TO: Legislative Colleagues

FROM: Sen. Erpenbach, Sen. Roth

Rep. Schraa, Rep. Kolste

DATE: February 26, 2019

RE: CO-SPONSORSHIP OF LRB 2190/1, relating to: registration and regulation of pharmacy benefit managers, drug pricing transparency, granting rule-making authority, and providing a penalty

Deadline: March 8, 2019

Pharmacy Benefit Managers (PBMs) are businesses that administer and manage prescription drug benefits, typically on behalf of health insurers. PBMs create formularies, contract with pharmacies, and process and pay prescription drug claims. Because of the contracts they negotiate with manufacturers, health plans, and pharmacies, PBMs play a crucial role in the prescription drug supply chain, including influencing pricing and drug selection.

Despite this important role, sometimes PBMs actually make it more difficult for patients to get the medications they need at a reasonable price. LRB 0448 is a comprehensive, patient-centered bill that will lower out-of-pocket drug costs and increase access to prescribed medications by ensuring that PBMs operate with consumers' interests at the forefront.

LRB 2190 includes the following provisions:

Prohibiting Gag Clauses: This bill prohibits a PBM from banning a pharmacist from informing a patient that there is a lower cost option to paying for a prescription drug.

Clawbacks: Sometimes, a patient's copay is more than the cost of the medication if the patient were to pay cash. For example, a patient could have a $15 copay for a medication with a cash price of $5, and the PBM would charge the patient $15 – driving up healthcare costs and forcing patients to spend more of their hard-earned money. This bill prohibits PBMs from charging a copay greater than the amount that the pharmacy would charge if the patient was not using insurance.

Rebate Transparency: Each PBM registered in the state will submit an annual report to the Office of the Commissioner of Insurance (OCI) and the legislature, indicating the amount of rebates received from pharmaceutical manufacturers and the percentage of that rebate amount that was retained by the PBM and not passed through to the health plan or their customers.

Drug Formulary Changes: This bill prevents the removal of prescription drugs from a formulary during a plan year as long as certain criteria are met. Decisions about prescription medication regimens should be made between prescribers and patients. Patients that have been taking the same prescription drug for years should not be at-risk of losing access to these drugs, or be charged more to obtain them, because of a decision that financially benefits a PBM.

Pharmacy Choice: PBMs would be required to provide an adequate network of pharmacies to consumers, not counting mail-order pharmacies. They would also be prohibited from financially penalizing a consumer for utilizing an in-network pharmacy. If the pharmacy is within the PBM's network, patients should be allowed to use the pharmacy of their choice without being penalized with higher copays.

Fair Pharmacy Audit Provisions: PBMs must give two weeks' notice before conducting an initial audit at a pharmacy. The audit period cannot exceed a lookback period of two years and clerical or record-keeping errors shall not be subject to the recoupment of funds unless the errors are intentionally fraudulent.

Registration with OCI: This bill would require PBMs to register annually with OCI. The insurance commissioner can also require reports and conduct examinations to ensure that PBMs are acting in the best interests of the consumer, just like they can with insurance companies.

At least 33 states have passed legislation regulating PBMs, including similar legislation that was passed in Arkansas in 2018 with broad bipartisan support.

Analysis by the Legislative Reference Bureau

This bill generally allows the commissioner of insurance to regulate pharmacy benefit managers by requiring them to register. The bill also establishes certain price transparency requirements and requirements on contracts the pharmacy benefit manager enters into with pharmacies, pharmacists, or health benefit plan sponsors among other requirements.

Registration of pharmacy benefit managers

The bill prohibits a person, except an insurer already regulated by the commissioner, from performing any activities of a pharmacy benefit manager in this state without first registering with the commissioner. Certain pharmacy benefit managers must be licensed by the Pharmacy Examining Board and registered as a pharmacy benefit manager. If the Pharmacy Examining Board revokes the pharmacy or distributor license for such a pharmacy benefit manager, the commissioner must revoke the pharmacy benefit manager's registration. An applicant for registration as a pharmacy benefit manager must file an appropriate application and pay any registration fee set by the commissioner. A registration is valid for one year. The commissioner may refuse to register a pharmacy benefit manager for which a previous registration was suspended or revoked.

Under the bill, the commissioner, after a hearing, may suspend or revoke a registration of a pharmacy benefit manager if the registered pharmacy benefit manager, or an officer, director, or employee of a registered pharmacy benefit manager, does any of the actions specified in the bill. The commissioner may promulgate rules necessary to carry out the intent of pharmacy benefit manager registration. The bill also allows the commissioner to use his or her authority that is granted to regulate insurers to similarly regulate pharmacy benefit managers, including the authority to require reports, conduct examinations, and issue orders. The commissioner is required to promulgate certain rules, including rules regarding formulary development, required disclosures, and a standardized medical exceptions approval process, among others.

The bill requires pharmacy benefit managers to provide a reasonably adequate and accessible network of pharmacies. Pharmacy benefit managers are not allowed to include mail-order pharmacies in their calculation of network adequacy. The bill requires pharmacy benefit managers to submit a network adequacy report to the commissioner. The bill also imposes on pharmacy benefit managers a current law requirement on health maintenance organizations, limited service health organizations, and preferred provider plans that provide coverage of pharmaceutical services when performed by one or more selected pharmacists to provide an annual period of at least 30 days during which any pharmacist may elect to participate in the organization or plan under its terms as a selected provider for at least one year.

Pharmacy benefit manager regulation

The bill requires pharmacy benefit managers to refrain from certain actions in their interactions with pharmacists or pharmacies including charging a pharmacist or pharmacy a fee related to the adjudication of a claim, requiring pharmacist or pharmacy accreditation or certification requirements in addition to, more stringent than, or inconsistent with requirements of the pharmacy examining board, reimbursing a pharmacist or pharmacy less than the amount reimbursed to an affiliate of the pharmacy benefit manager for the same services, failing to make payments for services properly provided by a pharmacist or pharmacy before the termination of the pharmacist or pharmacy from the network, and restricting or limiting a pharmacy or pharmacist from disclosing information to a governmental official or law enforcement that is investigating a complaint or conducting a review. The bill requires a pharmacy benefit manager to disclose to a health benefit plan sponsor any activity, policy, or practice that presents a conflict of interest and, if the pharmacy benefit manager makes a formulary substitution to a higher cost drug, the cost of the drug and any benefit that accrues to the pharmacy benefit manager related to the substitution. A pharmacy benefit manager is prohibited in the bill from retroactively denying a pharmacist's or pharmacy's claim unless the original claim was fraudulent, the payment of the original claim was incorrect because it had already been paid, or the pharmacy services were not rendered by the pharmacist or pharmacy. The bill requires every pharmacy benefit manager to submit annual transparency reports containing information specified in the bill to the commissioner and to certain committees of the legislature.

Current law requires pharmacy benefit managers to agree in their contracts to make certain disclosures regarding prescription drug reimbursement, including updating maximum allowable cost pricing information for prescribed drugs or devices at least every seven business days, reimbursing pharmacies or pharmacists subject to the updated maximum allowable cost pricing, and modifying information in the maximum allowable cost information in a timely fashion. Pharmacy benefit managers currently must also include in each contract with a pharmacy a process to appeal, investigate, and resolve pricing disputes in accordance with the specifics in current law. These current law requirements are unchanged by the bill.

Audits of pharmacists or pharmacies

The bill sets requirements on a pharmacy benefit manager, insurer, defined network plan, such as a health maintenance organization, or a third-party payer that is conducting an audit of pharmacist or pharmacy records, including requiring at least two weeks' notice of an audit that is on the premises of a pharmacist or pharmacy, refraining from conducting the audit within the first seven days of the month unless the pharmacist or pharmacy consents, limiting the audit to claims submitted no more than two years before the date of the audit, establishing a written appeals process allowing for appeals of preliminary and final reports and mediation by either party, and allowing a pharmacist or pharmacy to use health care provider records to validate records and any prescription that complies with the pharmacy examining board requirements to validate claims. The bill requires an entity that has conducted an audit of a pharmacist or pharmacy to comply with certain timing requirements for delivery of the preliminary and final reports and for allowing a pharmacist or pharmacy to address any discrepancies and requires the entity to refrain from using extrapolation in calculating the recoupments or penalties from an audit among other requirements in the bill. If an audit identifies a clerical or record-keeping error, the pharmacy benefit manager or entity must prove that the pharmacist or pharmacy intended to commit fraud or that the error resulted in actual financial harm before requesting recoupment from the pharmacist or pharmacy based on the error. A pharmacy benefit manager or

other entity conducting an audit may not pay an auditor based on a percentage of the amount recovered in an audit.

Allowing disclosures to consumers

This bill prohibits a health insurance policy, referred to in the statutes as a disability insurance policy, or a governmental self-insured health plan from including in a contract for pharmacy services, or allowing a pharmacy benefit manager or another entity to include in a contract for pharmacy services, a provision that prohibits or penalizes a pharmacist's disclosure to an individual purchasing a prescribed drug or device of the cost of a prescribed drug or device, a less expensive therapeutically equivalent drug or device, or a less expensive method of purchasing the drug or device.

Cost sharing limitation, choice of provider, and drug substitution

The bill sets a limitation on the amount of cost sharing that a person who is covered under a health insurance policy or self-insured governmental health plan must pay at the point of sale for a prescription drug as specified in the bill. A policy or plan or a pharmacy benefit manager may not require a person covered under the policy or plan to pay an increased amount of cost sharing for a newly prescribed drug or device if the policy, plan, or pharmacy benefit manager requested the substitution of the original drug and if the newly prescribed drug or device is therapeutically equivalent to the originally prescribed drug or device. The bill requires health insurance policies, self-insured governmental health plans, and pharmacy benefits managers to develop a procedure to ensure that a policy or plan does not deny coverage to an insured or plan participant during a plan year or subject the insured or plan participant to new exclusions, limitations, deductibles, copayments, or coinsurance if the prescribed drug or device was covered under the policy or plan for the insured or plan participant when the insured or plan participant either enrolled in coverage or renewed coverage and if the prescribing health care provider states that the prescribed drug or device is more suitable for the insured's or plan participant's condition than alternative drugs or devices that are covered under the policy or plan. An insurer, self-insured governmental health plan, or pharmacy benefit manager may not require or penalize a person who is covered under a health insurance policy or plan to use or for not using a specific retail, specific mail order pharmacy, or other specific pharmacy within the policy's or plan's provider network.

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.