MN HOUSE RESEARCH

Bill Summary

S.F. 278

Conference Committee Report

Subject	Pharmacy Benefit Manager Licensure and Regulation
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Overview

This bill requires pharmacy benefit managers (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 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, sets time limits for filling certain specialty drug prescriptions, and includes provisions related to enrollee costs and disclosure, and synchronization of refills.

Summary

Section	Description
1	**Citation.** Adds § 62W.01. States that chapter 62W may be cited as the "Minnesota Pharmacy Benefit Manager Licensure and Regulation Act."
2	**Definitions.** 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, rebates, and specialty pharmacy.
3	**License to do business.** Adds § 62W.03. **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. **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 $8,500. Also requires submittal of the network adequacy report required under section

Section	Description

62W.05. Specifies timelines and procedures for application review and issuance of a license.

Subd. 3. Renewal. Provides that a license is valid for one year. Specifies renewal procedures and requires a network adequacy report and a renewal fee of $8,500. Allows the commissioner to deny a renewal or permit a plan to cure or correct under certain circumstances.

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.

Subd. 5. Penalty. Provides for a $5,000 per day fine if a PBM acts without a license.

Subd. 6. Enforcement. Clarifies that the commissioner will enforce this chapter pursuant to chapter 45.

4 **Pharmacy benefit manager general business practices.**

Adds § 62W.04. (a) Requires a PBM to 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.

(b) 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.**

Adds § 62W.05.

Subd. 1. Requirements. (a) Requires a PBM to provide an adequate and accessible pharmacy network that meets the relevant requirements in section 62K.10. States that a mail order pharmacy must not be included when determining the adequacy of a network.

(b) Requires a PBM to submit to the commissioner a pharmacy network adequacy report, with license applications and renewals.

Subd. 2. Network adequacy waiver. Allows a PBM to apply to the commissioner of health for a waiver of the network adequacy requirements in subdivision 1, and specifies waiver criteria.

Subd. 3. Accreditation standards. Prohibits a PBM from requiring pharmacy accreditation standards or recertification requirements that are inconsistent with, more stringent than, or in addition to federal and state requirements, unless authorized under this chapter.

Section	Description
6	**Pharmacy benefit manager transparency.** Adds § 62W.06. **Subd. 1. Transparency to plan sponsors.** (a) Beginning in the second quarter after the effective date of a contract with a plan sponsor, 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. (b) Allows a PBM to require a plan sponsor to agree to a nondisclosure agreement, before disclosing information to the plan sponsor. **Subd. 2. Transparency report to the commissioner.** Beginning June 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 claims level information, 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 and fee percentage. Classifies certain de-identified claims level information as confidential, protected nonpublic, or both. **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; pharmacy services.** 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. (b) Prohibits a PBM or health carrier from 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. (c) Provides an exemption from paragraph (b) if the PBM or health carrier offers an enrollee the same financial incentives for using a pharmacy in which the PBM has no ownership interest, and the pharmacy has agreed to the same pricing terms, conditions, and requirements as apply to a pharmacy in which the PBM has an ownership interest. (d) Prohibits a PBM or health carrier from imposing limits, including quantity or refill frequency limits, on an enrollee's access to medication, that differ solely on whether the

Section	Description
	health carrier or PBM has an ownership interest in a pharmacy, or the pharmacy has an ownership interest in the PBM. (e) Provides that paragraph (d) shall not be construed to prohibit a PBM from imposing different limits based on whether an enrollee uses a mail order or retail pharmacy, as long as the enrollee has an option to use a mail order pharmacy or retail pharmacy in which the PBM or health carrier does not have an ownership interest, to which the same limits apply. (f) Prohibits a PBM from discriminating against an entity participating in the 340B drug program or a pharmacy under contract with such an entity.
8	**Therapeutic alternative prescription drug.** Adds § 62W.075. Prohibits a PBM or health carrier from requiring, or demonstrating a preference for, a pharmacy to dispense a therapeutically equivalent or therapeutically alternative drug that costs the enrollee more out-of-pocket than the prescribed drug, unless the substitution is made for medical reasons. Before making a substitution, requires the pharmacy to obtain approval from the prescribing practitioner and inform the enrollee of the reason for the substitution.
9	**Specialty pharmacy.** Adds § 62W.076. Requires a PBM that contracts with a specialty pharmacy to disclose to an enrollee, upon request, the enrollee's out-of-pocket cost at the specialty pharmacy for a prescription drug and the enrollee's out-of-pocket cost at a network retail pharmacy identified by the enrollee.
10	**Preferred network.** Adds § 62W.077. Requires a PBM that uses a preferred network of pharmacies to disclose to an enrollee, upon request, the enrollee's out-of-pocket cost at the preferred pharmacy for a prescription drug and the enrollee's out-of-pocket cost at a nonpreferred pharmacy identified by the enrollee that is within the enrollee's network.
11	**Maximum allowable cost pricing.** 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 article.)
12	**Pharmacy audits.** 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 article.)

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13	**Synchronization.** 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. Also allows synchronization to be requested by the patient's parent or legal guardian if the patient is under age 18 or incapacitated, or by the patient's health care agent.
14	**Gag clause prohibition.** 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. (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). (c) States that a PBM or health carrier must not prohibit a pharmacist or pharmacy from discussing the information on the total cost for pharmacy services for a drug, including the patient's copayment and the pharmacy's usual and customary price. (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.
15	**Point of sale.** Adds § 62W.12. Prohibits a PBM or health carrier from 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; or (3) the amount the enrollee would pay purchasing the drug without using a health plan or other source of benefits or discounts.
16	**Retroactive adjustments.** Adds § 62W.13. Prohibits a PBM from retroactively adjusting a pharmacy claim for a prescription drug, unless the adjustment is a result of a: (1) pharmacy audit under section 62W.09; or (2) technical billing error.

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17	**Prompt filling for prescription drugs.** Adds § 62W.14. (a) Requires a health carrier or its contracted PBM that requires or provides financial incentives for enrollees to use a mail order pharmacy to fill a prescription for a specialty drug to ensure that the mail order pharmacy dispenses the prescription in a timely manner, so that the enrollee receives the filled prescription within seven business days of transmittal to the mail order pharmacy. Allows exemptions if certain conditions are met. (b) Defines "health carrier" to include managed care and county-based purchasing plans, and integrated health partnerships, under medical assistance and MinnesotaCare.
18	**Drug formulary.** 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.
19	**Coverage by substitution.** 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.
20	**Rulemaking authority.** Authorizes the commissioner of commerce to adopt rules to implement chapter 62W. States that the commissioner must not adopt rules under any other grant of rulemaking authority. Provides that if the commissioner does not adopt rules by January 1, 2022, rulemaking authority under this section is repealed. States that rulemaking authority under this section is not continuing authority to amend or repeal rules.
21	**Interpretation.** States that if an appropriation in this act is enacted more than once in the 2019 regular legislative session, the appropriation must be given effect only once.
22	**Appropriation.** Appropriates $340,000 in fiscal year 2020 and $383,000 in fiscal year 2021 from the general fund to the commissioner of commerce for licensing activities under chapter 62W. Specifies that the base for this appropriation is $425,000 in fiscal year 2022 and $425,000 in fiscal year 2023. Requires $246,000 each year to be used solely for staff costs for two enforcement investigators for chapter 62W.

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23	**Repealer.** Repeals the following statutory provisions: ▪ 151.214, subdivision 2 – prohibition on disclosure by pharmacy ▪ 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 ▪ 151.71 – maximum allowable cost pricing