

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 1935-04
Bill No.: SCS for SB 433
Subject: Attorney General; Drugs and Controlled Substances; Health Care; Health Care Professionals; Medicaid; Pharmacy; Public Assistance; Social Services Department
Type: Original
Date: March 24, 2017

Bill Summary: This proposal modifies and creates provisions relating to the MO HealthNet pharmacy program.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2018	FY 2019	FY 2020
General Revenue	\$13,002,806	\$20,759,542	\$21,178,133
Total Estimated Net Effect on General Revenue	\$13,002,806	\$20,759,542	\$21,178,133

ESTIMATED NET EFFECT ON OTHER STATE FUNDS			
FUND AFFECTED	FY 2018	FY 2019	FY 2020
Total Estimated Net Effect on <u>Other</u> State Funds	\$0	\$0	\$0

Numbers within parentheses: () indicate costs or losses.
This fiscal note contains 13 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 \$39 million annually and net to \$0.

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)			
FUND AFFECTED	FY 2018	FY 2019	FY 2020
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

FISCAL ANALYSIS

ASSUMPTION

§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.

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%.

ASSUMPTION (continued)

- **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.
- 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.

ASSUMPTION (continued)

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.

§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 provides that MO HealthNet anticipates a savings of \$2,591,784 as a result of this section. The MO HealthNet spend for antipsychotic drugs (this includes spend for Lithium, Carbamazepine, Valproate, Lamotrigine, Oxcarbazepine, Topiramate, and Gabapentin) in FY 16 was \$217,797,015. Amounts were subtracted from the total spend amount to account for participants being allowed to utilize drugs on which they are currently stable.

For non-preferred clinically appropriate drugs, the total spend was reduced by \$43,559,403. For non-preferred drugs, found to be safe and effective for a given individual, total spend was reduced by \$43,559,403. A reduction of \$54,449,254 was made for patients not required to change antipsychotic drugs and for patients transferring from state psychiatric hospital to community based setting continuing their current medication regimen total spend was reduced by \$10,889,851. Total adjusted spend was \$65,339,104. Using an anticipated savings percentage based on utilizing a preferred drug list of 3.97% the estimated annual savings from implementation of this section would be \$2,591,784 (GR \$953,051; Federal \$1,638,733). MO HealthNet assumes FY 18 savings of six months to allow for necessary system changes. \$1,295,892 (GR \$463,152; Federal \$832,740)

FY16 Total Spend for Antipsychotic Drugs	\$217,797,015
Non-preferred clinically appropriate drugs	- \$43,559,403
Non-preferred drugs found to be safe & effective	- \$43,559,403
Patients not required to change drugs	- \$54,449,254
Patients transferring to community-based settings	<u>- \$10,889,851</u>
Adjusted drug spend	\$ 65,339,104
X estimated savings rate	<u>0.0397</u>
Estimated savings	\$2,591,784 rounded

ASSUMPTION (continued)

§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 provides that while the main provision under 208.227.5 appears to enhance the ability of MO HealthNet to obtain supplemental rebates, the addition of provisions under 208.227.5(1) through (8) will limit supplemental rebates due to a reduction in the market size. As a result, this section will increase supplemental rebate earnings by an unknown amount.

§208.227.7 and .8 - Requires the 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 the additional duties can be absorbed with existing resources.

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

MHD 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 have no fiscal impact on MHD.

§208.231 - Co-payments for outpatient drugs

MO HealthNet, subject to CMS approval, shall require participants to pay a nominal co-payment for covered outpatient drugs. \$4.00 for drugs on the Preferred Drug List (PDL) and \$8.00 for drugs not on the PDL.

MHD assumes for the purpose of the calculation below, there will be no change in how participants access drugs and no adjustments were made for maximum cost sharing which, per federal law is five percent of monthly aggregate family income for all cost sharing requirements. MO HealthNet estimates 3,566,325 claims would require a participant co-payment. Of these claims 1,379,803 would pay the PDL co-pay of \$4.00 (\$5,519,212) and 2,186,522 would pay the non-PDL copay of \$8.00 (\$17,492,177). The estimated MO HealthNet savings would be \$23,011,389 (\$5,519,212 + \$17,492,177). GR savings would be \$8,224,270; Federal savings

ASSUMPTION (continued)

would be \$14,787,119. If it is assumed this amount reduces the pharmacy gross receipts, then the pharmacy reimbursement allowance tax amount would be reduced by \$319,858 (GR \$114,317; Federal \$205,541) at the current tax rate of 1.39%. This proposed legislation could result in more people selecting preferred drugs over non-preferred drugs and, as a result, will have an unknown impact on supplemental rebate earnings. Because this will require system work and state plan approval from CMS, only 6 months of savings are included in FY 2018: \$11,345,765 (\$23,011,389 total co-pays - \$319,858 pharmacy reimbursement allowance tax = \$22,691,531 / 2 = \$11,345,765; GR \$4,054,977; Federal \$7,290,788). Also, MHD cannot implement this co-payment on top of the shared dispensing fee authorized under 13 CSR 70-4.051 at the \$4 for preferred and \$8 for non-preferred level, because federal regulation sets the maximum co-payment for preferred drugs and non-preferred drugs. Either the preferred drug and non-preferred drug co-payment amount will need to be lowered or the previously established copayment (shared dispensing fee) will need to be eliminated.

Oversight notes the MHD has indicated that section 208.227.5 may result in an unknown increase in supplemental rebate earnings. In addition, MHD has indicated that section 208.228.6 may result in a decrease in federal rebate earnings for the state. Therefore, for fiscal note purposes, Oversight is not presenting these unknown rebate earnings, either positive or negative.

Bill as a Whole

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

Officials from the **Department of Mental Health (DMH)** state there may be an increase in some administrative duties related to the Memorandum of Understanding (MOU) with the MO HealthNet Division. Any additional administrative duties could be covered by current staff; therefore, no fiscal impact is assumed.

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** and the **Office of State Courts Administrator** each assume the proposal would not fiscally impact their respective agencies.

ASSUMPTION (continued)

Officials from the **Office of the Secretary of State (SOS)** did not respond to **Oversight's** request for a statement of fiscal impact. However, in response to the previous version of this proposal, the 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 (6 Mo.)	FY 2019	FY 2020
GENERAL REVENUE FUND			
<u>Savings - DSS (§208.227.1)</u>			
Program savings	\$8,931,864	\$12,138,810	\$12,373,062
<u>Savings - DSS (§208.227.4)</u>			
Program savings	\$463,152	\$944,830	\$963,726
<u>Savings - DSS (§208.231)</u>			
Program savings from co-payments	<u>\$4,054,977</u>	<u>\$8,272,152</u>	<u>\$8,437,595</u>
Total <u>Savings - DSS</u>	<u>\$13,449,993</u>	<u>\$21,355,792</u>	<u>\$21,774,383</u>
<u>Costs - DSS (§208.227.1)</u>			
Increased contractor costs	<u>(\$447,187)</u>	<u>(\$596,250)</u>	<u>(\$596,250)</u>
ESTIMATED NET EFFECT ON THE GENERAL REVENUE FUND			
	<u>\$13,002,806</u>	<u>\$20,759,542</u>	<u>\$21,178,133</u>
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>Savings - DSS (§208.227.4)</u>			
Reduction in program costs	\$832,740	\$1,698,790	\$1,732,766
<u>Savings - DSS (§208.231)</u>			
Program savings from co-payments	<u>\$7,290,789</u>	<u>\$14,873,209</u>	<u>\$15,170,673</u>
Total <u>Income and Savings - DSS</u>	<u>\$24,630,075</u>	<u>\$38,993,653</u>	<u>\$39,746,275</u>

<u>FISCAL IMPACT - State Government</u>	FY 2018 (6 Mo.)	FY 2019	FY 2020
FEDERAL FUNDS (continued)			
<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	(\$16,059,359)	(\$21,825,404)	(\$22,246,586)
<u>Loss - DSS (§208.227.4)</u>			
Reduction in program reimbursements	(\$832,740)	(\$1,698,790)	(\$1,732,766)
<u>Loss - DSS (§208.231)</u>			
Reduction in program reimbursements due to co-payments	(\$7,290,789)	(\$14,873,209)	(\$15,170,673)
Total <u>Costs and Losses - DSS</u>	<u>(\$24,630,075)</u>	<u>(\$38,993,653)</u>	<u>(\$39,746,275)</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

This act addresses several aspects of the MO HealthNet pharmacy program, including: (1) polypharmacy and antipsychotic medications; (2) prescription drug rebates; and (3) prescription drug co-payments.

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. 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.

If the Division implements any new policy or clinical edit for an antipsychotic drug, the Division shall continue to allow MO HealthNet participants access to any antipsychotic drug that they use and on which they are stable or that they have successfully used in the past. Additionally, the following shall apply to the prescribing of antipsychotics:

- (1) If an antipsychotic drug is listed as "non-preferred" by the Division and is considered clinically appropriate for an individual patient, prior authorization shall be simple and flexible;
- (2) If an antipsychotic drug is listed as "non-preferred" and is known or found to be safe and effective for a patient, the Division shall not restrict the patient's access to the drug and such drug shall be considered "preferred" for that patient;
- (3) A patient shall not be required to change antipsychotic drugs due to changes in medication management policy, prior authorization, or a change in the payor responsible for the benefit; and
- (4) Patients transferring from state psychiatric hospitals to community-based settings shall be permitted to continue their medication regimens.

The Division's medication policy and clinical edits shall provide MO HealthNet participants initial access to multiple FDA-approved antipsychotic drugs that have substantially the same clinical differences and adverse effects that are predictable across patients and whose manufacturers have entered into rebate agreements with the federal Department of Health and Human Services. The act specifies the categories of available drugs that shall be made available to participants.

FISCAL DESCRIPTION (continued)

PRESCRIPTION DRUG REBATES (Section 208.229)

Under this act, pharmaceutical manufacturers shall pay to the State, in accordance with federal law, rebates on eligible utilization of covered outpatient drugs dispensed to MO HealthNet participants as follows: (1) for single source drugs and innovator multiple source drugs, rebates shall reflect the manufacturer's best price; and (2) for single source drugs and innovator and noninnovator multiple source drugs, any additional rebates as necessary to account for certain price increases in excess of inflation.

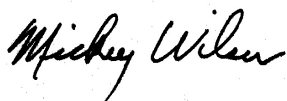
PRESCRIPTION DRUG CO-PAYMENTS (Section 208.231)

This act shall require MO HealthNet participants to pay a nominal co-payment for covered outpatient drugs as permitted by federal law. Drugs on the preferred drug list shall be subject to a \$4 co-payment and drugs not on the preferred drug list shall be subject to a \$8 co-payment. Certain MO HealthNet participants and services, specified in federal law, shall be excluded from the co-payment requirements. The co-payments shall be considered separate from any shared dispensing fee obligation on the part of the participant.

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 Mental Health
Department of Corrections
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



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