COMMITTEE ON LEGISLATIVE RESEARCH OVERSIGHT DIVISION

FISCAL NOTE

<u>L.R. No.</u> :	0471-05
Bill No.:	Truly Agreed To and Finally Passed CCS for HCS for SCS for SB 139
Subject:	Pharmacy; Drugs and Controlled Substances; Health and Senior Services
	Department
<u>Type</u> :	Original
Date:	June 5, 2017

Bill Summary: This proposal modifies provisions relating to health care.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND				
FUND AFFECTED	FY 2018	FY 2019	FY 2020	
General Revenue	\$6,474,850	\$6,737,010	\$6,971,262	
Total Estimated Net Effect on General Revenue	\$6,474,850	\$6,737,010	\$6,971,262	

ESTIMATED NET EFFECT ON OTHER STATE FUNDS					
FUND AFFECTED	FY 2018	FY 2019	FY 2020		
MO Rx Plan	(\$3,879,438)	(\$4,655,326)	(\$4,655,326)		
Board of Pharmacy	(Unknown)	(Unknown)	(Unknown)		
Total Estimated Net Effect on <u>Other</u> State Funds	(Greater than \$3,879,438)	(Greater than \$4,655,326)	(Greater than \$4,655,326)		

Numbers within parentheses: () indicate costs or losses.

This fiscal note contains 12 pages.

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ESTIMATED NET EFFECT ON FEDERAL FUNDS					
FUND AFFECTED	FY 2018	FY 2019	FY 2020		
Federal*	\$0	\$0	\$0		
Total Estimated Net Effect on <u>All</u> Federal Funds	\$0	\$0	\$0		

*Income, savings, costs and losses exceed \$22.4 million annually and net to \$0.

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)					
FUND AFFECTED FY 2018 FY 2019 FY 202					
Total Estimated Net Effect on FTE	0	0	0		

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 2018	FY 2019	FY 2020	
Local Government	\$0	\$0	\$0	

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FISCAL ANALYSIS

ASSUMPTION

§196.990 - Epinephrine auto-injectors

Officials from the **Department of Social Services (DSS)** state Division of Youth Services (DYS) personnel currently authorized to administer epinephrine auto-injectors are trained by a company meeting the criteria put forth in the proposed legislation. There is a good faith effort requirement to gain the verbal consent of a parent or guardian prior to administering the injection to an individual under 18 years of age. DYS does not anticipate any fiscal impact.

There is no impact to the MO HealthNet Division (MHD). MHD does not pay to stock items. Furthermore, it is likely that ambulances already have epinephrine auto-injectors in the ambulance.

Oversight assumes since the provisions regarding the prescription of epinephrine auto-injectors by a physician to an authorized entity and the acquiring of a stock supply of epinephrine auto-injectors by the authorized entity are permissive that no university, county or local health department would incur additional costs unless the entity chooses to incur them.

§208.227 - Pharmaceutical case management/Polypharmacy program

Officials from the **Department of Social Services (DSS)**, **MO HealthNet Division (MHD)** and the **Division of Legal Services (DLS)** state the FY2018 DSS requested budget includes funding for both dual and non-dual eligibles. The FY2018 DSS Truly Agreed To and Finally Passed budget includes funding for only dual eligibles.

DSS officials provide the following assumptions:

<u>§208.227.1</u> requires MO HealthNet to establish a pharmaceutical case management or polypharmacy program for high-risk MO HealthNet participants with numerous or multiple prescribed drugs or medications.

MHD officials state that MHD currently employs several tools as part of its behavioral health pharmacy and opioid surveillance program:

Care Management Technologies (CMT) – CMT has a contract with DHSS and other partners (DMH, the Missouri Coalition for Community Behavioral Healthcare) to provide healthcare data analytics services, in particular through their Behavioral Pharmacy Management (BPM), and Opioid Prescription Intervention (OPI) programs. BPM is designed to optimize therapeutic

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ASSUMPTION (continued)

outcomes of pharmacological treatment for behavioral health conditions. CMT reviews pharmacy claims and applies proprietary algorithms to identify prescribing practices that deviate from evidence-based best practice standards, including polypharmacy, dosing outside of therapeutic ranges, and patient medication nonadherence. Once identified, CMT communicates directly with providers to alert them of these concerns and the need for further clinical review. Separate interventions exist for adults and for children under age 18.

OPI was developed to help balance a desire to improve access to evidence-based analgesic therapies for chronic pain sufferers with the urgent need to assist prescribers in addressing narcotic misuse and associated adverse events. The OPI uses pharmacy claims data to identify patients whose patterns of obtaining and filling opioid prescriptions is suspicious (e.g., obtaining opioid prescriptions from a large number of different providers, or filling opioid prescriptions at a large number of different pharmacies), and identifies providers whose opioid prescribing patterns deviate from evidence-based best practice standards (e.g., prescribing opioids to persons without supporting diagnoses, giving opioid-containing cold medication to children). At present the top 2,000 providers (based on the cost of flagged prescriptions) receive a direct communication from CMT explaining the OPI program and identifying patients and/or prescribing habits that warrant further attention.

MHD proposes expanding this contract to address a larger provider group and to also identify patient populations that could benefit from education about opioids. The polypharmacy utilizes the ProAct technology environment provided by CMT to supply compliance measures specific to comorbid disease states. The capabilities include utilization patterns, pharmacy indicators, gaps in care, adherence, compliance measures and other elements. MO HealthNet proposes expansion of this program to cover an additional provider participation of 25%.

- BPM: MO HealthNet assumes 35,023 new participants will be impacted at a per-member-per-year (PMPY) cost savings of \$1,026 each, for a total cost savings of \$35,934,102 (35,023 X \$1,026 rounded). This anticipated cost savings would be offset by pharmacy rebates that would not be earned in the amount of \$13,834,629, with an assumed net cost savings of \$22,099,473. Further, MHD anticipates an increased cost for the BPM program of \$192,000. The net BPM cost savings is estimated to be \$21,907,473.
- OPI: MO HealthNet assumes 96,000 new participants will be impacted at a PMPY cost savings of \$142.44 each, for a total cost savings of \$13,674,240. This anticipated cost savings would be offset by pharmacy rebates that would not be earned in the amount of \$5,264,582, with an assumed net cost savings of \$8,409,658. Further, MHD anticipates an increased cost for the OPI program of \$438,000. The net OPI cost savings is estimated to be \$7,971,658.

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ASSUMPTION (continued)

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- Polypharmacy: MO HealthNet assumes the current polypharmacy contract would be expanded to include additional provider participation of an estimated 25%. This would result in an increase in contract cost of \$562,500. MO HealthNet assumes an annual cost savings from the contract expansion of \$2,812,500 for a net annual cost savings of \$2,250,000.
 - MO HealthNet anticipates annual net savings of 32,129,131 [(21,907,473 + 7,971,658 + 2,250,000 = 32,129,131); GR 11,312,902; 20,816,230 Federal]. MHD assumes that 9 months of that savings will be realized in FY 2018; therefore, FY18 savings will be **\$8,484,677** GR and **\$15,612,172** Federal (**\$24,096,849** total for 9 months).

1. **Cyber Access** - Cyber Access is MHD's Electronic Health Records (EHR). Cyber Access is claims-based and allows one to view the services a patient has received and where those services were provided. This includes all pharmacy claims, including for opioids. Thus a provider can review services that they provide as well as services that others provide to their patients to have a better understanding of the entire patient experience. All enrolled providers have access to Cyber Access. Primary Care Health Homes are required to use Cyber Access as part of their patient care management initiatives.

2. MHD has opportunities to collaborate with local jurisdictions and state and local public health agencies in their surveillance effort.

3. MHD is updating its clinical edits for opioid prescribing along the Centers for Disease Control and Prevention (CDC) guidelines for opioid naive patients. As part of routine surveillance of opioid prescribing guidelines and evidence-base, this will update MHD's pharmacy protocol to the most recent evidence-based guidelines. MHD can then perform data analysis to monitor prescribing patterns against the new guidelines and develop indicated interventions.

 $\underline{\$208.227.3}$ - The division shall issue a provider update no less than twice annually to enumerate treatment and utilization principles for MO HealthNet providers.

MHD will issue provider blasts (similar to bulletins). It is assumed the cost of this section can be absorbed within the existing MO HealthNet budget. No fiscal impact.

<u>\$208.227.4</u> - If the division implements any new policy or clinical edit for an antipsychotic drug, the division shall continue to allow the MO HealthNet participant's access to any antipsychotic drug that they utilize and are stable.

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ASSUMPTION (continued)

MHD assumes these provisions will have no fiscal impact as section 208.227.1 states no restrictions to access will be imposed that preclude availability of any individual atypical antipsychotic monotherapy for the treatment of schizophrenia, bipolar disorder, or psychosis associated with severe depression.

<u>§208.227.5</u> - The division's medication policy and clinical edits shall provide MO HealthNet participants initial access to multiple Food and Drug Administration-approved antipsychotic drugs that have substantially the same clinical differences and adverse effects that are predictable across individual patients and whose manufacturers have entered into a federal rebate agreement with the Department of Health and Human Services.

MHD assumes the provisions will have no fiscal impact as section 208.227.1 states no restrictions to access will be imposed that preclude availability of any individual atypical antipsychotic monotherapy for the treatment of schizophrenia, bipolar disorder, or psychosis associated with severe depression.

<u>§208.229 - Pharmaceutical manufacturers shall pay to the state</u>, in accordance with 42 U.S.C. Section 1396r-8, rebates on drugs dispensed to MO HealthNet participants.

MHD states MO HealthNet collects rebates on drugs dispensed to MO HealthNet participants under the Medicaid Drug Rebate Program which is authorized by Section 1927 of the Social Security Act. This section will not have a fiscal impact on MHD.

§§208.790 and 208.798- Extends MO Rx Program for dual eligibles

MHD officials state this section of the legislation extends the MO Rx program for Medicaid dual eligible individuals through August 28, 2022. Currently the MO Rx program is available for dual (Medicare and Medicaid) and non-dual (Medicare only) participants. If this legislation is enacted, the program will only be available for dual participants. The projected average number of non-duals in FY18 is 63,670. Using a per member per year cost of \$303, the projected annual cost savings would be \$19,281,685 (10 months of cost savings in FY18 represents \$16,068,071). In addition, MO HealthNet would have a loss of rebate revenue into the MORx Fund of (\$2,992,195) in FY18. Because MORx rebates are earned 6 months in arrears, the FY19 impact would be (\$5,984,391) which would reflect a full 12 month loss in rebates. The FY18 net cost savings would be \$13,075,876 and the FY19 net cost savings would be \$13,279,294.

Oversight assumes extending the termination date for section 208.798 to 08-28-22 (currently 08-28-17) will result in a <u>continuation</u> of costs to the State. Oversight notes the Governor's recommendations for FY18 includes funding for the MO Rx Drug Program of \$22,758,170 (General Revenue \$18,102,844 and Other State Funds (MO Rx Plan Fund # 0779) of \$4,655,326).

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ASSUMPTION (continued)

For fiscal note purposes, Oversight will assume funding for the MO Rx Drug Program will be \$22,758,170 (GR \$18,102,844; Other State Funds \$4,655,326) for each FY18, FY19 and FY20. Oversight will reflect 10 months of impact in FY 2018.

Expenditures for the program have been:	\$22,287,547 in FY 2016;
	\$22,127,661 in FY 2015; and
	\$21,529,983 in FY 2014

§334.506 - Referral from doctor no longer needed by physical therapists

Officials from the **Department of Insurance, Financial Institutions and Professional Registration (DIFP)** assume the proposal would not fiscally impact their agency.

Officials from the **Department of Social Services (DSS), MO HealthNet Division** state since this bill does not revise Chapters 208 or 376, RSMo, MHD assumes MO HealthNet can continue to rely upon a physician order for physical therapy before reimbursing the services. Therefore, there is no fiscal impact.

Oversight notes the provisions of this proposal have removed proposed language from previous versions that would have allowed physical therapists to provide services without a referral from a doctor. As a result, current law that provides "a physical therapist will not initiate treatment for a new injury or illness without a prescription from an approved health care provider" remains.

§338.700-710 - Rx Cares for Missouri Program

Officials from the **Department of Insurance, Financial Institutions and Professional Registration (DIFP)** state the proposal would have an unknown fiscal impact to the Missouri Board of Pharmacy contingent on potential future appropriations made by the General Assembly to fund the Rx Cares for Missouri Program.

Oversight notes the balance of the Board of Pharmacy Fund on November 30, 2016 was \$7,165,391. Oversight assumes the Board of Pharmacy has the funds available to make the appropriation for the Rx Cares for Missouri Program without raising licensing fees. However, Oversight also assumes if the operation of this program reduces the cash balance of the Board of Pharmacy Fund below the operating cash needs of the Board, the Board would have the ability to raise licensing fees. This program expires on August 28, 2019 (FY 2020).

Officials from the **DSS**, **MHD** assume these provisions of the proposal will have no fiscal impact on MO HealthNet.

HWC:LR:OD

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ASSUMPTION (continued)

Bill as a Whole

Officials from the **Department of Mental Health (DMH)** assume the proposal would not fiscally impact their agency. However, this legislation will impact DMH consumers and places a direct obligation on the DMH to create and administer, through the creation of an MOU (Memorandum of Understanding), the programs mandated under this proposal.

There are several provisions within this proposal that are vague, making it difficult for the DMH to determine the extent to which this proposed legislation will impact the department. Specifically, this bill requires that the MO HealthNet Division establish a pharmaceutical case management or polypharmacy program for "high risk" MO HealthNet participants. "High risk" is not identified, making it difficult for the DMH to determine how many of its consumers may be impacted by this newly established case management or polypharmacy program.

Additionally, this legislation outlines guidelines for the MO HealthNet prescription drug formulary, including that if a medication is considered to be clinically appropriate for an individual patient based on a patient's previous response, prior authorization shall be "simple and flexible." It is unclear what this language means, and will be difficult to gauge during the creation and administration of the programs mandated in this legislation.

Officials from the **Office of Attorney General (AGO)** assume any potential costs arising from the proposal could be absorbed with existing resources. The AGO may seek additional appropriations if the proposal results in a significant increase in referrals.

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.

Officials from the **Department of Corrections** defer to the Department of Social Services for a statement of the potential fiscal impact of this proposal.

Officials from the **Department of Health and Senior Services**, the **Department of Revenue**, the **Office of Administration**, **General Services Division** and the **Office of State Treasurer** each assume the proposal would not fiscally impact 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

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ASSUMPTION (continued)

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.

FISCAL IMPACT - State Government	FY 2018 (9 Mo.)	FY 2019	FY 2020
GENERAL REVENUE FUND	(*)		
<u>Savings</u> - DSS (§208.227.1) Program savings	\$8,931,864	\$12,138,810	\$12,373,062
<u>Savings</u> - DSS (§208.790) MO Rx program savings	<u>\$16,068,071</u>	<u>\$19,281,685</u>	<u>\$19,281,685</u>
Total <u>Savings</u> - DSS	<u>\$24,999,935</u>	\$31,420,495	\$31,654,747
<u>Costs</u> - DSS (§208.227.1) Increased contractor costs	(\$447,187)	(\$596,250)	(\$596,250)
<u>Costs</u> - DSS (extension of §208.798 termination date) On-going MO Rx Drug Program			
expenditures Total <u>Costs</u> - DSS	<u>(\$15,085,703)</u> (\$15,532,890)	<u>(\$18,102,844)</u> (\$18,699,094)	<u>(\$18,102,844)</u> (\$18,699,094)
Loss - DSS (§208.790) Reduction in rebate revenue	<u>(\$2,992,195)</u>	<u>(\$5,984,391)</u>	<u>(\$5,984,391)</u>
ESTIMATED NET EFFECT ON THE GENERAL REVENUE FUND	<u>\$6,474,850</u>	<u>\$6,737,010</u>	<u>\$6,971,262</u>

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FISCAL IMPACT - State Government	FY 2018 (9 Mo.)	FY 2019	FY 2020
MO Rx PLAN FUND	() 1100)		
<u>Costs</u> - DSS (extension of §208.798 termination date) On-going MO Rx Drug Program expenditures	(\$3,879,438)	(\$4,655,326)	(\$4,655,326)
ESTIMATED NET EFFECT ON THE MO Rx PLAN FUND	<u>(\$3,879,438)</u>	<u>(\$4,655,326)</u>	<u>(\$4,655,326)</u>
BOARD OF PHARMACY FUND (#637)			
Costs - DIFP Rx Care for MO Program expenditures (§§338.700-338.710)	(Unknown)	(Unknown)	(Unknown)
ESTIMATED NET EFFECT ON BOARD OF PHARMACY FUND	<u>(Unknown)</u>	<u>(Unknown)</u>	<u>(Unknown)</u>
	<u>(Unknown)</u>	<u>(Unknown)</u>	<u>(Unknown)</u>
BOARD OF PHARMACY FUND	<u>(Unknown)</u> \$447,187	<u>(Unknown)</u> \$596,250	<u>(Unknown)</u> \$596,250
BOARD OF PHARMACY FUND FEDERAL FUNDS Income - DSS (§208.227.1)	<u> </u>		<u> </u>
BOARD OF PHARMACY FUND FEDERAL FUNDS Income - DSS (§208.227.1) Contractor cost reimbursements Savings - DSS (§208.227.1)	\$447,187	\$596,250	\$596,250
BOARD OF PHARMACY FUND FEDERAL FUNDS <u>Income</u> - DSS (§208.227.1) Contractor cost reimbursements <u>Savings</u> - DSS (§208.227.1) Reduction in program costs <u>Costs</u> - DSS (§208.227.1)	\$447,187 \$16,059,359	\$596,250 \$21,825,404	\$596,250 \$22,246,586

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FISCAL IMPACT - Local Government	FY 2018 (10 Mo.)	FY 2019	FY 2020
	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>

FISCAL IMPACT - Small Business

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

FISCAL DESCRIPTION

POLYPHARMACY AND ANTIPSYCHOTIC MEDICATIONS (Section 208.227)

This act replaces existing language relating to psychotrophic medications with new language relating to the establishment of a polypharmacy program and the prescribing of antipsychotic medications. The MO HealthNet Division shall establish a polypharmacy program for high-risk MO HealthNet participants with numerous or multiple prescribed drugs or medications. The Department shall also establish a behavioral health pharmacy and opioid surveillance program to encourage the use of best medical evidence-supported prescription practices. The Division shall issue provider updates to enumerate specified treatment and utilization principles for MO HealthNet providers, including treatment principles relating to antipsychotic drugs or medications.

MEDICAID DUAL ELIGIBLES (Section 208.790)

The provisions of this section mandate applicant household income limits for eligibility to only apply to Medicaid dual eligible individuals.

MO Rx PRESCRIPTION DRUG PROGRAM (Section 208.798)

This bill modifies provisions relating to the Missouri Rx Prescription Drug Program by extending the termination date of the program from August 28, 2017 to August 28, 2022.

Rx CARES FOR MISSOURI PROGRAM (Section 338.700 - 338.710)

This act creates the Rx Cares for Missouri Program to be administered by the Board of Pharmacy in consultation with the Department of Health and Senior Services. The goals of the program are to promote medication safety and prevent prescription drug abuse. The Board may expend funds appropriated to the Board to private and public entities for the development of programs and education in order to meet these goals.

HWC:LR:OD

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FISCAL DESCRIPTION (continued)

The Board of Pharmacy may enter into interagency agreements with the Department of Health and Senior Services so that the Department may assist in the operation of the program. The program shall expire on August 28, 2019.

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 Attorney General Department of Health and Senior Services Department of Insurance, Financial Institutions and Professional Registration Department of Mental Health Department of Corrections Department of Revenue Department of Social Services -MO HealthNet Division Division of Legal Services Joint Committee on Administrative Rules Office of Administration -General Services Division Office of Secretary of State Office of State Treasurer

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Mickey Wilson, CPA Director June 5, 2017

Ross Strope Assistant Director June 5, 2017