State of Wisconsin
2021 - 2022 LEGISLATURE

LRB-0588/P3
EKL:wlj&cdc

DOA:.....Lessner, BB0168 – Pharmaceutical drug supply chain transparency and reporting

FOR 2021-2023 BUDGET -- NOT READY FOR INTRODUCTION

AN ACT ...; **relating to:** the budget.

Analysis by the Legislative Reference Bureau

INSURANCE

Registration of pharmacy benefit managers; drug cost reporting

This bill generally requires certain prescription drug cost reporting by drug manufacturers, pharmacy benefit managers, insurers, and pharmacy services administrative organizations.

Under the bill, each insurer that offers a health insurance policy that covers prescription drugs must submit to OCI an annual report that identifies the 25 prescription drugs that are the highest cost to the insurer and the 25 prescription drugs that have the highest cost increases over the 12 months before the submission of the report. Health insurance policies are referred to in the bill as disability insurance policies.

The bill requires a drug manufacturer to notify OCI if it increases the wholesale acquisition cost of a brand-name or generic drug on the market in Wisconsin by more than an amount specified in the bill, or if it intends to introduce to market a brand-name or generic drug that has an annual wholesale acquisition cost of more than a specified amount. The manufacturer must include with the notice justification for and documentation regarding the price increase. The bill requires each manufacturer to provide OCI an annual description of each

manufacturer–sponsored patient assistance program in effect during the previous year. Each manufacturer must also report to OCI the value of price concessions provided to each pharmacy benefit manager for each drug sold.

The bill requires pharmacy benefit managers to report to OCI the amount received from manufacturers as drug rebates and the value of price concessions provided by manufacturers for each drug. OCI is required under the bill to publicly post information submitted, analyze data collected, publish a report on emerging trends in prescription prices and price increases, and annually conduct a public hearing based on that analysis. OCI must also conduct a statistically valid survey of pharmacies regarding whether the pharmacy agreed to not disclose that customer drug benefit cost sharing exceeds the cost of the dispensed drug.

The bill requires pharmacy services administrative organizations to annually report to OCI the negotiated reimbursement rates of the 25 prescription drugs with the highest reimbursement rates, the 25 prescription drugs with the largest year–to–year change in reimbursement rate, and the schedule of fees charged to pharmacies.

This proposal may contain a health insurance mandate requiring a social and financial impact report under s. 601.423, stats.

For further information see the state fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 632.796 of the statutes is created to read:

632.796 Drug cost report. (1) DEFINITION. In this section, "disability insurance policy" has the meaning given in s. 632.895 (1) (a).

(2) REPORT REQUIRED. Annually, at the time the insurer files its rate request with the commissioner, each insurer that offers a disability insurance policy that covers prescription drugs shall submit to the commissioner a report that identifies the 25 prescription drugs that are the highest cost to the insurer and the 25 prescription drugs that have the highest cost increases over the 12 months before the submission of the report.

SECTION 2. 632.8665 of the statutes is created to read:

632.8665 Prescription drug cost reporting. (1) DEFINITIONS. In this section:

(a) "Brand–name drug" means a prescription drug approved under 21 USC 355 (b) or 42 USC 262.

(b) "Generic drug" means a prescription drug approved under 21 USC 355 (j).

(c) "Manufacturer" has the meaning given in s. 450.01 (12). "Manufacturer" does not include an entity that is engaged only in the dispensing, as defined in s. 450.01 (7), of a brand–name drug or generic drug.

(d) "Manufacturer–sponsored assistance program" means a program offered by a manufacturer or an intermediary under contract with a manufacturer through which a brand–name drug or generic drug is provided to a patient at no charge or at a discount.

(e) "Pharmacy benefit manager" has the meaning given in s. 632.865 (1) (c).

(f) "Pharmacy services administrative organization" means an entity that provides contracting and other administrative services to a pharmacy to assist the pharmacy in interactions with a 3rd–party payer, pharmacy benefit manager, wholesale drug distributor, or other entity.

(g) "Wholesale acquisition cost" means the most recently reported manufacturer list or catalog price for a brand–name drug or generic drug available to wholesalers or direct purchasers in the United States, before application of discounts, rebates, or reductions in price.

(2) PRICE INCREASE OR INTRODUCTION NOTICE; JUSTIFICATION REPORT. (a) A manufacturer shall notify the commissioner if it is increasing the wholesale acquisition cost of a brand–name drug on the market in this state by more than 10 percent or by more than $10,000 during any 12–month period or if it intends to

introduce to market in this state a brand–name drug that has an annual wholesale acquisition cost of $30,000 or more.

(b) A manufacturer shall notify the commissioner if it is increasing the wholesale acquisition cost of a generic drug by more than 25 percent or by more than $300 during any 12–month period or if it intends to introduce to market a generic drug that has an annual wholesale acquisition cost of $3,000 or more.

(c) The manufacturer shall provide the notice under par. (a) or (b) in writing at least 30 days before the planned effective date of the cost increase or drug introduction with a justification that includes all documents and research related to the manufacturer's selection of the cost increase or introduction price and a description of life cycle management, market competition and context, and estimated value or cost–effectiveness of the product.

(3) NET PRICES PAID BY PHARMACY BENEFIT MANAGERS. By March 1 annually, the manufacturer shall report to the commissioner the value of price concessions, expressed as a percentage of the wholesale acquisition cost, provided to each pharmacy benefit manager for each drug sold in this state.

(4) REBATES AND PRICE CONCESSIONS. By March 1 annually, each pharmacy benefit manager shall report to the commissioner the amount received from manufacturers as drug rebates and the value of price concessions, expressed as a percentage of the wholesale acquisition cost, provided by manufacturers for each drug.

(5) MANUFACTURER-SPONSORED ASSISTANCE PROGRAMS. By March 1 annually, each manufacturer shall provide the commissioner with a description of each manufacturer–sponsored patient assistance program in effect during the previous year that includes all of the following:

(a) The terms of the programs.

(b) The number of prescriptions provided to state residents under the program.

(c) The total market value of assistance provided to residents of this state under the program.

(6) PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS. By March 1 annually, each pharmacy services administrative organization shall report to the commissioner all of the following information:

(a) The negotiated reimbursement rate of the 25 prescription drugs with the highest reimbursement rates during the previous year.

(b) The 25 prescription drugs with the highest year–to–year change in reimbursement rate for the previous year.

(c) The schedule of fees charged by the organization to pharmacies.

(7) CERTIFICATION AND PENALTIES FOR NONCOMPLIANCE. Each manufacturer and pharmacy services administrative organization that is required to report under this section shall certify each report as accurate under the penalty of perjury. A manufacturer or pharmacy services administrative organization that fails to submit a report required under this section is subject to a forfeiture of no more than $10,000 each day the report is overdue.

(8) HEARING AND PUBLIC REPORTING. (a) The commissioner shall publicly post manufacturer price justification documents. The commissioner shall keep any trade secret or proprietary information confidential.

(b) The commissioner shall analyze data collected under this section and publish annually a report on emerging trends in prescription prices and price increases and shall annually conduct a public hearing based on the analysis under this paragraph. The report under this paragraph shall include analysis of

manufacturer prices and price increases and analysis of how pharmacy benefit manager discounts and net costs compare to retail prices paid by patients.

SECTION 9123. Nonstatutory provisions; Office of Commissioner of Insurance.

(1) PRESCRIPTION DRUG COST SURVEY. The commissioner of insurance shall conduct a statistically valid survey of pharmacies in this state regarding whether the pharmacy agreed to not disclose that customer drug benefit cost sharing exceeds the cost of the dispensed drug.

(END)