

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 3351-06
Bill No.: Truly Agreed To and Finally Passed CCS for HCS for SCS for SB 724
Subject: Drugs and Controlled Substances; Licenses, Professional; Nurses
Type: Original
Date: May 27, 2008

Bill Summary: This legislation gives advanced practice registered nurses prescriptive authority for scheduled drugs.

This legislation establishes a drug monitoring program and modifies existing record keeping for controlled substances and pseudoephedrine products.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2009	FY 2010	FY 2011
General Revenue	(\$783,515)	(\$512,011)	(\$518,417)
Total Estimated Net Effect on General Revenue Fund	(\$783,515)	(\$512,011)	(\$518,417)

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

Numbers within parentheses: () indicate costs or losses.
This fiscal note contains 11 pages.

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 Courts Administrator, Missouri State Highway Patrol, Department of Public Safety, Department of Mental Health** and the **Office of Prosecution Services** each assume the proposal would have no fiscal impact on their respective agencies.

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 **Department of Social Services** assume 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.

In response to a previous version of this proposal, officials from the **Department of Insurance, Financial Institutions & Professional Registration (DIFP)** assume this proposal authorizes advanced practice nurse to prescribe prescriptive authority for scheduled drugs under a controlled substance collaborative practice agreements. This proposal requires the Board of Healing Arts and Board Nursing to jointly promulgate rules regulating the use of the agreements.

ASSUMPTION (continued)

Having reviewed the proposed legislation and having sought the conclusion of the appropriate board(s), DIFP are of the opinion that this fiscal note in its present form has no fiscal impact to our Division. However, should multiple pieces of legislation pass the General Assembly requiring the board to hold additional meetings, additional appropriation may be requested.

Officials from the **Department of Health and Senior Services (DHSS)** assume costs associated with the proposed bill relate to the implementation of Sections 195.017.12, which requires the implementation of an electronic log of transactions involving the sale of ephedrine, phenylpropanolamine, or pseudoephedrine products.

Bureau of Narcotics and Dangerous Drugs (BNDD) Costs:

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

- 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

ASSUMPTION (continued)

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. 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 the DHSS in purchasing and customizing a data system to provide pharmacies in this state access to a realtime electronic logbook for the purposes of entering into the realtime logbook any transaction required to be reported under section 195.017, RSMo.

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. \$673,500 in FY 09, \$250,000 in FY10 and FY11.

The total amount for hardware and leasing requirements is \$96,391 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.

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.

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.

Section 195.070.2 and 335.019:

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.

ASSUMPTION (continued)

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 - Department of Health and Senior Services</u>			
Registration Fees	\$255,600	\$47,925	\$47,925
<u>Costs - Department of Health and Senior Services</u>			
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 & Purchase of Application	(\$673,500)	(\$250,000)	(\$250,000)
Specialized Computer Equipment	(\$96,391)	(\$96,391)	(\$96,391)
Consultant Costs	<u>(\$143,000)</u>	<u>\$0</u>	<u>\$0</u>
Total Costs - DHSS	<u>(\$1,039,115)</u>	<u>(\$559,936)</u>	<u>(\$566,342)</u>
FTE Change - DHSS	3 FTE	3 FTE	3 FTE
ESTIMATED NET EFFECT ON GENERAL REVENUE FUND	<u>(\$783,515)</u>	<u>(\$512,011)</u>	<u>(\$518,417)</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. Any cost incurred may be offset somewhat by the benefits provided by being able to maintain this purchase information electronically and by having purchases denied as exceeding that individual's purchase threshold.

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

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. Schedule III narcotic controlled substance prescriptions shall be limited to a 120 hour supply without refill. Certified registered nurse anesthetists do not have this authority.

The legislation contains requirements that must be contained in all collaborative practice agreements including:

- Names, addresses, and phone numbers of the collaborating individuals.
- A list of offices where the collaborating physician has authorized the APRN to prescribe.

FISCAL DESCRIPTION (continued)

- A requirement that notice shall be displayed at all offices where an APRN is prescribing, that informs patients that they may be seen by an APRN.
- All specialty or board certifications.
- The details of the collaboration including geographic proximity, and how absences are handled.
- A description of the prescriptive authority including a list of controlled substances the physician authorizes.
- A list of all other practice agreements involving the collaborating individuals.
- The duration of the agreement.
- A description of the time and manner of the collaborating physician's review of the APRN's prescribing practices

The legislation modifies requirements for all collaborative arrangements including the following:

- Physicians shall not collaborate with more than three full time APRNs
- APRNs shall practice for one month in a setting where the collaborating physician is continuously present.
- Neither physicians nor APRNs shall be required to enter collaborative practice agreements.

Collaborative practice arrangements shall not delegate the authority to administer schedule II, IV, or V controlled substances to induce sedation or for general anesthesia for therapeutic, diagnostic or surgical procedures.

Certified registered nurse anesthetists shall be permitted to provide anesthesia services without a collaborative practice arrangement provided that he or she is under the supervision of an anesthesiologist, physician, dentist, or podiatrist who is immediately available if needed.

Rules relating to dispensing or distribution of controlled substances by prescription or prescription drug orders under a collaborative practice arrangement shall be subject to the approval of the Department of Health and Senior Services and the state board of pharmacy.

FISCAL DESCRIPTION (continued)

The legislation defines advanced practice registered nurse, certified advanced registered nurse practitioner, certified clinical nurse specialist, certified nurse midwife, and certified registered nurse anesthetist.

The legislation includes experience and practice requirements that are prerequisites for the board of nursing to grant a certificate of controlled substance prescriptive authority.

Current law requires certain documentation relating to the sale of products containing pseudoephedrine. For non-prescription pseudoephedrine products, this act 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. Logs of required transactions create a rebuttable presumption that the person whose name appears in the logs is the person whose transactions are recorded in the logs. 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. The current 30 day period limit of 9 grams to a person applies without regard to the number of transactions. Within a twenty-four hour period, no person may obtain more than 3.6 grams without regard to the number of transactions.

The legislation repeals provisions that exempted the liquid and liquid-filled gel capsule forms of pseudoephedrine from record keeping and log maintenance requirements.

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.

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

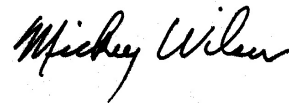
FISCAL DESCRIPTION (continued)

The legislation removes a provision defining Christian Science nurses as those listed as such in the Christian Science Journal and allows them to use the name Christian Science nurse when providing services to those who choose to rely upon healing by spiritual means alone.

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

Department of Health and Senior Services
Department of Social Services
Department of Insurance, Financial Institutions & Professional Registration
Office of the State Courts Administrator
Missouri State Highway Patrol
Department of Public Safety
Department of Mental Health
Office of Prosecution Services
Office of the Secretary of State



Mickey Wilson, CPA
Director
May 27, 2008