

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 4495-03
Bill No.: HB 1568 with SA 1 and SA 2
Subject: Liability; Drugs and Controlled Substances; Medical Procedures and Personnel
Type: Original
Date: April 26, 2016

Bill Summary: This proposal allows physicians to prescribe naloxone to any individual to administer, in good faith, to another individual suffering from an opiate-induced drug overdose and modifies provisions concerning hemp extract.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
General Revenue	(\$944,600)	(\$169,817)	(\$221,691)
Total Estimated Net Effect on General Revenue	(\$944,600)	(\$169,817)	(\$221,691)

ESTIMATED NET EFFECT ON OTHER STATE FUNDS			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
Criminal Records	Unknown	Unknown	Unknown
Total Estimated Net Effect on Other State Funds	Unknown	Unknown	Unknown

Numbers within parentheses: () indicate costs or losses.

This fiscal note contains 14 pages.

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

* Income and expenditures net to \$0.

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
General Revenue	5	69	69
Total Estimated Net Effect on FTE	5	69	69

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

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

FISCAL ANALYSIS

ASSUMPTION

§§195.206 and 338.205

In response to the previous version of this proposal, officials from the **Department of Social Services (DSS), MO HealthNet Division (MHD)** stated the proposal allows physicians to prescribe and pharmacists and pharmacy technicians to dispense, naloxone to an individual to administer, in good faith, to another individual suffering from an opiate-induced drug overdose. The intra-nasal Naloxone was not approved by the Federal Drug Administration (FDA) last year and, therefore, is not MO HealthNet eligible. Naloxone hydrochloride, an opioid overdose blocker was only recently approved by the FDA for intra-nasal use, and therefore, is now eligible for MO HealthNet reimbursement.

Participants with a diagnosis of opioid abuse or opioid dependence would be eligible to receive this opioid antagonistic drug/device. This drug/device would be covered if it met the MHD criteria that would promote appropriate utilization of the drug.

There are currently 10,697 MHD participants who have a diagnosis of opioid or opioid dependence.

MHD assumed that 50% of the participants ($10,697 \times 50\% = 5,349$ rounded) with a relevant diagnosis would receive the opioid antagonistic in the first year. MHD further assumed that there would be 90% utilization ($5,349 \times 90\% = 4,814$) for the intra-nasal and 10% utilization ($5,349 \times 10\% = 535$) for the injectable for participants with an opioid abuse/opioid dependence diagnosis. The current cost for the injectable is \$87.50 and \$50.00 for the intra-nasal. MHD assumes a 3% increase each year in costs. The impact in the first year would be \$287,513 ($((4,814 \times 50) + (535 \times \$87.50))$) (\$181,789 Federal; \$105,724 State). In subsequent years, MHD assumed that there would be 10% growth in the FY17 claims (5% due to new individuals seeking the opioid antagonistic and 5% due to participants accessing a drug refill, so the participant count for the injectable would be 54 ($535 \times 10\%$) and 481 ($4,814 \times 10\%$) for intra-nasal for each year. Therefore, in FY18 there will be an impact of \$4,876 for the injectable and \$24,772 for the intra-nasal (\$18,740 Federal; \$10,899 State); for FY19 there will be an impact of \$5,013 for the injectable and \$25,515 for the intra-nasal (\$19,302 Federal; \$11,226 State). Costs are split Federal/State 63.228%/36.772% , respectively.

In response to the previous version of this proposal, officials from the **Department of Health and Senior Services, the Department of Insurance, Financial Institutions and Professional Registration, the Department of Public Safety, Missouri State Highway Patrol, the Office of Administration and the Office of State Courts Administrator** each assume the proposal would not fiscally impact their respective agencies.

ASSUMPTION (continued)

Senate Amendment 1:

Oversight assumes Senate Amendment 1 will have no fiscal impact.

Senate Amendment 2 (§§192.945, 192.947, 195.207, and 261.265):

In response to similar legislation (SB 822), officials from the **Department of Health and Senior Services (DHSS)** stated under Section 192.945, RSMo, DHSS is currently issuing hemp extract registration cards for persons suffering from intractable epilepsy. This proposal would expand the current program by allowing the issuance of registration cards for persons with other chronic or debilitating diseases and conditions.

DHSS states the State of Oregon has a similar program in place that allows for the issuance of a registration card for conditions similar to those being proposed for the issuance of a hemp extract registration card under this proposed legislation. For purposes of this fiscal note, the State of Oregon's program will be benchmarked.

Applications

An October 2014 study by the nonprofit entity ProCon organization published the rates of patient registration cards issued for each state with a medical marijuana program (<http://medicalmarijuana.procon.org/view.resource.php?resourceID=005889>). This study found that Oregon was issuing qualified patient cards at a ratio of 17.7 per 1,000 residents. While the Oregon program was initiated in May 1999 and therefore has an established program, the state of Missouri's chronic disease rates are generally higher and the qualifying medical conditions accepted under Missouri's proposal are broader than those of Oregon. Missouri does allow for parents or legal guardians (could be more than one) of minors to be registered. For this fiscal note, we have termed additional parents or guardians as secondary registrants or caregivers.

Calculation of applications:

- Patients: According to the 2014 U.S. Census Bureau information, Missouri's population is at 6,063,589. Applying the rate of 17.7 applications per 1,000 residents, Missouri would estimate issuing 107,326 patient registration cards annually $((6,063,589/1,000) \times 17.7)$.
- Caregivers: According to the October 1, 2015 data on Oregon's Medical Marijuana Program Website, the ratio of patient registration cards to caregiver cards is calculated at 2.09. Calculating this same ratio, Missouri would estimate issuing 51,352 caregiver cards (secondary registrants) annually $(107,326/2.09)$.

ASSUMPTION (continued)

Section 192.945 requires the establishment of a the hemp extract program through promulgation of rules, including the development of program forms, registration card, and a system to record the name of each registrant and each minor receiving care from a registrant. As a result, DCPH anticipates the need to hire the following staff beginning on August 28, 2016 (FY 2017) to begin development of the system:

One Program Manager Broad Band 2 (\$65,000 annually) - will serve as Chief of the Hemp Extract Bureau. Duties will include overall program management, including involvement in rule promulgation, development of forms, program policies and procedures, information system development, and initial program set-up.

One Health Program Representative III (\$38,928 annually) - duties will include assistance in rule promulgation, program policies and procedures, forms development, information system development/troubleshooting and maintenance, and initial program set-up.

One Administrative Office Support Assistant (\$28,104 annually) - duties will include providing administrative assistance to the Bureau Chief and HPR III positions. As allowed, this position will also assist in initial processing of applications for registration cards.

For fiscal note purposes, DCPH calculated 45 minutes of processing time per patient and caregiver application. Based on this assumption, it was determined 57 FTE will be needed (158,678 applications X .75 hour per application/ 2,080 hours per year = 57.22 FTE). It is estimated that 1,650 practitioners will submit an application to the department for inclusion in the public registry of physicians and neurologists who recommend hemp extract. This estimation is based off the number of practitioners in Oregon who are affiliated with certifications for their program. It is also estimated that each practitioner application will take 45 minutes of processing time and the practitioner applications will need to be renewed each year. Based on this assumption, it was determined that an additional one (1) FTE is needed. The following staff will be hired effective July 1, 2017 upon completion of the system development and implementation of the program:

39 Senior Office Support Assistant (SOSA) positions (\$25,824 annually, each) - duties will include

- processing of paper applications for the practitioner registry as well as the hemp oil program, to include opening and date stamping of mail,
- initial entry of application information into the electronic registry for patients, caregivers, physicians and neurologists,
- initial verification of applicant and physician identification,
- preparation of patient and caregiver registration cards,
- answering and assisting telephone callers, and
- mailing of applicant correspondence, renewal notices, and registration cards.

ASSUMPTION (continued)

19 Health Program Representative II (HPR II) positions (\$34,944 annually, each) - duties will include

- supervision of the SOSA positions,
- quality assurance checks of the application including valid, Missouri licensed practitioners and required documentation of allowed condition,
- verification and approval of applications including final approval of application rejects and card issuances,
- drafting of correspondence for incomplete, inaccurate or unapproved applicants,
- dealing with applicant and medical complaints and concerns, and
- processing of physician and neurologist registrations for the public registry.

Printing

DCPH assumes that 90% of registrants will renew each year and renewal cards will also need to be printed for each registrant annually. DCPH also estimates new applicants to grow by 10 percent annually. DCPH will purchase three card printers for \$8,719 each and three magnetic strip encoders for \$695 each. The supplies (including ribbon, te-transfer set, etc) for the printers and encoders average \$0.63 per card. The cards itself cost \$96 per 500. DCPH will print 100,000 brochures each year the program is operational at a cost of \$.06 per brochure. This brochure will provide the public with information about the hemp extract program and assistance in completing a valid registration

	FY 2017	FY 2018	FY 2019
Cards for New Applicants	0	158,678	15,868
Cards for Renewals	0	0	142,810
Total Cards Issued	0	158,678	158,678

FY 2018

158,678 cards (\$96 per 500) = 318 X \$96 = \$30,528

158,678 cards (supplies x \$0.63 per card) = \$99,967

100,000 brochures (\$0.06 per brochure) = \$6,000

FY 2019

158,678 cards (\$96 per 500) = 318 X \$96 = \$30,528

158,678 cards (supplies x \$0.63 per card) = \$99,967

100,000 brochures (\$0.06 per brochure) = \$6,000

ASSUMPTION (continued)

Mailing costs

Each registrant will receive his/her card in the mail. Renewal cards will also be mailed to each registrant annually. It is also assumed five percent of applications (new and renewal) will be incomplete, requiring written notification of an incomplete application. It is also projected that 25 percent of the printed brochures (25,000) along with paper applications will be mailed to the public upon request. The other printed brochures will be available for distribution at conferences and other public venues.

Projected mailings are as follows:

	FY 2017	FY 2018	FY 2019
Cards mailed to new applicants	0	158,678	15,868
Renewal cards mailed	0	0	142,810
Brochures / app mailed	0	25,000	25,000
Incomplete Application	0	7,934	7,934
Total mailings	0	191,612	191,612

FY 2018

191,612 envelopes (\$41 per 1,000) = 192 X \$41 = \$7,872
 Postage (191,612 x \$0.39/postage rate) = \$74,729

FY 2019

191,612 envelopes (\$41 per 1,000) = 192 X \$41 = \$7,872
 Postage (191,612 x \$0.39/postage rate) = \$74,729

Application Storage Costs

In order to manage the final storage of paper applications submitted, Content Manager for electronic scanning and storage will be utilized. The costs for Content Manager are estimated at \$132 per month for the state data server costs, \$624 for an annual license for each user, and \$686 for an annual license for each position with ability to scan/import documents.

DHSS, Division of Administration (DA)

For fiscal note purposes DA estimates one Accounting Clerk can process 30,000 receipt transactions received per year. DHSS estimates 158,678 payments for applications will be processed in FY 2018 and 158,678 in FY 2019. (158,678/30,000=5.3) An Accounting Generalist I/II will be needed for every five Accounting Clerks.

ASSUMPTION (continued)

Five Accounting Clerk positions (\$25,824 annually, each) - duties will include

- Opens and sorts mail;
- Process and enter receipts into the departmental computer system;
- Prepares bank deposits and cash receipts documents;
- Reconciles daily receipts;
- Distributes supporting documentation to program.

One Accounting Generalist I/II position (\$36,204 annually) - duties will include

- Supervise and review the work of Account Clerks II who are processing the application fees.
-

DHSS - ITSD assumes 6,152 hours of programming would be needed to implement the program. Assuming a cost of \$75 per hour, ITSD assumes a cost of \$461,376 in FY 2017. For on-going support, DHSS assumes an annual cost of approximately \$95,000.

A 12 month project effort with three contractors has been assumed. It is assumed the application will be hosted in the State Data Center (SDC) on existing web application servers. Disk space has been assumed at 50 GB per environment (DEVO, TEST and PROD). Funding for ongoing maintenance will come from registration fees established by DHSS.

Fees:

This proposal allows the DHSS to establish a fee for the issuance of a hemp extract registration card. For purposes of this fiscal note, it estimated that DHSS would charge a \$30 registration fee.

The list of conditions that would be eligible for this registration is comparable to the conditions authorized in a similar program in Oregon. For purposes of this fiscal note, DHSS used the Oregon program to benchmark the estimation of annual registrants.

It is anticipated that Missouri will receive 158,678 new applications in its first year of operation, FY 2018. In subsequent years, new applications are estimated to grow by 10 percent annually; however, renewals are estimated to decline by 10 percent annually.

Projected fees received for the three years (FY 2017 - FY 2019) are as follows:

	FY 2017	FY 2018	FY 2019
Application & Renewals	0	158,678	158,678
Application Fees	\$0	\$4,760,340	\$4,760,340

ASSUMPTION (continued)

In summary, DHSS assumes need for 3 FTE in FY 2017 and 67 FTE in FY 2018 going forward. DHSS assumes a total cost of \$669,758 in FY 2017, \$4,767,045 in FY 2018, and \$4,373,466 in FY 2019.

In response to similar legislation (SB 822), officials from the **Department of Agriculture (AGR)** state because the list of persons who may receive a hemp extract registration card will be expanded with this legislation, it is anticipated that the production of hemp extract would increase as well. It is assumed that there could be as many as 10 licensed cultivation production facilities across the state. It is assumed that each production facility would have monthly inspections.

It is assumed that an inspection would be similar to other FDA inspections which we currently conduct for feed facilities which is calculated at 30 hours.

10 cultivation/production sites * 12 monthly inspections * 30 hours = 3,600 inspection hours.

Total inspection hours 3,600 / 1,800 hours = 2 (2 FTE).

The 2 FTE (Feed and Seed Inspector II) are at range A22 step M (\$40,380 annually). Inspectors would be responsible for monthly inspection of cultivation/production facilities. It is anticipated that facilities would be located in major metro areas of Missouri including St. Louis, Kansas City and Springfield.

In summary, AGR assumes a cost to the General Revenue Fund of \$169,118 in FY 2017, \$152,213 in FY 2018, and \$153,957 in FY 2019.

Oversight notes provisions within 261.265 provides that the AGR will issue a cultivation and production facility license to a nonprofit entity to grow or cultivate the cannabis plant used to make hemp extract or hemp on the entity's property if the entity "has been a resident of the state for at least five years and has completed a state and federal fingerprint-based criminal record check in accordance with section 43.543 and has paid all applicable criminal background check fees in accordance with section 43.530..." As a result, Oversight assumes this provision will have an impact the **Department of Public Safety (DPS), Missouri State Highway Patrol's (MHP) Criminal Records Fund**.

In response to provisions in other proposals that result in a fiscal impact to the Criminal Records Fund, DPS, MHP officials have provided that the cost for a fingerprint-based background check, to include state and federal checks for both open and closed records, is \$43.05. Twenty dollars is for the state fingerprint check, \$14.75 is for the federal check, and an \$8.30 charge for the electronic fingerprint option used through a third-party vendor (\$20 + 14.75 + 8.30 = \$43.05).

ASSUMPTION (continued)

Of this amount, the state retains the \$20 fee and \$2 of the federal charge of \$14.75 as a pass-thru fee. The \$8.30 charge is paid directly to the vendor at the time of application. **Oversight** assumes an unknown positive fiscal impact to the Criminal Records Fund

In response to similar legislation (SB 822), officials from the **Department of Insurance, Financial Institutions and Professional Registration** each assume the proposal would not fiscally impact their respective agencies.

In response to similar legislation (SB 822), according to officials from the **Office of the Secretary of State (SOS)**, 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, we also recognize 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 our office can sustain with our core budget. Therefore, we reserve 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 **Joint Committee on Administrative Rules** state this legislation is not anticipated to cause a fiscal impact beyond its current appropriation.

<u>FISCAL IMPACT - State Government</u>	FY 2017 (10 Mo.)	FY 2018	FY 2019
GENERAL REVENUE FUND			
<u>Income</u> - Department of Health and Senior Services - Fees from hemp registration (\$192.945.6)			
	\$0	\$4,760,340	\$4,760,340
<u>Costs</u> - DHSS - expansion of hemp extract program beyond epilepsy			
Personal Service	(\$110,027)	(\$1,988,112)	(\$2,007,993)
Fringe Benefits	(\$55,289)	(\$1,219,316)	(\$1,224,748)
ITSD programming	(\$461,632)	(\$94,896)	(\$97,269)
Office Space Rental	(\$12,076)	(\$14,852)	(\$15,223)
Expense and Equipment	(\$30,734)	(\$1,449,869)	(\$1,028,233)
<u>Total Costs</u> - DHSS	<u>(\$669,758)</u>	<u>(\$4,767,045)</u>	<u>(\$4,373,466)</u>
FTE Change - DHSS	3 FTE	67 FTE	67 FTE
<u>Costs</u> - AGR			
Personal Service (2 FTE)	(\$67,300)	(\$81,568)	(\$82,383)
Fringe Benefits	(\$35,206)	(\$42,468)	(\$42,691)
Vehicles	(\$38,686)	\$0	\$0
Laboratory Expenses	(\$20,833)	(\$25,625)	(\$26,266)
Other expense and equipment	(\$7,093)	(\$2,552)	(\$2,617)
<u>Total Costs</u> - AGR	<u>(\$169,118)</u>	<u>(\$152,213)</u>	<u>(\$153,957)</u>
FTE Change - AGR	2 FTE	2 FTE	2 FTE
<u>Costs</u> - DSS (§ 195.206)			
Program expenditures	(\$105,724)	(\$10,899)	(\$11,226)
ESTIMATED NET EFFECT ON THE GENERAL REVENUE FUND			
	<u>(\$944,600)</u>	<u>(\$169,817)</u>	<u>(\$221,691)</u>
Estimated Net FTE Change on the General Revenue Fund			
	5 FTE	69 FTE	69 FTE

<u>FISCAL IMPACT - State Government</u>	FY 2017 (10 Mo.)	FY 2018	FY 2019
CRIMINAL RECORDS FUND			
<u>Income</u> - MHP			
Background checks	Unknown	Unknown	Unknown
<u>Costs</u> - MHP			
Federal background check charge	<u>(Unknown)</u>	<u>(Unknown)</u>	<u>(Unknown)</u>
ESTIMATED NET EFFECT ON THE CRIMINAL RECORDS FUND	<u>Unknown</u>	<u>Unknown</u>	<u>Unknown</u>
FEDERAL FUNDS			
<u>Income</u> - DSS (§ 195.206)			
Increase in program reimbursements	\$181,789	\$18,740	\$19,302
<u>Costs</u> - DSS (§ 195.206)			
Increase in program expenditures	<u>(\$181,789)</u>	<u>(\$18,740)</u>	<u>(\$19,302)</u>
ESTIMATED NET EFFECT ON FEDERAL FUNDS	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>
<u>FISCAL IMPACT - Local Government</u>	FY 2017 (10 Mo.)	FY 2018	FY 2019
	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>

FISCAL IMPACT - Small Business

The proposal may have a minimal fiscal impact on small business pharmacies. (§§195.206 and 338.205)

FISCAL DESCRIPTION

This bill allows any licensed pharmacist to sell and dispense intranasal naloxone under physician protocol to any person who is at least 18 years old with a valid Missouri identification or driver license. The licensed pharmacist or pharmacy technician must record specified information pertaining to the sale.

FISCAL DESCRIPTION (continued)

The bill creates immunity from criminal prosecution, disciplinary actions from a professional licensing board, and civil liability for an individual who, acting in good faith and with reasonable care, administers an opioid antagonist to an individual whom he or she believes is suffering an opioid-related drug overdose. Any individual or organization may store and dispense an opioid antagonist without being subject to the licensing and permitting requirements in Chapter 338, RSMo, if he or she does not collect a fee or compensation for dispensing the opioid antagonist when the person or organization is acting under a standing order issued by a health care professional who is authorized to prescribe an opioid antagonist. (§§195.206 and 338.205)

Current law allows people with intractable epilepsy to possess and use hemp extract to treat their condition. This act also allows people with serious conditions to use hemp extract.

Serious condition is defined as cancer, HIV, AIDS, amyotrophic lateral sclerosis, Parkinson's disease, multiple sclerosis, spinal cord damage, inflammatory bowel disease, neuropathies, Huntington's disease, post-traumatic stress disorder, or certain specified symptoms or complications associated with the conditions listed above.

Under current law, the Department of Health and Senior Services must issue a registration card to a person who provides a statement signed by a neurologist that the person suffers from intractable epilepsy and may benefit from treatment with hemp extract. This act provides that the Department must issue a registration card to a person who provides a recommendation signed by a physician or neurologist that the person suffers from a serious condition or intractable epilepsy and may benefit from treatment with hemp extract, indicates the physician or neurologist is qualified to treat the condition, and states that the individual is under the neurologist or practitioner's continuing care.

This act requires neurologists and physicians to notify patients before providing a recommendation that hemp extract is not FDA approved and, by using hemp extract, the patient is accepting the risks involved in using an unapproved product.

This act specifies that only a neurologist or physician may recommend hemp extract as part of a treatment plan for a patient who has been diagnosed with intractable epilepsy or a serious condition.

The Department of Health and Senior Services must establish a public registry of physicians and neurologists who recommend hemp extract.

Under this act, no individual or health care entity organized under the laws of the state shall be subject to any adverse action by the state, including civil or criminal prosecution, denial of any right or privilege, the imposition of a civil or administrative penalty or sanction, or disciplinary action by any accreditation or licensing board or commission if such individual or health care

FISCAL DESCRIPTION (continued)

entity, in its normal course of business and within its applicable licenses and regulations, acts in good faith on any order, recommendation, or statement by a neurologist or practitioner relating to the medical use and administration of hemp extract.

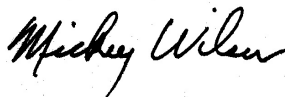
Current law allows the Department of Agriculture to license up to two cultivation and production facility licenses. This act allows the department to issue licenses for up to ten facilities.

This act requires nonprofit entities seeking such licensure to have had their residence in the state for at least five years. Cultivation and production facility licenses issued before August 28, 2015 continue to be valid even if the licensee fails to meet the residency requirement. (§§192.945, 192.947, 195.207, and 261.265)

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

SOURCES OF INFORMATION

Department of Agriculture
Department of Health and Senior Services
Department of Insurance, Financial Institutions and Professional Registration
Department of Public Safety -
 Missouri State Highway Patrol
Department of Social Services -
 MO HealthNet Division
Joint Committee on Administrative Rules
Office of Administration
Office of State Courts Administrator
Office of Secretary of State



Mickey Wilson, CPA
Director
April 26, 2016

Ross Strope
Assistant Director
April 26, 2016