drugs while operating under a collaborative practice agreement. This legislation authorizes advanced practice registered nurses who hold a certificate of controlled substance prescriptive authority from the board of nursing to prescribe controlled substances in schedules III, IV, and V while operating under a collaborative practice agreement.

The legislation contains requirements that must be contained in all collaborative practice agreements. The legislation defines advanced practice registered nurse, certified advanced registered nurse practitioner, certified clinical nurse specialist, and certified nurse midwife. The legislation includes experience and practice requirements that are prerequisites for the Board of Nursing to grant a certificate of controlled substance prescriptive authority.

In addition, this legislation modifies and adds to the current names of scheduled controlled substances.

The proposed legislation establishes the Pharmacy Rebates Fund for the purposes of depositing any revenues received by the state from pharmaceutical manufacturer rebates as required by state or federal law for use in the MO HealthNet pharmacy program.

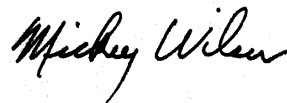
This legislation is not federally mandated, would not duplicate any other program and would not require additional capital improvements or rental space.

SOURCES OF INFORMATION

Office of the Attorney General
Office of the State Courts Administrator
Department of Public Safety
Office of the Secretary of State
Office of the State Public Defender
Department of Insurance, Financial Institutions & Professional Registration
Department of Mental Health
Department of Health and Senior Services

SOURCES OF INFORMATION (continued)

Department of Social Services
Missouri State Highway Patrol
Office of Prosecution Services
Department of Agriculture
Department of Corrections
Department of Revenue
Office of the State Treasurer

A handwritten signature in black ink that reads "Mickey Wilson". The signature is written in a cursive, flowing style.

Mickey Wilson, CPA
Director
April 29, 2008