

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 0274-10
#Bill No.: Perfected SS#2 for SB 386
Subject: Agriculture Department; Drugs and Controlled Substances; Health Care; Health Care Professionals; Health Department; Licenses - Miscellaneous
Type: Corrected
Date: April 21, 2015
 # Correct the Bill Number to reflect SS#2

Bill Summary: This proposal modifies provisions relating to hemp extract.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2016	FY 2017	FY 2018
General Revenue	(\$705,877)	(\$136,308)	\$177,755
Total Estimated Net Effect on General Revenue	(\$705,877)	(\$136,308)	\$177,755

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 12 pages.

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

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)			
FUND AFFECTED	FY 2016	FY 2017	FY 2018
General Revenue	4 FTE	58 FTE	59 FTE
Total Estimated Net Effect on FTE	4 FTE	58 FTE	59 FTE

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

Due to time constraints, **Oversight** prepared the fiscal note for the original bill without some agency responses. Oversight has received agency responses for this Senate Substitute (0274-10) and is reflecting their estimates in this fiscal note.

Officials from the **Department of Health and Senior Services (DHSS)** state the proposed legislation allows the Department of Agriculture to issue licenses to ten cultivation and production facilities in the state to grow or cultivate the cannabis plant used to make the hemp extract. There could be an unknown impact on small businesses that may serve as these facilities.

This proposal allows 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 \$19 registration fee.

The list of conditions that would be eligible for this registration is comparable to the conditions authorized in the Oregon Medical Marijuana Program (OMMP).

For purposes of this fiscal note, the OMMP will be benchmarked for the estimation of annual registrants.

It is anticipated that Missouri will receive 200,390 new applications in its first year of operation, FY 2017. In subsequent years, new applications and renewals are estimated to grow by two percent annually. The number of applications will grow to 204,398 in FY 2018.

Projected fees received for the three years (FY 2016 - FY 2018) are as follows:

	FY 2016	FY 2017	FY 2018
Application & Renewals	0	200,390	204,398
Application Fees	\$0	\$3,807,410	\$3,883,562

DHSS, Division of Community and Public Health (DCPH) - Section 192.945.2 requires DHSS to issue hemp extract registration cards to individuals age eighteen and older with intractable epilepsy or a serious condition or to the parent of a minor who suffers from intractable epilepsy or a serious condition upon submission of information and documentation also outlined in Section 192.945.2 and 192.945.3.

ASSUMPTION (continued)

Section 192.945.4 requires DHSS to maintain a record of the name of each registrant and the name of each minor receiving care from a registrant.

Section 192.945.5 requires DHSS to promulgate rules to implement the provisions of the hemp extract registration and allows DHSS to consider promulgating rules to authorize clinical trials involving hemp extract.

Office of Administration-Information Technology Services Division (ITSD) - state the proposal would require ITSD support to obtain vendor services to build a web application for recording applications, accepting registration fees and issuing registration cards. Data recorded in the system shall be treated as identifiable health data. Applications from registrants including supporting documentation will be received in paper format and data entered by DHSS staff. DHSS assumes an ITSD cost of \$308,558 in FY 2016, \$63,534 in FY 2017 and \$65,122 in FY 2018.

DHSS, DCPH - state the State of Oregon has a medical marijuana program in place that allows for the issuance of a medical marijuana 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. The Oregon program was initiated in May 1999. Information from the Oregon Medical Marijuana Program (OMMP) indicates the following as of January 1, 2015:

Number of OMMP patients	69,865
Number of current OMMP caregivers	34,914

Applications - for the purposes of fiscal note computations, DHSS assumes that the number of patients registered in Oregon will remain at 69,865 patients and 34,914 caregivers. Since the diagnoses accepted are broader under the proposed Missouri program and Missouri's rates of chronic diseases are generally higher than those of Oregon, DHSS is assuming 25 percent more applicants in Missouri. 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.

2014 Population of Oregon - 3,970,239 (Source -- US Census)
2014 Population of Missouri - 6,063,589 (Source -- US Census)

ASSUMPTION (continued)

Calculation of applications:

- Oregon - 69,865 patient registrants + 34,914 caregiver registrants = 104,779 annual applications.
- $6,063,589 \text{ Missouri population} / 3,970,239 \text{ Oregon population} = 1.53$. Applying the 1.53 factor to registrants = 160,312 (106,894 patients + 53,418 secondary registrants) Missouri registrants.
- $160,312 \text{ Missouri registrants} \times 1.25 \text{ (adjustment for additional diagnoses)} = 200,390 \text{ total Missouri registrants}$ (133,618 patients + 66,712 secondary registrants.) DHSS assumes total registrants will increase two percent each year.

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, 2015 (FY 2016) to begin development of the system:

One Program Manager Broad Band 2 (\$65,000) - 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 (A24, \$38,928) - 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 (A15, \$28,104) - 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 estimated it will take approximately 30 minutes to process an application from start to finish. Based on this assumption, it was determined 48 FTE will be needed ($200,390 \text{ applications} / 2 \text{ per hour results in } 100,195 \text{ work hours} / 2,080 \text{ hours per year} = 48.17 \text{ FTE}$). The following staff will be hired effective July 1, 2016 upon completion of the system development and implementation of the program:

ASSUMPTION (continued)

32 Senior Office Support Assistant (SOSA) positions (A12, \$25,824) - 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;
- initial verification of applicant and physician identification;
- preparation of patient and caregiver registration cards;
- answering and assisting telephone callers;
- mailing of applicant correspondence, renewal notices, and registration cards.

16 Health Program Representative II (HPR II) positions (A21, \$34,944) - 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;
- responsible for medical practitioner registration process.

Printing - DCPH assumes that each registrant will renew each year and renewal cards will also need to be printed for each registrant 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 medical cannabis program and assistance in completing a valid registration.

FY 2017

200,390 cards (\$96 per 500) = 401 X \$96 = \$38,496

200,390 cards (supplies x \$0.63 per card) = \$126,246

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

FY 2018

204,398 cards (\$96 per 500) = 409 X \$96 = \$39,264

204,398 cards (supplies x \$0.63 per card) = \$128,771

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

ASSUMPTION (continued)

	FY 2016	FY 2017	FY 2018
Cards mailed to new applicants	0	200,390	4,008
Renewal cards mailed	0	0	200,390
Total Cards	0	200,390	204,398

Mailing costs - each registrant will receive his/her card in the mail. It is assumed that each patient and caregiver will renew each year. Renewal cards will also be mailed to each registrant annually. It is also assumed five percent of applications 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 2016	FY 2017	FY 2018
Cards mailed to new applicants	0	200,390	4,008
Renewal cards mailed	0	0	200,390
Brochures/app mailed	0	25,000	25,000
Incomplete Application	0	10,019	10,219
Total mailings	0	235,409	239,617

FY 2017

235,409 envelopes (\$41 per 1,000) = $236 \times \$41 = \$9,676$

Postage (235,409 x \$0.39/postage rate) = \$91,810

FY 2018

239,617 envelopes (\$41 per 1,000) = $240 \times \$41 = \$9,840$

Postage (239,617 x \$0.39/postage rate) = \$93,451

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.

ASSUMPTION (continued)

DHSS, Division of Administration (DA)

For fiscal note purposes DA estimates one Account Clerk I can process 50,000 payments received per year. DHSS estimates 200,390 payments for applications will be processed in FY 2017 and 204,398 in FY 2018. $(200,390/50,000=4.0078)$

Four Account Clerk I positions (A08, \$22,536) 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 Accountant I position (A18, \$30,984) duties will include

- Supervise and review the work of Account Clerk Is who are processing the application fees.

In summary, DHSS assumes the need for an additional 56 FTE (mostly added in FY 2017) with a total cost of \$610,797 in FY 2016, \$3,769,046 in FY 2017, and \$3,464,686 in FY 2018. DHSS assumes registration fees of approximately \$3.8 million per year, starting in FY 2017.

Officials from the **Department of Agriculture (AGR)** state this bill will expand the number of regulated hemp facilities from two to ten incrementally through 2018.

It is assumed that there will be 10 licensed cultivation production facilities across the state. It is assumed that each cultivation facility may have 10 distribution sites by 2018. It is also assumed that each production facility and distribution site 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 in 2018).

It is assumed that it would take 10 hours to audit a distribution site.
 $10 \text{ sites} * 10 \text{ hours} * 12 \text{ monthly inspections} = 1,200 \text{ inspection hours in 2018.}$

Total inspection hours 4,800/ 1,800 hours = 2.7 (3 FTEs) in 2018.

AGR assumes the need for 3 FTE Feed and Seed Inspectors (at \$40,380 annually, incrementally added). The Inspectors would be responsible for monthly inspection of cultivation/production

ASSUMPTION (continued)

facilities. The regulation currently holds MDA responsible for distribution of hemp extract as well. It is anticipated that facilities would be located in major metro areas of Missouri including St. Louis, Kansas City and Springfield with distribution sites located throughout. Inspectors would be located in each of these areas in the state.

In summary, AGR assumes a cost of \$95,080 in FY 2016, \$174,672 in FY 2017, and \$241,121 in FY 2018.

In response to a similar version of this bill, officials from the **Department of Insurance, Financial Institutions and Professional Registration** and the **Department of Public Safety - Missouri Highway Patrol** each assumed no fiscal impact to their respective agencies.

Officials from the **Joint Committee on Administrative Rules** state this legislation is not anticipated to cause a fiscal impact to their agency beyond its current appropriation.

<u>FISCAL IMPACT - State Government</u>	FY 2016 (10 Mo.)	FY 2017	FY 2018
GENERAL REVENUE			
<u>Income</u> - Department of Health and Senior Services - Fees from hemp registration §192.945.6			
	\$0	\$3,807,410	\$3,883,562
<u>Costs</u> - Department of Health and Senior Services - expansion of hemp extract program beyond epilepsy.			
Personal Service	(\$110,027)	(\$1,655,018)	(\$1,671,569)
Fringe Benefits	(\$57,220)	(\$860,692)	(\$869,299)
ITSD programming	(\$308,558)	(\$63,534)	(\$65,122)
Office space rent	(\$11,558)	(\$221,134)	(\$226,662)
Expense and Equipment	<u>(\$123,434)</u>	<u>(\$968,668)</u>	<u>(\$632,034)</u>
Total Costs - DHSS	(\$610,797)	(\$3,769,046)	(\$3,464,686)
FTE Change - DHSS	3 FTE	56 FTE	56 FTE
<u>Costs</u> - Department of Agriculture			
Personal Service	(\$33,650)	(\$81,568)	(\$123,575)
Fringe Benefits	(\$17,500)	(\$42,419)	(\$64,265)
Vehicles	(\$19,343)	(\$19,923)	(\$20,521)
Laboratory Expenses	(\$20,833)	(\$25,625)	(\$26,266)
Expense & Equipment	<u>(\$3,754)</u>	<u>(\$5,137)</u>	<u>(\$6,494)</u>
Total Costs - AGR	<u>(\$95,080)</u>	<u>(\$174,672)</u>	<u>(\$241,121)</u>
FTE Change - AGR	1 FTE	2 FTE	3 FTE
ESTIMATED NET EFFECT TO THE GENERAL REVENUE FUND	<u>(\$705,877)</u>	<u>(\$136,308)</u>	<u>\$177,755</u>
Estimated Net FTE Change for the General Revenue Fund	4 FTE	58 FTE	59 FTE
<u>FISCAL IMPACT - Local Government</u>	FY 2016 (10 Mo.)	FY 2017	FY 2018
	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>

FISCAL IMPACT - Small Business

Small hemp businesses could be impacted as a result of this proposal.

FISCAL DESCRIPTION

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 practitioner or neurologist that the person suffers from a serious condition or intractable epilepsy and may benefit from treatment with hemp extract, indicates the practitioner or neurologist is qualified to treat the condition, states that the individual is under the neurologist or practitioner's continuing care, and recommends the form of hemp extract the patient may consume, including the method of consumption. The practitioner must be a licensed physician.

This act requires neurologists and practitioners 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.

Registration cards currently expire after one year. This act provides that the practitioner or neurologist may specify an earlier date of expiration.

Under this act, a person may only possess a form of hemp extract that complies with the neurologist or practitioner's recommendations.

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

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

FISCAL DESCRIPTION (continued)

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 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.

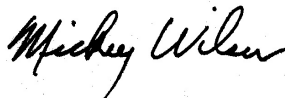
Current law allows the Department of Agriculture to license up to two cultivation and production facility licenses. This act allows the department issue licenses for up to five facilities in 2016, up to eight facilities in 2017, and up to ten facilities in 2018 and each year thereafter.

This act requires nonprofit entities seeking such licensure to have had their domicile 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 requirement for entities to be domiciled in Missouri for at least five years.

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

SOURCES OF INFORMATION

Department of Health and Senior Services
Department of Insurance, Financial Institutions and Professional Registration
Department of Agriculture
Department of Public Safety
Office of the Secretary of State
Joint Committee on Administrative Rules



Mickey Wilson, CPA
Director
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