COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 0167-04
Bill No.: SB 310
Subject: Boards, Commissions, Committees, and Councils; Drugs and Controlled Substances; Health Care; Health and Senior Services Department; Insurance - Health; Insurance, Financial Institutions, and Professional Registration Department; Pharmacy; Social Services Department
Type: Original
Date: April 2, 2019

Bill Summary: This proposal enacts provisions relating to prescription drug costs.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2020	FY 2021	FY 2022
General Revenue	$0	($1,608,400 or $1,612,850)	$1,271,374 or $1,400,550
Total Estimated Net Effect on General Revenue	**$0**	**($1,608,400 or $1,612,850)**	**$1,271,374 or $1,400,550**

ESTIMATED NET EFFECT ON OTHER STATE FUNDS			
FUND AFFECTED	FY 2020	FY 2021	FY 2022
Total Estimated Net Effect on Other State Funds	**$0**	**$0**	**$0**

Numbers within parentheses: ( ) indicate costs or losses.
This fiscal note contains 17 pages.

ESTIMATED NET EFFECT ON FEDERAL FUNDS			
FUND AFFECTED	FY 2020	FY 2021	FY 2022
Total Estimated Net Effect on <u>All</u> Federal Funds	**$0**	**$0**	**$0**

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)			
FUND AFFECTED	FY 2020	FY 2021	FY 2022
General Revenue	0 FTE	10 or 12 FTE	10 or 12 FTE
Total Estimated Net Effect on FTE	**0 FTE**	**10 or 12 FTE**	**10 or 12 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 2020	FY 2021	FY 2022
Local Government	**$0**	**$0 to Unknown**	**$0 to Unknown**

FISCAL ANALYSIS

ASSUMPTION

§376.2061 - Drug Cost Review Commission

Officials from the **Department of Insurance, Financial Institutions and Professional Registration (DIFP)** state this legislation establishes the "Drug Cost Review Commission" within DIFP for the purpose of protecting state residents, state and local government, commercial health benefit plans, health care providers, pharmacies licensed in the state, and other stakeholders within the health care system from excessive costs of prescription drugs. The seven members (5 members and 2 alternates) of the commission will receive reimbursement for the actual and necessary expenses incurred in attending meetings of the commission. The chairman of the commission will hire an executive director, general counsel, and staff for the commission. Compensation of commission staff will be provided in the budget of the commission. The commission is required to hold a public meeting at least every six weeks to review prescription drug product information submission unless the chairman cancels or postpones a meeting if there are no prescription drug product submissions to review.

In order to complete the statutory work required under this legislation (see section summaries below), the DIFP estimates the commission will need the following FTE and associated equipment and expenses:

One (1) Commission Executive Director FTE ($80,000): required by this legislation and chosen by the chairman of the commission. The position will oversee the operation of the commission.

One (1) Commission General Counsel FTE ($75,000): required by this legislation and chosen by the chairman of the commission. The position will provide legal oversight of the commission's operations.

One (1) Administrative Office Support Assistant FTE ($36,000): provides office and clerical support to the commission and commission staff.

One (1) Legal Counsel FTE ($55,000): assists the General Counsel and the commission with legal guidance and support on commission reporting and enforcements of statute. The legal counsel (and paralegal) will also assist with commission meetings and hearings.

One (1) Paralegal FTE ($40,000): provides legal support to the General Counsel, Legal Counsel. The paralegal (and legal counsel) will also assist with commission meeting and hearings.

ASSUMPTION (continued)

Two (2) Pharmaceutical Consultant FTEs ($95,000 each): provides interpretation, auditing, and investigations of the statutory, regulatory, reporting, pricing, and other requirements required under this legislation, including conducting field investigations as necessary.

One (1) Research Analyst IV FTE ($64,000); provides oversight of the research analysts hired by the commission to ensure reporting is done properly and timely.

Two (2) Research Analyst II FTEs ($40,000 each): receives and analyzes data received and creates the annual reports required by this legislation, in conjunction with the commission's pharmaceutical consultants and other commission staff.

The DIFP assumes the FTE and funding for the commission and its work would come from General Revenue and would be requested to begin in the FY 2021 budget (a FY 2020 supplemental could possibly be required to accomplish the August 2020 tasks). Assessments that would reimburse General Revenue described in §§376.2072 and 376.2073 would begin the following fiscal year. The department is unsure if the assessments are for the entire work of the commission or the work specific to the two sections listed. The DIFP has shown the assessment as the cost of the commission's entire work for the purposes of this fiscal note. The assessment process will need to be created by the commission and could require additional IT cost than the estimate provided by the Office of Administration, Information Technology Services Division (OA, ITSD) depending upon the assessment system created.

The commission would need space to operate in Jefferson City. The DIFP estimates the commission needing approximately 2,860 sq. ft. (260 sq. ft. x 10 FTE), costing an estimated $21.50 per sq. ft. for rental space, etc. at a total cost of $55,900 annually.

The DIFP expects the commission to have at least 9 meetings annually at an estimated cost of $15,000 per meeting (which includes commission and commission staff expense reimbursements, room rental, equipment rental, copying, etc.) for a total of $135,000 ($15,000 *9 meetings) annually.

Upon the creation of the commission and as commission work begins, the commission may determine additional staff and expenses are necessary. The commission would request additional staffing and expenses through the state's budgeting process. There could also be additional costs for commission meetings, commission rental space, commission IT systems and web development, etc. The commission would request any additional expense and equipment appropriation needed through the state's budgeting process.

Oversight does not have any information to the contrary. Therefore, Oversight will reflect the costs provided by DIFP for fiscal note purposes.

ASSUMPTION (continued)

Officials from the **Office of the Governor (GOV)** state §376.2061 establishes the "Drug Cost Review Commission" which will include the GOV or his or her designee.

There should be no added cost to the GOV as a result of this measure.

Oversight does not have any information to the contrary. Therefore, Oversight will no fiscal impact for the GOV for fiscal note purposes.

§376.2062 - Pharmacy benefit manager reports

DIFP officials state the proposal provides that no later than March 1, 2022, and annually thereafter, each pharmacy benefits manager shall file a report with the commission for the immediately preceding calendar year. The report shall contain the following information for health carriers that delivered, issued for delivery, renewed, amended, or continued health benefit plans that included a pharmacy benefit managed by the pharmacy benefits manager during such calendar year:

(1) The aggregate dollar amount of all rebates concerning drug formularies used by such health carriers which such manager collected from pharmaceutical manufacturers that manufactured outpatient prescription drugs that:

(a) Were covered by such health carriers during such calendar year; and

(b) Are attributable to patient utilization of such drugs during such calendar year; and

(2) The aggregate dollar amount of all rebates, excluding any portion of the rebates received by such health carriers, concerning drug formularies that such manager collected from pharmaceutical manufacturers that manufactured outpatient prescription drugs that:

(a) Were covered by such health carriers during such calendar year; and

(b) Are attributable to patient utilization of such drugs by covered persons under such health care plans during such calendar year.

In consultation with pharmacy benefit managers, the commission shall establish a standardized form for reporting the information required under this section. The form shall be designed to minimize the administrative burden and cost of reporting on the commission and on pharmacy benefit managers.

No later than July 1, 2022, and annually thereafter, the commission shall submit a report to the standing committees of the general assembly having jurisdiction over health insurance matters. The report shall contain an aggregation of the information submitted to the commission pursuant to subdivision (1) for the immediately preceding calendar year, and such other information as the commission in its discretion deems relevant for the purposes of this section. The commission shall provide each pharmacy benefits manager and any third party affected by submission of a report required by this subsection with a written notice describing the content of the report.

ASSUMPTION (continued)

§376.2064 - Continuation of health benefit plans by health carriers

Any health carrier that delivers, issues for delivery, renews, amends, or continues a health benefit plan on or after January 1, 2022, shall submit specific information and data to the commission, for such health benefit plan for the immediately preceding calendar year, at the time that the health carrier submits a rate filing for such health benefit plan pursuant to §376.465 or §379.321.

Officials from the **Office of Administration (OA), Information Technology Services Division (ITSD)/DIFP** state it is assumed that every new IT project/system will be bid out because all ITSD resources are at full capacity.

It is assumed §§376.2062 and 376.2064 will result in the need to make system changes to the DIFP system. It is estimated these changes will require 2,214 IT consultant contract hours at $75/hour for a cost of $166,050 plus equipment and expense costs of $5,476. Total costs to the General Revenue (GR) Fund in FY 2021 are estimated at $171,526 ($166,050 + $5,476). On-going support costs to GR are estimated at approximately $40,774 ($34,040 IT contract consultants + $6,734 equipment and expense).

Oversight notes ITSD assumes that every new IT project/system will be bid out because all their resources are at full capacity. For this bill, ITSD assumes they will contract out the programming changes needed for DIFP system updates/changes. ITSD estimates the project would take 2,214 hours at a contract rate of $75 per hour for a total cost to the state of $166,050 (all GR funds). Oversight notes that an average salary for a current IT Specialist within ITSD is $51,618, which totals roughly $80,000 per year when fringe benefits are added. Assuming that all ITSD resources are at full capacity, Oversight assumes ITSD may (instead of contracting out the programming) hire 2 additional IT Specialist to perform the work required from this bill ($166,050/$75 = 2,214 contract hours/2,080 hours per year per FTE = 1.06 FTE, rounded up). Therefore, Oversight will range the fiscal impact from the cost of contracting out the work ($166,050 for FY 2021) to hiring 2 additional FTE IT Specialist (roughly $80,000 per year, each, beginning in FY 2021).

§376.2066 - Written certifications from health carriers

DIFP officials provide that no later than March 1, 2023, and annually thereafter, each health carrier shall submit to the director, in a form and manner prescribed by the director, a written certification for the immediately preceding calendar year, certifying that the health carrier accounted for all rebates in calculating the premium for health benefit plans that such health carrier delivered, issued for delivery, renewed, amended, or continued during such calendar year.

ASSUMPTION (continued)

§376.2068 - Report to general assembly

No later than March 1, 2023, and annually thereafter, the commission shall submit a report to the standing committees of the general assembly having jurisdiction over health insurance matters. The report shall contain:

(1) An aggregation of the information and data submitted to the commission pursuant to section 376.2064 for the immediately preceding calendar year;

(2) A description of the impact of the cost of outpatient prescription drugs on health insurance premiums in this state; and

(3) Such other information as the commission, in its discretion, deems relevant to the cost of outpatient prescription drugs in this state.

§376.2070 - Report on rebate practices of health carriers

No later than March 1, 2022, and annually thereafter, the commission shall prepare a report, for the immediately preceding calendar year, describing the rebate practices of health carriers. The report shall be published on the DIFP's public web site and shall contain:

(1) An explanation of the manner in which health carriers accounted for rebates in calculating premiums for health benefit plans delivered, issued for delivery, renewed, amended, or continued during such year;

(2) A statement disclosing whether, and describing the manner in which, health carriers made rebates available to enrollees at the point of purchase during such year; and,

(3) Any other manner in which health carriers applied rebates during such year.

§376.2072 - Drug/license application with the Food and Drug Administration

Beginning January 1, 2021, each sponsor of a pipeline drug shall submit to the commission, in a form and manner prescribed by the commission, written notice that such sponsor has filed with the federal Food and Drug Administration a new drug application or biologics license application for a pipeline drug, not later than sixty days after such sponsor receives an action date from the federal Food and Drug Administration regarding such application; or a biologics license application for a biosimilar drug, not later than sixty days after such sponsor's receipt of an action date from the federal Food and Drug Administration regarding such application.

ASSUMPTION (continued)

Beginning January 1, 2021, and not more than annually thereafter, the commission may, in consultation with the commissioner of administration, conduct a study of each pharmaceutical manufacturer of a pipeline drug that, in the opinion of the commission in consultation with the commissioner of administration and the director of the department of social services, may have significant impact on state expenditures for outpatient prescription drugs. The commission may work with the commissioner of administration to utilize existing state resources and contracts, or contract with a third party, including but not limited to an accounting firm, to conduct such study.

§376.2072.3(2) states each pharmaceutical manufacturer that is the subject of a study conducted as specified by this legislation will submit to the commission, or to any contractor engaged by the commission or the commissioner of administration to perform such study, the following information for the pipeline drug that is the subject of such study:

(a) The primary disease, condition, or therapeutic area studied in connection with such drug, and whether such drug is therapeutically indicated for such disease, condition, or therapeutic area;

(b) Each route of administration studied for such drug;

(c) Clinical trial comparators, if applicable, for such drug;

(d) The estimated year of market entry for such drug;

(e) Whether the federal Food and Drug Administration has designated the drug as an orphan drug, a fast track product, or a breakthrough therapy; and

(f) Whether the federal Food and Drug Administration has designated the drug for accelerated approval and, if the drug contains a new molecular entity, for priority review.

No later than March 1, 2021, and annually thereafter, the commission, in consultation with the commissioner of administration, the director of the department of social services, and the director of the department of health and senior services, shall prepare a list of not more than ten outpatient prescription drugs that the commission, in its discretion, determines are provided at substantial cost to the state, considering the net cost of such drugs, or are critical to public health. The list shall include outpatient prescription drugs from different therapeutic classes of outpatient prescription drugs and at least one generic outpatient prescription drug.

Oversight notes §376.2072.5 provides that the commission may impose a penalty not to exceed seven thousand five hundred dollars ($7,500) on pharmaceutical manufacturers or sponsors for each violation of this section.

Oversight contacted DIFP officials regarding proposed penalties. DIFP can not estimate if penalties would be collected or how much might be collected. It is assumed any penalties collected would go to schools. Therefore, for fiscal note purposes, Oversight assumes $0 to Unknown penalties will be distributed to school districts.

ASSUMPTION (continued)

§376.2073 - Threshold for manufacturer reporting

DIFP officials state the commission, in consultation with stakeholders and experts, shall establish a threshold for manufacturer reporting of brand prescription drugs, including biologics and biosimilars. The reporting threshold shall apply to brand name prescription drugs that are not reported under subsection 1 of this section but that impose costs on the state health care system that create significant challenges to affordability.

The commission, in consultation with stakeholders and experts, shall establish a threshold for manufacturer reporting of generic and off-patent sole source branded prescription drugs. The reporting threshold established by the commission shall apply to generic and off-patent sole source branded prescription drugs that are not reported under this section but that impose costs on the state health care system that create significant challenges to affordability.

The commission shall allow the public to request commission review of the cost of any prescription drug reported under this section or §376.2072.

§376.2073.8(1) provides if the commission finds that the spending on a prescription drug product reviewed under this section creates excess costs for health carriers or consumers, the commission shall establish the level of reimbursement that shall be billed and paid among:

(a) Health carriers and pharmacies or administering providers;

(b) Wholesalers and distributers and pharmacies or administering providers; and

(c) Pharmacies or administering providers and uninsured consumers or enrollees in a deductible period.

Paragraph (2) of subsection .8 provides that the commission shall determine how each participant in the supply chain of the prescription drug shall be remunerated.

The commission, after public notice and comment, shall establish standards for the information to be considered proprietary, including standards for heightened consideration of proprietary information for submissions for a cost review of a drug that is not yet approved by the federal Food and Drug Administration.

Subsection .10 provides subject to statutory provisions, the commission shall be funded by an assessment on each manufacturer required to provide notice to the commission. The commission shall determine by rule the amount of the assessment required.

The commission shall be established using funds appropriated from general revenue, which shall be repaid to the state with the assessments required under provisions of this legislation.

ASSUMPTION (continued)

No later than August 28, 2020, and annually thereafter, the commission shall publish on the DIFP's public web site a report on:

(1) Prescription drug price trends;

(2) The number of manufacturers required to notify the commission about drug pricing under subsections 1 or 3 of this section; and

(3) The number of products that were subject to commission review, including the results of the review and the number and disposition of appeals and administrative or judicial reviews of commission decisions.

Oversight notes §376.2073.10 provides the commission shall be funded by an assessment on each manufacturer required to provide notice to the commission under provisions of this proposal and the commission shall determine by rule the assessment required. In addition, the commission shall be established using funds appropriated from general revenue, which shall be repaid to the state with the assessments required. The DIFP assumes assessments collected in FY 2022 to be $2,711,355. This assessment amount will cover FY 2022 estimated costs of $1,270,031 thereby leaving available $1,441,324 in funds to reimburse the GR fund for FY 2021 expenses. However, it should be noted DIFP did not included ITSD costs in its assessments on manufacturers.

Bill as a whole

Officials from the **Department of Public Safety (DPS), Missouri State Highway Patrol (MHP)** anticipate no fiscal impact. However, the DPS, MHP defers to the Missouri Department of Transportation (MoDOT), Employee Benefits Section for response on behalf of the Highway Patrol. Please see MoDOT's fiscal note response for the potential fiscal impact of this proposal.

Officials from the **Office of Administration (OA)** assume the proposal will have no fiscal impact. It is assumed if any agency needs additional space, those potential costs will be included in the agencies' responses.

Oversight does not have any information to the contrary. Therefore, Oversight will no fiscal impact for the OA for fiscal note purposes.

Oversight notes the **Office of Attorney General**, the **Department of Health and Senior Services**, the **Department of Social Services**, the **Missouri Consolidated Health Care Plan**, the **Missouri Department of Conservation** and the **Missouri Department of Transportation** have stated the proposal would not have a direct fiscal impact on their organizations. Oversight does not have any information to the contrary. Therefore, Oversight will reflect a zero impact in the fiscal note for these organizations.

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.

Oversight assumes JCAR will be able to administer any rules resulting from this proposal with existing resources.

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 $5,000. 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 require additional resources.

FISCAL IMPACT - State Government	FY 2020 (10 Mo.)	FY 2021	FY 2022
GENERAL REVENUE FUND			
Income - DIFP (§§376.2060 - 376.2073)			
Assessment income	$0	$0	$2,711,355
Costs - DIFP (§§376.2060 - 376.2073)			
Personal service	$0	($626,200)	($632,462)
Fringe benefits	$0	($316,923)	($318,831)
Equipment and expense	$0	($498,201)	($318,738)
Total Costs - DIFP	$0	($1,441,324)	($1,270,031)
FTE Change - DIFP	$0	10 FTE	10 FTE
Costs - OA, ITSD (§§376.2062 and 376.2064)			
DIFP system changes (ranged from contracting out the programming to hiring 2 additional FTE IT Specialists) and on-going expenses	$0	($161,600 or $166,050)	($34,040 or $163,216)
Equipment and expense	$0	($5,476)	($6,734)
Total Costs - OA, ITSD	$0	($167,076 or $171,526)	($40,774 or $169,950)
FTE Change - OA, ITSD	0 FTE	0 or 2 FTE	0 or 2 FTE
ESTIMATED NET EFFECT ON THE GENERAL REVENUE FUND*	**$0**	**($1,608,400 or $1,612,850)**	**$1,271,374 or $1,400,550**
Estimated Net FTE Change on the General Revenue Fund	0 FTE	10 or 12 FTE	10 or 12 FTE

* Before inclusion of OA-ITSD costs, DIFP assessment income in FY 2022 is sufficient to reimburse its FY 2021 costs.

FISCAL IMPACT - Local Government	FY 2020 (10 Mo.)	FY 2021	FY 2022
LOCAL GOVERNMENTS - SCHOOL DISTRICTS			
Income - School Districts			
Distribution of fine revenue	$0	$0 to Unknown	$0 to Unknown
ESTIMATED NET EFFECT ON LOCAL GOVERNMENTS - SCHOOL DISTRICTS	**$0**	**$0 to Unknown**	**$0 to Unknown**

FISCAL IMPACT - Small Business

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

FISCAL DESCRIPTION

This act creates the "Drug Cost Review Commission" ("the Commission") within the Department of Insurance, Financial Institutions, and Professional Registration. The act specifies the Commission's unpaid membership, prohibits conflicts of interest, and instructs the Commission's chairman to hire an executive director, general counsel, and staff for the Commission. (Section 376.2061.1-3)

The Commission shall hold a public meeting at least every 6 weeks to review prescription drug product information unless there are no submissions to review, and shall provide notice, written materials, and opportunity for public comment as specified in the act. Certain specified actions may be made only in public meetings, and Commission members shall recuse themselves if there is a conflict of interest as specified in the act. (Section 376.2061.4)

Beginning March 1, 2022, this act requires pharmacy benefit managers to annually report to the Commission certain information about rebates for the pharmaceutical benefits they manage, including the aggregate dollar amounts of the pharmaceutical rebates received and used by health carriers. The Commission shall establish a form for reporting this information, and shall not disclose the information in a way that compromises the financial, competitive, or proprietary nature of the information, or would enable a third party to identify a health benefit plan, health carrier, pharmacy benefits manager, or value of a rebate. Information submitted pursuant to this requirement shall not be subject to disclosure under the Sunshine Law, except to the extent an aggregated report to the General Assembly is required as specified in the act. (Section 376.2062.1-3)

FISCAL DESCRIPTION (continued)

No later than July 1, 2022, and annually thereafter, the Commission shall submit to the General Assembly a report of the aggregated information submitted under these provisions, as well as any other information the Commission deems relevant. The Commission shall provide notice of the report's content to each pharmacy benefits manager and any third party affected by submission of the report. The Commission may impose a penalty of not more than $7,500 on a pharmacy benefits manager for a violation of these provisions. (Section 376.2062.4-5)

The act requires health carriers offering health benefit plans after January 1, 2022, to submit certain information from the previous calendar year to the Commission at the time they submit their rate filings. Health carriers must submit the names of the 25 most frequently prescribed outpatient prescription drugs, the 25 outpatient prescription drugs covered at the greatest cost, and the 25 outpatient prescription drugs with the greatest year-over-year increase in cost. Health carriers shall also report the portion of the premium cost attributable to certain categories of prescription drugs as specified in the act, as well as the percent year-over-year increase per member per month in the cost of each category. Health carriers shall submit a comparison of the year-over-year increase in drug cost versus increases in other contributing factors to premium costs, the name of each specialty drug covered by the health benefit plan, and the names of the 25 most frequently prescribed outpatient prescription drugs for which the health carrier received rebates from pharmaceutical manufacturers. (Section 376.2064)

No later than March 1, 2023, and annually thereafter, health carriers are required to certify that they have accounted for all rebates in calculating premiums. (Section 376.2066)

No later than March 1, 2023, and annually thereafter, the Commission shall submit to the committees of the General Assembly having jurisdiction over health insurance matters a report containing an aggregation of the data submitted by health carriers under this act, a description of the impact outpatient prescription drugs have on health insurance premiums in the state, and any other information the Commission deems relevant. (Section 376.2068)

No later than March 1, 2022, and annually thereafter, the Commission shall also prepare a report on health carriers' rebate practices as specified in the act. (Section 376.2070)

Beginning January 1, 2021, this act requires entities submitting drugs for FDA approval to inform the Commission when certain submissions are made as specified in the act. The Commission may, in consultation with the Commissioner of the Office of Administration, conduct a study of each pharmaceutical manufacturer of a pipeline drug, as defined in the act, that may have a significant impact on state expenditures. The act requires pharmaceutical manufacturers to submit certain information for the purposes of such study. (Section 376.2072.2-3)

FISCAL DESCRIPTION (continued)

No later than March 1, 2021, and annually thereafter, the Commission, in consultation with the Commissioner of the Office of Administration, the Director of the Department of Health and Senior Services, and the Director of the Department of Social Services, shall prepare a list of up to 10 outpatient prescription drugs that are provided at substantial cost to the state or are critical to public health. The list shall include drugs from different therapeutic classifications, and at least one generic drug. The list shall not include a drug unless the drug's wholesale acquisition cost: has increased by at least 20 percent in the previous calendar year or 50 percent across the previous three calendar years, and cost more than $60 for a thirty day supply or for a course of treatment lasting less than thirty days. Manufacturers of the pharmaceuticals on the list prepared by the Commission shall submit to the Commission a written description of the factors causing the increase in drug cost, and aggregate company-level research and development costs or other capital expenditures deemed relevant by the Commission. The Commission in consultation with pharmaceutical manufacturers shall establish a standardized form for manufacturer reporting pursuant to these provisions. (Section 376.2072.4)

The Commission may impose a fine of up to $7,500 for each violation of the reporting requirements. (Section 376.2072.5)

Manufacturers of patent-protected drugs shall notify the Commission if a drug's wholesale acquisition cost is increasing by more than 10% or $10,000 in any 12-month period, or if they intend to introduce a brand-name drug with a wholesale acquisition cost of over $30,000 per calendar year or course of treatment. Manufacturers of generic or off-patent sole source drugs shall notify the Commission if they are increasing the drug's wholesale acquisition cost by more than 25% or $300 in any twelve month period. The notice required under these provisions shall be given in writing at least 30 days prior to the effective date of the increase or the introduction of the drug to market, and shall include a justification for the price increase as specified in the act. The Commission, in consultation with stakeholders and experts, shall establish thresholds for manufacturer reporting of drugs that significantly increase costs to the health care system but are otherwise not reported under these provisions. (Section 376.2073.1-4)

Where possible, the Commission shall utilize price justifications made public by other states. Otherwise, the Commission shall require manufacturers to submit certain price justification documentation as specified in the act. (Section 376.2073.5)

The Commission shall inform the public about the wholesale acquisition cost reports and price justifications provided under these provisions, and shall allow the public to request review of reported drugs. The Chairman or members of the Commission may initiate review of a drug as specified in the act. (Section 376.2073.6)

FISCAL DESCRIPTION (continued)

If the Commission conducts a review of the cost of a prescription drug, the review shall determine whether the FDA-approved use of the drug has led or will lead to excess cost for health care systems in the state. In conducting their review, the Commission shall consider cost-driving factors as specified in the act or by rule. The act provides additional factors for if the Commission is otherwise unable to determine whether a drug will produce or has produced excess costs. (Section 376.2073.7)

If the Commission's review of a drug determines the drug creates excess costs for health carriers or consumers, the Commission shall establish levels of reimbursement among: health carriers and pharmacies or administering agencies; wholesalers and distributors and pharmacies or administering providers; or pharmacies or administrating providers and uninsured consumers or enrollees in a deductible period. The Commission shall determine how each participant is to be remunerated. (Section 376.2073.8)

The Commission, after public notice and comment, shall establish standards for when information submitted as part of a drug cost review shall be considered proprietary. Non-proprietary submissions made to the Commission under the cost review process shall be made available to the public. (Section 376.2073.9)

The Commission shall be established using funds appropriated from general revenue, but thereafter shall be funded by an assessment made by the Commission on manufacturers required to submit to the drug cost reviews. (Section 376.2073.10)

No later than August 28, 2020, and annually thereafter, the Commission shall publish on the web site for the Department of Insurance, Financial Institutions, and Professional Registration a report on prescription drug price trends, the number of manufacturers required to notify the Commission about price information under these provisions, and the number of products that were subject to Commission review, as specified in the act. (Section 376.2073.11)

This legislation is not federally mandated and would not duplicate any other program. However, the legislation would 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 Public Safety -
Missouri State Highway Patrol

SOURCES OF INFORMATION (continued)

Department of Social Services
Office of the Governor
Joint Committee on Administrative Rules
Missouri Consolidated Health Care Plan
Missouri Department of Conservation
Missouri Department of Transportation
Office of Administration
Office of Secretary of State

Kyle Rieman
Director
April 2, 2019

Ross Strope
Assistant Director
April 2, 2019

HWC:LR:OD