HB 4348 by Rep. Julie Calley

Licensing & Regulation of Pharmacy Benefit Managers

Issue Background

Pharmacy Benefit Managers (PBMs) are multi-billion-dollar corporations hired by health plans to administer pharmacy benefits for covered individuals and create the networks of pharmacies needed to provide those benefits. PBMs have tremendous control over drug benefit design, drug pricing, pharmacy network configuration and reimbursement. **Just three PBMS — Caremark, Express Scripts and Optum — control 85% of the U.S. pharmacy benefit market.** The power of PBMs has grown immensely with their expansion into health care and pharmacy operations. Caremark, the nation's largest PBM, also owns CVS — the largest U.S. drug chain — as well as insurance giant Aetna. Express Scripts and Optum (like CVS/Caremark) also operate huge mail-order and specialty pharmacies that compete directly with the retail pharmacies in their provider networks.

There is a pronounced lack of transparency concerning the millions of dollars PBMs receive in rebates from drug manufacturers and the spread pricing they practice that charges health plans more for drugs and pays pharmacies less. PBMs have enormous wealth and have regulatory-like control over community pharmacies despite serious conflicts of interest and numerous self-serving practices. The actions of PBMs raise costs for patients, health plans and the state; reduce patient choice and access to pharmacy care; and financially punish the state's small, locally owned pharmacies. PBMs earn hundreds of millions of dollars a year in Michigan with no real state oversight and no licensing requirements. **They essentially enjoy a protected monopoly status.**

HB 4348 establishes the following provisions in the Insurance Code to license and regulate PBMs in Michigan:

Section 11. Licensing

- **Effective Jan. 1, 2022, any PBM operating in Michigan must be licensed by the state** and must disclose to the Dept. of Insurance and Financial Services (DIFS) its financial assets, major officers and stockholders and provide details of its services, facilities and personnel. It also must attest that its contracts and practices conform with state law.
- DIFS can suspend or revoke the license of any PBM for specified violations and may assess a fine not to exceed $5,000 a month until the violations are remedied.

Section 15. Good Faith & Fair Dealing

- A PBM shall provide each network pharmacy its final reimbursement amount when a claim is adjudicated at the point of sale.
- **A PBM shall not retroactively charge a network pharmacy any fee, charge or other amount after it has communicated the final reimbursement amount on a claim.**
- A PBM shall not charge a pharmacy or hold it responsible for any fee related to transmitting a claim or for establishment or participation in a claims transmission system.

Section 17. Pharmacy Network Adequacy

- **Each PBM must submit to DFIS a network adequacy report that details the PBM's pharmacy provider network in the state and patient accessibility to that network.**

Section 19. Prohibitions on Self-Dealing

- A PBM cannot reimburse a pharmacy less for a covered drug than the amount it charges a health plan for the same drug or reimburse a non-affiliated pharmacy less than it reimburses an affiliated pharmacy for the same drug or service.
- **A PBM, health plan or carrier may not steer or direct a patient to use only an affiliated pharmacy, nor require a patient to use an affiliated pharmacy. Nor may they require or induce a patient to use an affiliated pharmacy through reduced copayments.**
- A PBM, health plan or carrier may not require a non-affiliated pharmacy to transfer a prescription to an affiliated pharmacy without the patient's prior consent.

Section 21. Prohibition of Gag Clauses & Clawbacks

- **A provider contract may not prohibit a pharmacy from giving a patient information about the cost or coverage of a drug or dispensing a less-expensive alternative.**
- A PBM, health plan or carrier may not require a patient to pay more for a drug than the lesser of the applicable copayment or amount reimbursed to the dispensing pharmacy.

Section 23. Quarterly Transparency Reports

- **Beginning Jan. 1, 2022, a PBM must file a quarterly transparency report that details the wholesale acquisition costs for each therapeutic drug category for all plan sponsors.** The report must include total rebates received for all plan sponsors, total fee payments received, and total rebates and fee payments not passed through to health plans or insurers.
- **DIFS shall annually review all claims to identify any cost-sharing and reimbursement variations and shall prepare and file an annual report based on the information.**

Section 27. Pharmacy Reimbursement & Prompt Payment of Claims

- **A network pharmacy must be reimbursed for a medication in an amount no less than the National Average Drug Acquisition Cost (NADAC) for the drug plus a dispensing fee equal to that paid by Michigan Medicaid.** If no NADAC cost is available, payment must not be less than the Wholesale Acquisition Cost of the drug plus the Medicaid dispensing fee.
- Each PBM that maintains a Maximum Allowable Cost (MAC) list shall give its network pharmacies access to the list and update the list at least every 7 days. The PBM must disclose the data source(s) used to determine the MAC price of each listed drug.
- The PBM must establish an appeals process to allow any network pharmacy to challenge a MAC price and, if an appeal is denied, provide the appealing pharmacy the NDC of the product and the supplier at which the drug is available at or below the appealed MAC price.
- **All clean claims submitted electronically by a network pharmacy to a PBM shall be paid within 15 days after adjudication at the point of sale.**

Section 28. Pharmacy Audit Guidelines

- A PBM or carrier auditing a pharmacy must fully disclose its audit procedures and appeals process and must notify a pharmacy in writing at least four weeks prior to an on-site audit.
- An audit can cover only claims that were submitted or adjudicated within the one-year period preceding the audit and may not include the dispensing fee in a finding of overpayment. In validating pharmacy records, a PBM or carrier must accept written or electronic records from hospitals or physicians or any prescription that complies with state and federal law.
- **An appeals process must be established to allow a pharmacy to contest preliminary or final audit reports. Either party may seek mediation if it contests the appeal results.**
- An audited pharmacy must receive a preliminary written audit report within 60 days of audit completion and must have 30 days after receiving the report to address any discrepancy identified. The final audit report must be sent within 90 days after the preceding process ends or within 90 days of the conclusion of an appeal.
- **Extrapolation may not be used to calculate recoupment, restoration or penalties.**
- A clerical or record-keeping error cannot be considered fraud on its face and cannot be the basis of criminal penalties without proof of intent to commit fraud.

Section 29. Miscellaneous Provisions

- **A PBM or carrier may not prohibit a pharmacy from delivering or mailing a drug to a patient on the patient's request,** including charging a shipping and handling fee if the pharmacy discloses the fee in advance and that it may not be reimbursable.
- **It may not require pharmacy or pharmacist accreditation or recertification standards that are inconsistent with or more stringent than federal and state requirements.**