Bill Summary

# H.F. 728

Second engrossment

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| Subject | Pharmacy Benefit Manager Licensure and Regulation |
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## Overview

A pharmacy benefit manager (PBM) administers prescription drug benefits for health carriers and employers (often referred to as plan sponsors). PBMs maintain prescription drug formularies, process prescription drug claims, negotiate contracts with prescription drug manufacturers and wholesalers, manage pharmacy networks, and reimburse pharmacies. This bill requires PBMs to be licensed by the Board of Pharmacy under a new chapter of law, chapter 62W, in order to operate in Minnesota. The bill establishes requirements for PBMs related to fiduciary and other duties, network adequacy, transparency, and ownership interests. The bill also incorporates existing state laws related to PBM contracts with pharmacies into the new chapter of law, and includes provisions related to enrollee costs and disclosure, and synchronization of refills, that were part of last session's vetoed health and human services finance bill.

## Summary

| Section | Description |
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| 1 | **Citation.**<br>Adds § 62W.01. States that chapter 62W may be cited as the "Minnesota Pharmacy Benefit Manager Licensure and Regulation Act." |
| 2 | **Definitions.**<br>Adds § 62W.02. Defines the following terms: aggregate retained rebate, claims processing service, commissioner, enrollee, health carrier, health plan, mail order pharmacy, maximum allowable cost price, multiple source drugs, network pharmacy, other prescription drug or device services, pharmacist, pharmacy, pharmacy benefit manager, plan sponsor, specialty drug, retail pharmacy, and rebates. |
| 3 | **License to do business.**<br>Adds § 62W.03.<br>**Subd. 1. General.** Beginning January 1, 2020, prohibits a person from operating as a pharmacy benefit manager, unless the person has a license issued by the commissioner of commerce. States that licenses are nontransferable. |

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| | **Subd. 2. Application.** Requires PBMs seeking a license to apply to the commissioner of commerce. Specifies requirements for the application form. Requires each application to be accompanied by a nonrefundable fee of $3,000 and evidence of financial responsibility in the amount of $1,000,000. Also requires submittal of the network adequacy report specified in section 62W.05. Specifies timelines and procedures for application review and issuance of a license.<br><br>**Subd. 3. Renewal.** Provides that a license is valid for three years. Specifies renewal procedures and requires a renewal fee of $3,000. Requires the commissioner to deny a renewal or institute a plan to cure or correct under certain circumstances.<br><br>**Subd. 4. Oversight.** Authorizes the commissioner to suspend, revoke, or place on probation a PBM license, under specified circumstances. Also allows the commissioner to place restrictions or limitations on a license.<br><br>**Subd. 5. Penalty.** Provides for a $5,000 per day fine if a PBM acts without a license.<br><br>**Subd. 6. Rulemaking.** Allows the commissioner to adopt rules to implement this section.<br><br>**Subd. 7. Enforcement.** Clarifies that the commissioner will enforce this chapter pursuant to chapter 45. |
| 4 | **Pharmacy benefit manager general business practices.**<br>Adds § 62W.04. (a) States that a PBM has a fiduciary duty to a health carrier and must discharge that duty in accordance with state and federal law.<br><br>(b) Requires a PBM to perform its duties with care, skill, prudence, diligence, and professionalism, and exercise good faith and fair dealing in performance of its contractual duties. States that a provision in contract between a PBM and a health carrier or network pharmacy that attempts to waive or limit this obligation is void.<br><br>(c) Requires a PBM to notify a health carrier in writing of any activity, policy, or practice of the PBM that presents a conflict of interest. |
| 5 | **Pharmacy benefit manager network adequacy.**<br>Adds § 62W.05. (a) Requires a PBM to provide an adequate and accessible pharmacy network that provides access to pharmacies within a reasonable distance from an enrollee's residence. Requires a network to include a sufficient number of pharmacies to ensure that pharmacy services are available without unreasonable delay. Requires the commissioner to ensure the maximum travel distance or time to the nearest pharmacy |

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| | meets the requirements under section 62K.10. States that a mail order pharmacy must not be included when determining the adequacy of a network.<br><br>(b) Requires a PBM to submit to the commissioner a pharmacy network adequacy report, with license applications and renewals. |
| 6 | **Pharmacy benefit manager transparency.**<br>Adds § 62W.06.<br><br>**Subd. 1. Transparency to plan sponsors.** Requires a PBM to disclose, upon the request of a plan sponsor, specified information related to the sponsor's prescription drug benefit, including but not limited to, information on: the aggregate amount of rebates received by the PBM for each drug category, other fees received from a drug manufacturer or distributor, de-identified claims level information, the aggregate amount of payments made by the PBM to pharmacies owned and controlled by the PBM and not owned or controlled by the PBM, and fees imposed on or collected from network pharmacies.<br><br>**Subd. 2. Transparency report to the commissioner.** Beginning January 1, 2020, and annually thereafter, requires each PBM to submit to the commissioner a transparency report for the prior calendar year. Requires the report to include aggregate wholesale acquisition costs, the aggregate amount of rebates received, the aggregate of all fees received, aggregate retained rebates and other fees, aggregate retained rebate and fees percentage, de-identified and other specified information. Requires the report to be published on the agency website. Specifies the method to be used to calculate the aggregate retained rebate fee percentage.<br><br>**Subd. 3. Penalty.** Allows the commissioner to impose civil penalties of not more than $1,000 per day per violation of this section. |
| 7 | **Pharmacy ownership interest; specialty pharmacy services.**<br>Adds § 62W.07. (a) Requires PBMs with an ownership interest in a pharmacy (directly or through an affiliate or subsidiary) to disclose to the plan sponsor any difference between the amount paid to a pharmacy and the amount charged to the plan sponsor.<br><br>(b) Prohibits a PBM (or an affiliate or subsidiary) from owning or having an ownership interest in a patient assistance program or mail order specialty pharmacy, unless it agrees to fair competition, no self-dealing, and no interference with prospective economic advantage, and establishes a firewall between administrative functions and the mail order pharmacy.<br><br>(c) Prohibits a PBM or health carrier penalizing, requiring, or providing financial incentives to an enrollee as an incentive to use a retail, mail order, specialty, or other network pharmacy in which the PBM has an ownership interest, or that has an ownership interest in the PBM. |

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| | (d) Prohibits a PBM or health carrier from imposing limits, including quantity or refill frequency limits, on a patient's access to medication, based solely on whether the health carrier or PBM has an ownership interest in a pharmacy, or the pharmacy has an ownership interest in the PBM.<br><br>(e) Prohibits a PBM from requiring pharmacy accreditation standards or recertification requirements to participate in a network that are inconsistent with, more stringent than, or in addition to federal and state requirements for licensure as a pharmacy. |
| 8 | **Maximum allowable cost pricing.**<br>Adds § 62W.08. Regulates contracts between a PBM and a pharmacy related to maximum allowable cost pricing. (This language is similar to section 151.71, which is repealed in this bill.) |
| 9 | **Pharmacy audits.**<br>Adds § 62W.09. Specifies the procedures that PBMs must follow when conducting a pharmacy audit. (This language is similar to sections 151.61 to 151.70, which are repealed in the bill.) |
| 10 | **Synchronization.**<br>Adds § 62W.10. Requires a contract between a PBM and a pharmacy to allow for the synchronization of prescription drug refills for a patient at least one per year, if specified criteria are met. |
| 11 | **Gag clause prohibition.**<br>Adds § 62W.11. (a) States that a contract between a PBM or health carrier and a pharmacy or pharmacist may not prohibit, restrict, or penalize the pharmacy or pharmacist from disclosing to the enrollee any health care information deemed by the pharmacy or pharmacist as being appropriate, related to: the nature of treatment; risks or alternatives; the availability of alternative therapies, consultations, or tests; utilization review decisions; the process used to authorize or deny services or benefits; or financial incentives and structures.<br><br>(b) Requires a pharmacy or pharmacist to provide to an enrollee information on the enrollee's total cost for a prescription drug, where part or all of the cost is paid or reimbursed by the employer-sponsored plan, health carrier, or PBM, in accordance with section 151.214, subdivision 1 (this provision requires pharmacists to provide information on the patient's copayment and either the pharmacy's usual and customary price or the amount the pharmacy will be paid).<br><br>(c) States that a PBM or health carrier must not prohibit a pharmacist or pharmacy from discussing the information on the total cost of a drug, including the patient's copayment, the pharmacy's usual and customary price, and the net amount the pharmacy will receive from all sources for dispensing the drug. |

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| | (d) States that a PBM or health carrier must not prohibit a pharmacist or pharmacy from discussing the availability of any therapeutically equivalent alternative prescription drugs or alternative methods of purchase, including paying the pharmacy's usual and customary price when that is less expensive for the enrollee than payment through the enrollee's health plan. |
| 12 | **Point of sale.**<br>Adds § 62W.12. Prohibits a PBM or health carrier form requiring an enrollee to make a payment at the point of sale for a covered prescription drug in an amount greater than the lesser of: (1) the applicable copayment; (2) the allowable claim amount; (3) the amount the enrollee would pay purchasing the drug without using a health plan or other source of benefits or discounts; or (4) the amount the pharmacy will be reimbursed from the PBM or health carrier. |
| 13 | **Drug formulary.**<br>Amends § 151.21, subd. 7. Limits an exemption from drug substitution and other requirements when a drug is dispensed to persons covered by a managed care plan with a mandatory or closed drug formulary to subdivision 3 (required generic substitution except when prescriber indicates "dispense as written"), rather than all of section 151.21. |
| 14 | **Coverage by substitution.**<br>Amends § 151.21, by adding subd. 7a. When a pharmacist receives a prescription in which the prescriber has not expressly indicated is to be dispensed as communicated, and the prescribed drug is not covered under the purchaser's health or prescription drug plan, allows the pharmacist to dispense a therapeutically equivalent and interchangeable prescribed drug or biological product that is covered under the purchaser's plan, if the pharmacist has a written protocol with the prescriber. Specifies related notice requirements. |
| 15 | **Severability.**<br>Provides that if a provision of this act is held invalid or unenforceable, the remainder of the act is not enforceable and the provisions of this act are severable. |
| 16 | **Repealer.**<br>Repeals the following statutory provisions:<br>▪ 151.214, subdivision 2 – prohibition on disclosure by pharmacy<br>▪ 151.60, 151,61, 151.62, 151.63, 151.64, 151.65, 151.66, 151.67, 151.68, 151.69, and 151.70 – pharmacy audit integrity program<br>▪ 151.71 – maximum allowable cost pricing |