Department of Commerce

Proposed Permanent Rules Relating to Pharmacy Benefit Management

2737.0100 DEFINITIONS.

Subpart 1. **Scope.** For the purposes of this chapter, the terms defined in Minnesota Statutes, chapter 62W, have the meanings given them. For purposes of this chapter, the terms defined in this part have the meanings given them.

Subp. 2. **Aggregate.** "Aggregate" means the sum total of the particular reporting element at the national drug code level.

Subp. 3. **Doing business in Minnesota.** "Doing business in Minnesota" means a plan sponsor (1) is a Minnesota entity, or (2) makes a contract or engages in a terms of service agreement with a Minnesota resident that is performed in whole or in part by either party in Minnesota.

Subp. 4. **Machine readable format.** "Machine readable format" has the meaning given in United States Code, title 44, section 3502(18).

Subp. 5. **Owned pharmacy.** "Owned pharmacy" means (1) a pharmacy, whether retail, mail order, specialty, or other, or a pharmacy provider in which a pharmacy benefit manager has a direct or indirect ownership interest, or (2) a pharmacy provider has an ownership interest, whether direct or indirect, in the pharmacy benefit manager.

2737.0200 AUTHORITY, SCOPE, AND PURPOSE.

This chapter is promulgated pursuant to Minnesota Statutes, chapter 62W, and Laws 2019, chapter 39, section 20. This chapter applies to all pharmacy benefit managers that are licensed or authorized to do business in or otherwise doing business in Minnesota and subject to the provisions of the Minnesota Pharmacy Benefit Manager Licensure and Regulation Act. This chapter is promulgated to carry out the act, as amended, and to facilitate the act's full and uniform implementation, enforcement, and application.

2737.0300 GOVERNMENT PROGRAMS.

Subpart 1. **Governmental agencies providing pharmacy management services.** Where an agency of the state of Minnesota directly provides pharmacy management services, the agency is extended the exemption granted to the Department of Human Services.

Subp. 2. **Managed care plans in contract with state agencies.** A managed care plan that has entered into a contract with the Department of Human Services that otherwise meets the definition of a plan sponsor under Minnesota Statutes, section 62W.02, subdivision 16, is not entitled to the exemption granted to the Department of Human Services.

2737.0400 BUSINESS LICENSE REQUIREMENTS; INITIAL APPLICATION.

Subpart 1. **Application.** A pharmacy benefit manager doing business in Minnesota on or after January 1, 2020, must apply to the commissioner in the manner and form prescribed by the commissioner in order to perform, act, or do business in Minnesota as a pharmacy benefit manager. The forms must be submitted no later than 90 days prior to the first day business is effective, offered, or maintained.

Subp. 2. **Application contents.** Each application for a license as pharmacy benefit manager must:

A. be signed and sworn to by the applicant, or the applicant's owners, and be accompanied by the license fee required by Minnesota Statutes, section 62W.03. If the applicant is a corporate applicant, the application must be verified by the president and secretary of the corporation;

B. designate an agent for service of process in Minnesota;

C. provide the name, address, identifying information, official position, and professional qualifications of each person responsible for conducting the affairs of the pharmacy benefit manager, including owners, key employees, as well as all members of the board of directors, board of trustees, executive committee, or other governing board or

committee; for a corporation, the principal officers; or for a partnership or association, the partners or members;

D. for the applicant and each person identified under item C:

(1) provide detailed resumes, which must contain at a minimum each person's name, licensing history, and qualifications and experience relating to the work the person performs for the applicant;

(2) for an owner, partner, officer, or director of the applicant, fully describe any contract or other business relationship terminated for alleged misconduct on the part of any owner, partner, officer, or director of the applicant;

(3) fully describe any violations or investigations by any governmental agency;

(4) fully describe any professional or occupational license discipline or suspension;

(5) fully describe any criminal charges or convictions; and

(6) fully describe any delinquent tax obligation, bankruptcy, or demand or judgment for overdue money by an insurer, insured, pharmacy, or any other claimant, whether involving fraud, misappropriation of funds, failure to exercise good faith and fair dealing in the performance of contractual duties, or for any other reason;

E. provide the identities of any plan sponsors for whom the applicant provides pharmacy benefit manager services in Minnesota, and the identity of any utilization review companies required to be licensed under Minnesota Statutes, chapter 62W, that the applicant uses in Minnesota; and

F. provide the total number of insureds residing in Minnesota for each plan sponsor for which the applicant provides services.

Subp. 3. **Network adequacy report.** As part of any application for a license under this chapter, an applicant must provide a pharmacy network adequacy report to the Department of Health in the manner and form prescribed by the Department of Health. Pharmacy benefit managers must have a network adequacy report approval issued by the Department of Health no less than 90 days prior to the desired license effective date. The Department of Health's review of the report, and any geographic or other restrictions determined by the Department of Health, may become part of any license issued.

Subp. 4. **Fee.** Each initial pharmacy benefit manager application for licensure must be accompanied by a nonrefundable fee of $8,500. An additional administration fee may be charged by the service provider retained by the commissioner.

Subp. 5. **Updated information required.** If any of the information provided on the initial application under subpart 2, item C, D, or E, changes at any time following submission, the applicant must provide updated information to the commissioner within 30 days of the date the applicant becomes aware of the changed information. If any of the information provided on the network adequacy report changes at any time following submission, the applicant must provide updated information to the Department of Health within 30 days of the date the applicant becomes aware of the changed information.

2737.0500 BUSINESS LICENSE REQUIREMENTS; RENEWAL APPLICATION.

Subpart 1. **Renewal application.** In order to obtain a renewal of a license, a pharmacy benefit manager must annually meet the requirements needed to obtain an initial pharmacy benefit management license under part 2737.0400. The commissioner must consider those areas of law described in part 2737.0700, subpart 2, in order to determine whether to approve the renewal of a pharmacy benefit manager's license each year.

Subp. 2. **Timeline.**

A. **Renewal application.** Applications for renewal may be submitted as soon as 90 days before the date the current license expires, but must be submitted no later than 60 days before the date the current license expires. Renewal applications must be submitted in the manner and form prescribed by the commissioner. Applications submitted after the required date are considered a late application and may result in enforcement action, in addition to the late fee provided under subpart 3.

B. **Network adequacy report.** As part of any renewal application for a license under this chapter, an applicant must provide a pharmacy network adequacy report to the Department of Health, in the manner and from prescribed by the Department of Health. Pharmacy benefit managers must submit a complete network adequacy report to the Department of Health no less than 90 days prior to the date the current license expires. The Department of Health's review of the report, and any geographic or other restrictions determined by the Department of Health, may become part of any license issued.

C. **Determination.** Within 90 days after the date a completed renewal application, the network adequacy report, and the license fee are received, the commissioner must review the application and issue a license if the applicant is deemed qualified under this part. If the commissioner determines the applicant is not qualified, the commissioner must notify the applicant and must specify the reason or reasons for the denial.

Subp. 3. **Fee.** Each application for pharmacy benefit manager licensure renewal must be accompanied by a nonrefundable fee of $8,500. The deadline for submitting the renewal application is 60 days before the date the license expires. A renewal application submitted after the renewal deadline must be accompanied by a nonrefundable $500 late fee. An additional administration fee may be charged by the service provider retained by the commissioner.

Subp. 4. **Updated information required.** If any of the information provided on the renewal application changes at any time following submission, the applicant must provide updated information to the commissioner within 30 days after the date the applicant becomes aware the information changed. If any of the information provided on the network adequacy report changes at any time following submission, the applicant must provide updated information to the Department of Health within 30 days after the date the applicant becomes aware the information changed.

2737.0600 REVIEW BY COMMISSIONER.

Subpart 1. **Additional information.** The commissioner may request additional information within 30 days of receiving completed initial or renewal application data. The 30-day initial review period does not begin until complete application data has been submitted to the commissioners of commerce and health. Incomplete applications will not be reviewed, but incomplete items will be identified and communicated within 30 days.

Subp. 2. **Determination.** Within 90 days after the date a complete initial or renewal application is received, the commissioner must:

A. issue an initial or renewal license if the applicant is determined to be qualified;

B. issue a limited or restricted license; or

C. notify the applicant if the submission is denied, specifying the reason for the denial. If the applicant provides a remedy for the denial within 30 days of the date the denial notice is received, or submits and receives approval for a corrective action plan to cure and correct deficiencies within 30 days of the date the denial notice is received, the commissioner must not assess a new application fee. The commissioner may provide temporary, contingent approval for a pharmacy benefit manager while the pharmacy benefit manager is participating in the corrective action plan process.

Subp. 3. **Limited or restricted license.** As part of a license application review, the commissioner may issue a restricted or limited license, including limitations based on the network adequacy report. A pharmacy benefit manager whose application for a full license results in a limited or restricted license may provide the Department of Commerce with additional information that addresses the basis for the limited or restricted license and request that a full license be restored.

Subp. 4. **Appeals process.** The commissioner's decision to deny a license, deny a renewal, or issue a limited or restricted license may be appealed subject to the following procedure:

A. within 30 days of the date the denial or limited or restricted license is issued, a pharmacy benefit manager must make a written request to the commissioner for a hearing to determine whether the decision or action complies with this chapter and Minnesota Statutes, chapter 62W;

B. the commissioner must conduct a hearing within 30 days after the date the hearing request is made and must give not less than ten days' written notice of the hearing date, time, and location;

C. within 15 days after the hearing date, the commissioner must affirm, reverse, or modify the denial or limited or restricted license issuance and specify in writing the reasons for the decision or action. The effective date of the commissioner's action or decision may be suspended or postponed pending the completion of the hearing before the commissioner;

D. nothing in this subpart requires the commissioner to observe formal rules of pleading or evidence at any hearing; and

E. the commissioner's order or decision is a final decision subject to appeal under Minnesota Statutes, chapter 14.

Subp. 5. **License continuity.** If a renewal license is not granted before the previous year's license expires and the pharmacy benefit manager has a timely filed renewal application pending, the pharmacy benefit manager may continue to provide services under the terms of the previous year's license until the renewal application is approved or denied.

2737.0700 ENFORCEMENT BY COMMISSIONER.

Subpart 1. **Acting without a license.** If a pharmacy benefit manager acts without a license, the pharmacy benefit manager may be subject to a fine of up to $5,000 per day for the period the pharmacy benefit manager is found to be in violation. The commissioner must consider timeliness of responses, content of responses, and progress toward licensure when assessing fines.

Subp. 2. **Basis for suspension, revocation, or probation.** The commissioner may consider the following when suspending, revoking, or placing a pharmacy benefit manager license on probation:

A. failure to comply with relevant state and federal law:

(1) Minnesota Statutes, chapter 62W; and

(2) state health care and pharmacy laws:

(a) insurance laws codified in Minnesota Statutes, chapters 60A, 62A to 62W, and related rules;

(b) health laws codified in Minnesota Statutes, chapter 151, and related rules;

(c) the electronic health record technology requirements under Minnesota Statutes, section 62J.495, the electronic prescription drug program requirements under Minnesota Statutes, section 62J.497, the uniform electronic transactions standards under Minnesota Statutes, section 62J.536, the implementation of electronic data interchange

standards under Minnesota Statutes, section 62J.56, and the Minnesota uniform health care identification card requirements under Minnesota Statutes, section 62J.60; and

(d) for pharmacy benefit managers providing benefits to a person covered by workers' compensation, the pharmacy benefit manager must comply with the processes, cost sharing, and treatment access described in Minnesota Statutes, section 176.135, in relation to compensable prescriptions, including the requirement that a pharmacy or network of pharmacies may be required only if a designated pharmacy is located within 15 miles of the employee's place of residence;

B. fraudulent activity that constitutes a violation of state or federal law;

C. consumer, plan sponsor, or health care provider complaints that have led to a civil or criminal action to protect the safety and interests of consumers;

D. failure to pay any fees and penalties; and

E. compliance with federal pharmacy laws, including but not limited to the following laws, regulations, and guidance, as applicable to the plan sponsor or product that the pharmacy benefit manager serves.

Subp. 3. **Notice.** The commissioner must provide a 30-day notice before suspending, revoking, or placing a pharmacy benefit manager license on probation. If the pharmacy benefit manager demonstrates remedy or good faith progress toward remediation before the 30-day notice period expires, the commissioner may approve the license, reduce the enforcement action to probation, or provide an extended timeline for probation and remediation.

2737.0800 ADEQUATE NETWORK.

Subpart 1. **Pharmacy type.** A network is adequate if it contains at least one of each of the following types of pharmacies:

A. retail;

B. specialty;

C. home infusion;

D. mail order;

E. long-term care; or

F. Indian health service, Tribal organizations, and urban Indian organizations.

Subp. 2. **Plan to provide services.** If a pharmacy benefit manager does not include a pharmacy type listed in subpart 1, the pharmacy benefit manager must provide the Department of Health an explanation why the pharmacy type is excluded and describe how an enrollee requiring services from the excluded pharmacy types may access them.

2737.0900 ACCESSIBLE NETWORK; RETAIL PHARMACY.

The relevant portion of Minnesota Statutes, section 62K.10, for purposes of determining accessibility for retail pharmacies is subdivision 2.

2737.1000 TRANSPARENCY REPORTS TO PLAN SPONSORS.

Subpart 1. **Publication of template.** The commissioner must post on the Department of Commerce's website a template that a plan sponsor may use to submit a transparency request of the data provided under Minnesota Statutes, section 62W.06, subdivision 1, paragraph (a). A plan sponsor is not required to use this template to submit a transparency data request.

Subp. 2. **Time to respond.** A pharmacy benefit manager doing business in Minnesota must reply to a formal transparency report request within 60 days of the date the request is made. A formal request is made when:

A. the plan sponsor has met criteria to request a transparency report from the pharmacy benefit manager under Minnesota Statutes, section 62W.06, subdivision 1, for the first time (but not for data prior to the execution of the initial contract start date); or

B. the plan sponsor provides evidence of perceived negligence with respect to a contractual duty between the pharmacy benefit manager and plan sponsor during the last contractual year.

Subp. 3. **Penalties and fines.** If a plan sponsor believes a pharmacy benefit manager has violated Minnesota Statutes, section 62W.06, subdivision 1, paragraph (a), the plan sponsor may file a complaint with the department 60 days after the date the transparency report request was made. A transparency report requested under Minnesota Statutes, section 62W.06, subdivision 1, paragraph (a), is untimely and subject to penalties on the 61st day after the date the report was requested by the plan sponsor.

2737.1100 TRANSPARENCY REPORTS TO COMMISSIONER.

Subpart 1. **Publication of submission form.** Annually no later than 60 days before the transparency reporting deadline date, the commissioner must post to the department's website the transparency report submission process, including the format, data specifications, and other pertinent information necessary to collect and report all data, including templates used for submission of the aggregate data required by Minnesota Statutes, section 62W.06, subdivision 2, paragraph (a), clauses (1) to (6), the claims-level data required by Minnesota Statutes, section 62W.02, subdivision 2, paragraph (a), clause (7), and the data publicly reported by the commissioner under Minnesota Statutes, section 62W.02, paragraph (b).

Subp. 2. **Use of submission forms and templates.** Unless given written permission by the commissioner not to, the templates annually published by the commissioner for submission of aggregate data, claims-level data, and data to be publicly reported, must be used.

Subp. 3. **Notice of no data to report.** A pharmacy benefit manager that claims to be exempt from the requirement to submit the transparency reports under Minnesota Statutes, section 62W.06, subdivision 2, must, no later than the date the reports are due, submit to the commissioner a statement specifying the basis for nonreporting.

Subp. 4. **Therapeutic categories.** The commissioner must select a preexisting and commonly used therapeutic classification system to group drugs into like categories. The commissioner may consult with state agencies and other experts in the field in order to determine the best classification system. The commissioner must publish the classification system on the department's website at the same time transparency report templates are published. The classification system must be consistent with industry standards and must be reviewed on a periodic basis.

Subp. 5. **Delegation of data collection.** The commissioner may delegate or engage staff within the various divisions of the Department of Commerce, an outside third party, or another state agency to assist in data collection and analysis. The commissioner must ensure that delegated persons do not have a conflict of interest with respect to a particular data review.

Subp. 6. **Use of third party for data submission.** A pharmacy benefit manager may satisfy the requirements of Minnesota Statutes, section 62W.06, subdivision 2, paragraph (a), clause (7), by delegating data submission to a third-party administrator, health carrier, or another pharmacy benefit manager. The pharmacy benefit manager and the third-party administrator, health carrier, or other pharmacy benefit manager must have a contract provision that dictates which party is responsible for claims-level reporting. If a contract provision does not exist, the commissioner must enforce the data submission requirements of this subpart on the pharmacy benefit manager responsible for processing pharmacy claims. The transparency reporting submission process must provide an opportunity for a pharmacy benefit manager doing business in Minnesota to indicate the party that is submitting

claims-level data on behalf of the pharmacy benefit manager. A pharmacy benefit manager's use of third parties for data submission does not absolve the licensed pharmacy benefit manager of any responsibility for compliance issues determined during the department's report review.

Subp. 7. **Penalties and fines.** If a pharmacy benefit manager has violated Minnesota Statutes, section 62W.06, by failing to timely submit a transparency report, the commissioner may assess a penalty of up to $1,000 per day until the pharmacy benefit manager provides the requested transparency report. A transparency report requested under Minnesota Statutes, section 62W.06, subdivision 2, paragraph (a), is untimely and subject to penalties beginning the day after the date the report is due.

2737.1200 PHARMACY OWNERSHIP INTEREST.

Subpart 1. **Networks with only owned pharmacies.** A pharmacy benefit manager requires an enrollee to use a pharmacy if the pharmacy benefit manager establishes a network of pharmacies that includes only pharmacies directly or indirectly owned by the pharmacy benefit manager.

Subp. 2. **Exemptions to prohibitions.** A pharmacy benefit manager is exempt from the prohibitions in Minnesota Statutes, section 62W.07, paragraph (b), if the owned and nonowned pharmacies are of the same type, as provided in this subpart.

A. **Retail.** To be exempt from Minnesota Statutes, section 62W.07, paragraph (b), if the pharmacy benefit manager or health carrier attempts to incentivize use of an owned retail pharmacy, the pharmacy benefit manager or health carrier must provide the same incentive at a nonowned retail pharmacy.

B. **Specialty.** To be exempt from Minnesota Statutes, section 62W.07, paragraph (b), if the pharmacy benefit manager or health carrier attempts to incentivize use of an

owned specialty pharmacy, the pharmacy benefit manager or health carrier must provide the same incentive at a nonowned specialty pharmacy.

C. **Mail order.** To be exempt from Minnesota Statutes, section 62W.07, paragraph (b), if the pharmacy benefit manager or health carrier attempts to incentivize use of an owned mail order pharmacy, the pharmacy benefit manager or health carrier must provide the same incentive at a nonowned mail order pharmacy.

Subp. 3. **Use of quantity and refill limits.** A pharmacy benefit manager may use quantity and refill limits only as provided in this subpart.

A. **Retail.** A pharmacy benefit manager or health carrier may only impose quantity limits or refill frequency limits at an owned retail pharmacy where the pharmacy benefit manager or health carrier provides the enrollee access to a nonowned retail pharmacy with the same limits.

B. **Mail order.** A pharmacy benefit manager or health carrier may only impose quantity limits or refill frequency limits at an owned mail order pharmacy where the pharmacy benefit manager or health carrier provides the enrollee access to a nonowned mail order pharmacy with the same limits.

Subp. 4. **Single mail order pharmacy networks.** If a pharmacy benefit manager administers a network with a single mail order pharmacy that is an owned pharmacy, the pharmacy benefit manager is prohibited from (1) offering financial incentives to use the mail order pharmacy, or (2) imposing limits on an enrollee's access to medication.

2737.1300 SECTION 340B PARTICIPANTS.

Subpart 1. **Prohibition on 340B participants.** A pharmacy benefit manager is prohibited from adopting a rule, requirement, or condition that provides that, in order to be included in the pharmacy benefit manager's pharmacy network, a pharmacy, mail order pharmacy, or specialty pharmacy is prohibited from participating in the federal 340B Drug

Pricing Program under section 340B of the Public Health Service Act, United States Code, title 42, chapter 6A.

Subp. 2. **Continued access.** A pharmacy benefit manager is prohibited from conditioning continued access to network status on nonparticipation in the 340B program.

Subp. 3. **Specific terms or reimbursement rates.** A pharmacy benefit manager is prohibited from requiring that 340B participants agree to specific terms or reimbursement rates, based on the participant's participation in the 340B program, in order to access network status.

2737.1400 OUT-OF-POCKET COST COMPARISONS.

Subpart 1. **Request format.** A pharmacy benefit manager may create specific forms, rules, or guidelines for an enrollee to request out-of-pocket cost information. Any forms, rules, or guidelines a pharmacy benefit manager creates must not be unreasonably onerous or burdensome.

Subp. 2. **Response format.** The pharmacy benefit manager's response to an enrollee's request must be consistent with the manner in which the request is made. If a pharmacy benefit manager creates specific forms, rules, or guidelines for out-of-pocket cost information requests, the pharmacy benefit manager must provide an enrollee with information regarding the format of the pharmacy benefit manager's response. The response must use plain language that clearly delineates the difference in out-of-pocket costs based on the pharmacy used.

Subp. 3. **Time to respond.** A pharmacy benefit manager must respond to an enrollee's request for out-of-pocket cost information within five business days of the date of the request.

Subp. 4. **Existing system.** If an enrollee seeks the information available under Minnesota Statutes, section 62W.076 or 62W.077, and if a pharmacy benefit manager maintains an online system that is easily accessible, the pharmacy benefit manager may comply with this part by directing the enrollee to the online system.

2737.1500 MAXIMUM ALLOWABLE COST PRICING.

Subpart 1. **Maximum allowable cost price list.** A pharmacy benefit manager subject to Minnesota Statutes, section 62W.08, must make available to all pharmacies the pharmacy benefit manager has a contract with a version of the pharmacy benefit manager's maximum allowable cost price list that comports with the following requirements:

A. **Form.** Pharmacy benefit managers must allow pharmacies the pharmacy benefit manager contracts with to review the maximum allowable cost price list in electronic, paper, or telephonic format.

B. **Electronic availability.** A pharmacy benefit manager must ensure that the electronically available maximum allowable cost price list is presented in a machine readable format, such as CSV, JSON, XML, or another commonly available digital format.

C. **Date updated.** The date the maximum allowable cost price list was last updated must be prominently displayed on both electronic and paper formats of the list and must be clearly announced via the telephonic format.

D. **Updated items.** A list must clearly identify prices that have changed.

Subp. 2. **Contracts.** A pharmacy benefit manager is prohibited from requiring a pharmacy to waive or modify Minnesota Statutes, section 62W.08, as a condition of inclusion in a network. Contract provisions related to appeal, investigation, and dispute resolution processes regarding maximum allowable cost pricing that are in addition to the requirements under Minnesota Statutes, section 62W.08, paragraph (c), clauses (1) to (3), are not a modification to Minnesota Statutes, section 62W.08.

2737.1600 PHARMACY AUDITS.

Subpart 1. **Publication of pharmacy audit standards.**

A. A pharmacy benefit manager must make available to a pharmacy or pharmacist the standards and parameters under which the pharmacy or pharmacist is audited.

B. The entity conducting the audit must provide the entity under audit with information regarding the written appeals process at the commencement of the audit, as well as at any time the entity under an audit is provided a report that could be appealed.

Subp. 2. **Contracts.** Except as authorized under Minnesota Statutes, section 62W.09, subdivision 6, a pharmacy benefit manager is prohibited from requiring a pharmacy to waive or modify Minnesota Statutes, section 62W.09, as a condition of inclusion in a network.

2737.1700 ALLOWABLE CLAIM AMOUNT.

The allowable claim amount is equivalent to the net amount the pharmacy receives from the pharmacy benefit manager for dispensing the prescription.

2737.1800 RETROACTIVE ADJUSTMENTS.

Subpart 1. **Contracts.** Minnesota Statutes, section 62W.13, must not be waived or modified by contract.

Subp. 2. **Billing errors.** A claim for a billing error must be documented and the information supporting the claim, if any, must be provided to the pharmacy upon request. A pharmacy benefit manager must allow a pharmacy an opportunity to rebut a billing error claim.

Subp. 3. **Fees not subject to adjustment.** Payment for quality performance metrics included in a prescription drug plan that are based on a pharmacy's quality performance and calculated on prescription count are not retroactive claim adjustments. Retroactive adjustments must not include payments to the pharmacy based on meeting certain performance metrics and must not be based on related prescription count.