

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 0471-04
Bill No.: HCS for SCS for SB 139
Subject: Pharmacy; Drugs and Controlled Substances; Health and Senior Services
Department
Type: Original
Date: April 21, 2017

Bill Summary: This proposal establishes the Controlled Substance Abuse Prevention Fund and the Rx Cares for Missouri Program and modifies the MO HealthNet Pharmacy program.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2018	FY 2019	FY 2020
General Revenue	\$6,474,850	\$6,010,547	\$6,099,507
Total Estimated Net Effect on General Revenue	\$6,474,850	\$6,010,547	\$6,099,507

ESTIMATED NET EFFECT ON OTHER STATE FUNDS			
FUND AFFECTED	FY 2018	FY 2019	FY 2020
Controlled Substance Abuse Prevention	\$0	\$78,566	\$127,148
MO Rx Plan	(\$3,879,438)	(\$4,655,326)	(\$4,655,326)
Total Estimated Net Effect on <u>Other</u> State Funds	(\$3,879,438)	(\$4,576,760)	(\$4,528,178)

Numbers within parentheses: () indicate costs or losses.

This fiscal note contains 14 pages.

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 2020
Controlled Substance Abuse Prevention	0	10 FTE	10 FTE
Total Estimated Net Effect on FTE	0	10	10

☒ 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

FISCAL ANALYSIS

ASSUMPTION

§195.430 - Controlled Substance Abuse Prevention Fund

Officials from the **Department of Health and Senior Services (DHSS)** state that currently under Section 195.030.1, RSMo, all fees collected by the DHSS, Bureau of Narcotics and Dangerous Drugs (BNDD) for the issuance of registrations to manufacture, distribute, or dispense controlled substances are deposited into the General Revenue Fund. DHSS assumes the proposal would require all BNDD fees collected to be deposited into the newly created Controlled Substance Abuse Prevention Fund. In FY16 the total fees collected by BNDD was \$871,755.

Officials from the **Department of Social Services (DSS), MO HealthNet Division (MHD)** assume the provisions of 195.430 would not fiscally impact their agency.

§195.435 - Employment of Investigators

Officials from the **DHSS** state currently the BNDD processes approximately 30,000 controlled substance registrants per year and has one Band I Investigator Manager and two Investigator II FTEs. With limited staff, the bureau is not able to monitor registrants who have been disciplined and the majority of the investigation work is reactive based on information obtained by the BNDD. The proposed language requires the bureau to employ investigators as needed based on the number of registrants. BNDD believes this language would increase the scope of its current activities to conduct more inspections and monitoring of registrants who have been disciplined. Additional investigators would allow the BNDD to inspect and monitor registrants on a proactive basis. The bureau may take disciplinary actions on registrants in the form of warnings, censures, probations, suspensions, and revocations. BNDD would need the following additional staff:

One Investigator III (\$41,184 annually) to assist and conduct on-site inspections of the 30,000 registrants. This position will also provide the basic supervision and oversight of the 8 Investigators II.

Eight Investigators II (\$38,304 annually, each) to travel throughout the state to conduct on-site inspections of the 30,000 registrants. Upon discovery of a violation, they can correct the issue on-site or refer it to central office for any kind of censure or corrective action. These staff will also respond and investigate complaints received in BNDD.

Investigative staff within BNDD have higher than normal travel expenditures as they travel extensively. Travel cost for the nine investigators is estimated to be \$10,000 per FTE annually.

ASSUMPTION (continued)

One Senior Office Support Assistant (\$26,340 annually) to provide support to BNDD investigative staff.

Based on the above estimates, DHSS has concerns that the Controlled Substance Abuse Prevention fund could have cash flow issues during FY20 and FY21 as there may not be enough fund balance to cover expenses of the program depending on the timing of deposits or if deposits are actually lower than anticipated. If there are cash flow issues, there may be a need to request funding from General Revenue or borrow from the budget reserve fund.

Oversight assumes the DHSS would not need additional rental space for the 2 new FTE for this single proposal (excludes (8) Investigator FTEs as DHSS assumes they are telecommuters). However, Oversight notes, depending on the number of proposals passed during the legislative session, that cumulatively, DHSS may need additional rental space or capital improvements as determined by the Office of Administration, Facilities Management, Design and Construction.

Oversight notes Section B of proposal provides that sections 195.430 and 195.435 will become effective on August 28, 2019.

Officials from the **DSS**, **MHD** assume the provisions of 195.435 would not fiscally impact their agency.

§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)** provide the following assumptions:

§208.227.1 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 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.

ASSUMPTION (continued)

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.
- **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.

ASSUMPTION (continued)

- 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.

Division of Legal Services (DLS) officials provide that section 208.227.1 requires DSS to partner with the Department of Mental Health through a Memorandum of Understanding (MOU). DLS assumes MHD would require legal assistance to help draft and complete a legal review of the MOU.

§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.

ASSUMPTION (continued)

§208.227.4 - 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.

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.

§208.227.5 - 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.

§208.227.7 and .8 - Requires DSS implement rules/regulations to enact this proposal and also submit state plan amendments and waivers to CMS.

DLS assumes MHD will require legal assistance to help draft and complete a legal review of the regulations and/or state plan amendments. DLS assumes no additional FTE will be needed as the additional duties can be absorbed with existing staff.

§208.229 - Pharmaceutical manufacturers shall pay to the state, 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 - 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. Currently the MO Rx program is available for dual (Medicare and Medicaid) and non-dual (Medicare only) participants.

ASSUMPTION (continued)

If this legislation is enacted, the program will only be available for dual participants. The projected average number of non-duals in FY 18 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 FY 18. Because MORx rebates are earned 6 months in arrears, the FY19 impact would be (\$5,984,391) which would reflect a full 12 months loss in rebates. The FY 18 net cost savings would be \$13,075,876 and the FY19 net cost savings would be \$13,279,294.

§208.798 - Extension of termination date for MO Rx Plan program

In response to similar provisions from the current session (SB 423/1945-03), officials from the **DSS**, **MHD** and **DLS** assumed the proposal will have no fiscal impact on their organization.

Oversight assumes extending the termination date for section 208.798 to 08-28-22 (currently 08-28-17) will result in a continuation 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).

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

§338.700 - 710 - Rx Cares for Missouri Program

Officials from the **DSS**, **MHD** assume the proposal would not fiscally impact their agency.

Bill as a Whole

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.

ASSUMPTION (continued)

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 **Department of Insurance, Financial Institutions and Professional Registration**, the **Department of Mental Health**, the **Department of Revenue**, the **Office of State Courts Administrator** and the **Office of State Treasurer** each assume the proposal would not fiscally impact their respective agencies.

In response to the previous version of this proposal, 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 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.

<u>FISCAL IMPACT - State Government</u>	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>	<u>\$31,420,495</u>	<u>\$31,654,747</u>
<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	<u>(\$15,085,703)</u>	<u>(\$18,102,844)</u>	<u>(\$18,102,844)</u>
Total <u>Costs</u> - DSS	<u>(\$15,532,890)</u>	<u>(\$18,699,094)</u>	<u>(\$18,699,094)</u>
<u>Loss</u> - DHSS (§195.430)			
Controlled Substance Registrant Fees	\$0	(\$726,463)	(\$871,755)
<u>Loss</u> - 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>\$6,010,547</u>	<u>\$6,099,507</u>

<u>FISCAL IMPACT - State Government</u>	FY 2018 (9 Mo.)	FY 2019	FY 2020
CONTROLLED SUBSTANCE ABUSE PREVENTION FUND			
<u>Income</u> - DHSS (\$195.430)			
Controlled Substance Registrant Fees	\$0	\$726,463	\$871,755
<u>Costs</u> - DHSS (\$195.435)			
Salaries	\$0	(\$317,894)	(\$385,287)
Fringe Benefits	\$0	(\$197,749)	(\$217,818)
Equipment and Expenses	\$0	(\$132,254)	(\$141,502)
Total <u>Costs</u> - DHSS	\$0	(\$647,897)	(\$744,607)
FTE Change - DHSS	0 FTE	10 FTE	10 FTE
ESTIMATED NET EFFECT ON THE CONTROLLED SUBSTANCE ABUSE PREVENTION FUND	<u>\$0</u>	<u>\$78,566</u>	<u>\$127,148</u>
Estimated Net FTE Change on the Controlled Substance Abuse Prevention Fund	0 FTE	10 FTE	10 FTE
MO Rx PLAN FUND			
<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>

<u>FISCAL IMPACT - State Government</u>	FY 2018 (9 Mo.)	FY 2019	FY 2020
FEDERAL FUNDS			
<u>Income - DSS (§208.227.1)</u>			
Contractor cost reimbursements	\$447,187	\$596,250	\$596,250
<u>Savings - DSS (§208.227.1)</u>			
Reduction in program costs	\$16,059,359	\$21,825,404	\$22,246,586
<u>Costs - DSS (§208.227.1)</u>			
Contractor expenditures	(\$447,187)	(\$596,250)	(\$596,250)
<u>Loss - DSS (§208.227.1)</u>			
Reduction in program reimbursements	<u>(\$16,059,359)</u>	<u>(\$21,825,404)</u>	<u>(\$22,246,586)</u>
ESTIMATED NET EFFECT ON FEDERAL FUNDS	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>

<u>FISCAL IMPACT - Local Government</u>	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

CONTROLLED SUBSTANCE ABUSE PREVENTION FUND . (Sections 195.430 and 195.435)

This proposal creates a Controlled Substance Abuse Prevention Fund within the state treasury that is funded using fees collected by the Department of Health and Senior Services when issuing registrations to manufacture, distribute, or dispense controlled substances. Any money appropriated, gifted, granted, donated, bequested, or contributed for the purpose of funding the Bureau of Narcotics and Dangerous Drugs within the department must be deposited in the fund. The bureau is required to employ no less than one investigator for every 2,500 controlled substance registrants

Section B of the proposal provides that sections 195.430 and 195.435 will be effective August 28, 2019

FISCAL DESCRIPTION (continued)

POLYPHARMACY AND ANTIPSYCHOTIC MEDICATIONS (Section 208.227)

This act replaces existing language relating to psychotropic 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.

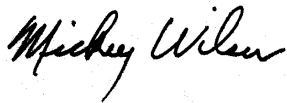
MO Rx PRESCRIPTION DRUG PROGRAM (Section 208.798)

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.

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 State Courts Administrator
Office of Secretary of State
Office of State Treasurer



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