COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 6096-01
Bill No.: HB 2562
Subject: Health and Senior Services Department; Health Care; Physicians; Drugs and Controlled Substances
Type: Original
Date: February 29, 2016

Bill Summary: This proposal changes the laws regarding the Cancer Information Reporting System.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
General Revenue	Unknown to (More than $293,011)	Unknown to (More than $240,112)	Unknown to (More than $243,109)
Total Estimated Net Effect on General Revenue	**Unknown to (More than $293,011)**	**Unknown to (More than $240,112)**	**Unknown to (More than $243,109)**

ESTIMATED NET EFFECT ON OTHER STATE FUNDS			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
Total Estimated Net Effect on Other State Funds	**$0**	**$0**	**$0**

Numbers within parentheses: ( ) indicate costs or losses.
This fiscal note contains 8 pages.

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

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
General Revenue	3	3	3
Total Estimated Net Effect on FTE	**3**	**3**	**3**

☒ 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

Oversight was unable to receive some of the agency responses in a timely manner due to the short fiscal note request time. Oversight has presented this fiscal note on the best current information that we have or on prior year information regarding a similar bill. Upon the receipt of agency responses, Oversight will review to determine if an updated fiscal note should be prepared and seek the necessary approval of the chairperson of the Joint Committee on Legislative Research to publish a new fiscal note.

Oversight notes that in response to similar legislation from the prior session for HB 1020 (LR # 2258-01), the following agency responses were received:

In response to HB 1020, officials from the **Department of Health and Senior Services (DHSS)** provided the following assumptions:

Section 192.654.2 requires DHSS to collect information from oncologists and other health care providers on off label drugs used to treat cancer and other terminal diseases. The Division of Community and Public Health (DCPH) will require a web-based data system to collect information and 0.5 FTE Research Analyst III ($40,380 annually) to manage the data system. In addition, this FTE will also analyze and/or manipulate data as needed for reporting and responding to data requests.

Section 192.654.3 requires DHSS to track clinical trials conducted in the state, share information on the clinical trials with oncologists, other health care providers and research institutes statewide and nationally, as well as sharing information with sponsors or investigators on off-label use of drugs. This, too, will require a web based data entry system, 0.5 FTE Research Analyst III, 1.0 FTE Health Program Representative III and a Senior Office Support Assistant.

The 0.5 FTE Research Analyst III ($40,380 annually) will manage the data system, analyze or manipulate data as needed for reporting and respond to data requests. This position will be responsible for writing the rules required by this bill in conjunction with the Health Program Representative.

1.0 FTE Health Program Representative III ($38,928 annually) will conduct outreach activities to provide awareness of and encourage participation in the program. This position will take the lead in mailings and contact with oncologists and health care professionals. This position will also be responsible for writing the rules required by this bill in conjunction with the Research Analyst.

ASSUMPTION (continued)

1.0 FTE Senior Office Assistant ($25,824 annually) will support the Research Analyst and Health Program Representative in their daily activities, will take phone calls and help with the mailing notification process and data entries.

Section 192.654.6 requires that rules be written to implement this bill. These rules will be written jointly by the Research Analyst III and Health Program Representative III.

Section 192.654.3 (2)(a) and (b) requires the DHSS to provide a notice to all licensed oncologists and other healthcare providers in the state, as well as the nationally recognized cancer research institutions within and outside the state, of the reported placebo-controlled clinical drug trial research projects. This notice is to accompany a request for voluntary notification of engagement in the use of off-label drugs for treatment of cancer. For fiscal note purposes DHSS estimates that this notification will occur once a month via a written notification (mailing). It is also assumed for purposes of this fiscal note that the notification will be targeted at licensed oncologists and the cancer research institutions (approximately 5,000) as these are the providers interested in and responsible for treatment of cancer. These mailings would begin in FY 2017 at an approximate cost of $1,950 (5,000 x $0.39) per month or $23,400 per year.

Section 192.654.3(2)(d) allows the DHSS to collect a fee to cover the costs of processing the data. At this time, the fee is unknown because the number of sponsors or investigators who would request the data is unknown.

DHSS submitted the response for the **Office of Administration (OA), Information Technology Services Division (ITSD)** in response to HB 1020. In it's response, ITSD stated the proposal would require ITSD support to obtain vendor services to develop a cancer information reporting system for the reporting of off-label usage of drug for treatment by oncologist and other health care providers. Additionally, the cancer information reporting system will be used for the reporting of intent to run a placebo-controlled clinical drug trial research project in the state including the drug or drugs that are being investigated. The information collected will be used for providing notice to designated licensed oncologists and other health care providers in the state as well as appropriate nationally recognized cancer research institutions within and outside of the country.

A 4 month project effort with two contractors has been assumed with a project duration to be determined. 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). It is assumed that every new IT project/system will be bid out because all ITSD resources are at full capacity. ITSD assume FY 2016 costs to the General Revenue (GR) Fund of $114,320. On-going support and expenses for FY 2017 are estimated at $23,715 and FY 2018 costs are estimated to be $24,308.

ASSUMPTION (continued)

The DHSS assumes the fiscal impact of this proposal on the General Revenue Fund, including ITSD costs and Unknown fees collected to cover the costs of processing data, to be Unknown to a cost of $293,011for FY 2016; Unknown to a cost of $240,112 for FY 2017; and Unknown to a cost of $243,109 for FY 2018.

In response to HB 1020, officials from the **University of Missouri (UM)** state the proposed legislation should not create additional expenses in excess of $100,000 per year.

Oversight assumes this is the materiality threshhold for the UM Health Care and that any costs incurred by UM can be absorbed within current resource levels.

In response to HB 1020, officials from the **Office of the Secretary of State (SOS)** stated 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 assumed 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.

In response to the current proposal, officials from the **Joint Committee on Administrative Rules (JCAR)** state the legislation is not anticipated to cause a fiscal impact to JCAR beyond its current appropriation.

For purposes of this fiscal note, **Oversight** as not adjusted agency estimates for inflation and will present costs as "more than" the numbers provided in last year's responses.

FISCAL IMPACT - State Government	FY 2017 (10 Mo.)	FY 2018	FY 2019
GENERAL REVENUE FUND			
Revenue - DHSS			
Data fees	Unknown	Unknown	Unknown
Costs - DHSS- DCPH (§192.654)	More than...	More than...	More than...
Personal service	($87,610)	($106,183)	($107,245)
Fringe benefits	($45,562)	($55,220)	($55,773)
Equipment and expense	($45,519)	($31,594)	($32,383)
Mailing costs	$0	($23,400)	($23,400)
Total Costs - DHSS- DCPH	(More than $178,691)	(More than $216,397)	(More than $218,801)
FTE Change - DHSS- DCPH	3 FTE	3 FTE	3 FTE
Costs - OA-ITSD	More than...	More than...	More than...
Contract consultants and on-going costs	($114,320)	($23,715)	($24,308)
ESTIMATED NET EFFECT ON THE GENERAL REVENUE FUND	**Unknown to (More than $293,011)**	**Unknown to (More than $240,112)**	**Unknown to (More than $243,109)**
Estimated Net FTE Change on the General Revenue Funds	3 FTE	3 FTE	3 FTE

FISCAL IMPACT - Local Government	FY 2017 (10 Mo.)	FY 2018	FY 2019
	$0	**$0**	**$0**

FISCAL IMPACT - Small Business

No direct fiscal impact to small businesses would be expected as a result of this proposal.

FISCAL DESCRIPTION

This bill allows oncologists and other health care providers to voluntarily notify the Department of Health and Senior Services if they are treating terminally ill patients with off-label drugs for treatment and which drugs they use and for what purposes.

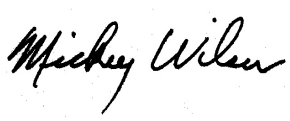
The bill requires the information reporting system database, maintained by the department to include the name, address, and specified off-label usage of a drug for treatment for each oncologist or health care provider who provided the department with this information. The department must be notified when specified providers intend to run a placebo-controlled clinical drug trial research project and notify the department of the drug or drugs being investigated and for what purpose. Upon notification by the provider the department must provide notice to all licensed oncologists, other health care providers, and nationally recognized cancer research institutions within and outside of the state, of the placebo-controlled clinical drug trial research project, the drug or drugs being investigated, and for what purpose along with a request for voluntary notification to the department as specified in the bill. The department must compile a list of the specified information and provide the sponsor or investigator with the list upon request and for a fee as determined by the department.

This bill requires any sponsor or investigator of a placebo-controlled clinical drug trial research project of a treatment drug for patients with terminal illness conducted in the state to provide prospective trial participants, a list of oncologists and other health care providers in the state who are engaged in the treatment of patients with medical conditions the same as or similar to the prospective trial participant's medical condition through the off-label usage of drugs for treatment. Any sponsor of a placebo-controlled clinical drug trial research project who willfully fails to obtain a trial participant's informed consent will be subject to a fine of $50,000.

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

SOURCES OF INFORMATION

Department of Health and Senior Services
Joint Committee on Administrative Rules
Office of Secretary of State
University of Missouri



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