HB 1186 -- DRUG COST REVIEW COMMISSION

SPONSOR: Clemens

This bill creates the "Drug Cost Review Commission" within the Department of Insurance, Financial Institutions, and Professional Registration. The bill 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, RSMo).

The commission shall hold a public meeting at least every six 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. Commission members shall recuse themselves if there is a conflict of interest (Section 376.2061.4).

Beginning March 1, 2022, the bill requires pharmacy benefit managers to annually report to the commission certain information about rebates for the pharmaceutical benefits they manage. The commission 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 (Section 376.2062.1-3).

No later than July 1, 2022, and annually thereafter, the commission shall submit to the General Assembly a report. 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 bill 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 bill, 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 bill, 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 bill (Section 376.2070).

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

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% in the previous calendar year or 50% across the previous three calendar years, and cost more than $60 for a 30 day supply or for a course of treatment lasting less than 30 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 12 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 bill. 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 bill (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 (Section 376.2073.6).

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 bill or by rule. The bill 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 (Section 376.2073.11).

This bill is the same as SB 310 (2019).