State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-FIRST SESSION

H. F. No. 728

02/04/2019 Authored by Mann, Liebling, Morrison, Hamilton, Halverson and others
The bill was read for the first time and referred to the Committee on Health and Human Services Policy
02/25/2019 Adoption of Report: Amended and re-referred to the Committee on Commerce

A bill for an act

relating to health care; creating licensure and regulations for pharmacy benefit managers; authorizing rulemaking; amending Minnesota Statutes 2018, section 151.21, subdivision 7, by adding a subdivision; proposing coding for new law as Minnesota Statutes, chapter 62W; repealing Minnesota Statutes 2018, sections 151.214, subdivision 2; 151.60; 151.61; 151.62; 151.63; 151.64; 151.65; 151.66; 151.67; 151.68; 151.69; 151.70; 151.71.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[62W.01] CITATION.**

This chapter may be cited as the "Minnesota Pharmacy Benefit Manager Licensure and Regulation Act."

Sec. 2. **[62W.02] DEFINITIONS.**

Subdivision 1. **Scope.** For purposes of this chapter, the following terms have the meanings given.

Subd. 2. **Aggregate retained rebate.** "Aggregate retained rebate" means the percentage of all rebates received by a pharmacy benefit manager from a drug manufacturer for drug utilization that is not passed on to the pharmacy benefit manager's health carrier's clients.

Subd. 3. **Claims processing service.** "Claims processing service" means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacy services that includes:

(1) receiving payments for pharmacy services;

(2) making payments to pharmacists or pharmacies for pharmacy services; or

(3) both clause (1) and clause (2).

Subd. 4. **Commissioner.** "Commissioner" means the commissioner of commerce.

Subd. 5. **Enrollee.** "Enrollee" means a natural person covered by a health plan and includes an insured, policyholder, subscriber, contract holder, member, covered person, or certificate holder.

Subd. 6. **Health carrier.** "Health carrier" has the meaning given in section 62A.011, subdivision 2.

Subd. 7. **Health plan.** "Health plan" means a policy, contract, certificate, or agreement defined in section 62A.011, subdivision 3.

Subd. 8. **Mail order pharmacy.** "Mail order pharmacy" means a pharmacy whose primary business is to receive prescriptions by mail, fax, or through electronic submissions, dispense prescription drugs to enrollees through the use of the United States mail or other common carrier services, and provide consultation with patients electronically rather than face-to-face.

Subd. 9. **Maximum allowable cost price.** "Maximum allowable cost price" means the maximum amount that a pharmacy benefit manager will reimburse a pharmacy for a group of therapeutically and pharmaceutically equivalent multiple source drugs. The maximum allowable cost price does not include a dispensing or professional fee.

Subd. 10. **Multiple source drugs.** "Multiple source drugs" means a therapeutically equivalent drug that is available from at least two manufacturers.

Subd. 11. **Network pharmacy.** "Network pharmacy" means a retail or other licensed pharmacy provider that directly contracts with a pharmacy benefit manager.

Subd. 12. **Other prescription drug or device services.** "Other prescription drug or device services" means services other than claims processing services, provided directly or indirectly, whether in connection with or separate from claims processing services, including:

(1) negotiating rebates, discounts, or other financial incentives and arrangements with drug manufacturers;

(2) disbursing or distributing rebates;

(3) managing or participating in incentive programs or arrangements for pharmacy services;

(4) negotiating or entering into contractual arrangements with pharmacists or pharmacies, or both;

(5) developing prescription drug formularies;

(6) designing prescription benefit programs; or

(7) advertising or promoting services.

Subd. 13. **Pharmacist.** "Pharmacist" means an individual with a valid license issued by the Board of Pharmacy under chapter 151.

Subd. 14. **Pharmacy.** "Pharmacy" or "pharmacy provider" means a place of business licensed by the Board of Pharmacy under chapter 151 in which prescription drugs are prepared, compounded, or dispensed, or under the supervision of a pharmacist.

Subd. 15. **Pharmacy benefit manager.** (a) "Pharmacy benefit manager" means a person, business, or other entity that contracts with a plan sponsor to perform pharmacy benefits management, including but not limited to:

(1) contracting directly or indirectly with pharmacies to provide prescription drugs to enrollees or other covered individuals;

(2) administering a prescription drug benefit;

(3) processing or paying pharmacy claims;

(4) creating or updating prescription drug formularies;

(5) making or assisting in making prior authorization determinations on prescription drugs;

(6) administering rebates on prescription drugs; or

(7) establishing a pharmacy network.

(b) "Pharmacy benefit manager" does not include the Department of Human Services.

Subd. 16. **Plan sponsor.** "Plan sponsor" means a group purchaser as defined under section 62J.03; an employer in the case of an employee health benefit plan established or maintained by a single employer; or an employee organization in the case of a health plan established or maintained by an employee organization, an association, joint board trustees, a committee, or other similar group that establishes or maintains the health plan. The term includes a person or entity acting for a pharmacy benefit manager in a contractual or employment relationship in the performance of pharmacy benefits management. Plan sponsor does not include the Department of Human Services.

Subd. 17. **Specialty drug.** "Specialty drug" means a prescription drug that:

(1) cannot be routinely dispensed at a majority of retail pharmacies;

(2) is used to treat chronic and complex, or rare, medical conditions; and

(3) meets a majority of the following criteria:

(i) requires special handling or storage;

(ii) requires complex and extended patient education or counseling;

(iii) requires intensive monitoring;

(iv) requires clinical oversight; and

(v) requires product support services.

Subd. 18. **Retail pharmacy.** "Retail pharmacy" means a chain pharmacy, a supermarket pharmacy, an independent pharmacy, or a network of independent pharmacies, licensed under chapter 151, that dispenses prescription drugs to the public.

Subd. 19. **Rebates.** "Rebates" means all price concessions paid by a drug manufacturer to a pharmacy benefit manager or plan sponsor, including discounts and other price concessions that are based on the actual or estimated utilization of a prescription drug. Rebates also include price concessions based on the effectiveness of a prescription drug as in a value-based or performance-based contract.

Sec. 3. **[62W.03] LICENSE TO DO BUSINESS.**

Subdivision 1. **General.** (a) Beginning January 1, 2020, no person shall perform, act, or do business in this state as a pharmacy benefits manager unless the person has a valid license issued under this chapter by the commissioner of commerce.

(b) A license issued in accordance with this chapter is nontransferable.

Subd. 2. **Application.** (a) A pharmacy benefit manager seeking a license shall apply to the commissioner of commerce on a form prescribed by the commissioner. The application form must include at a minimum the following information:

(1) the name, address, and telephone number of the pharmacy benefit manager;

(2) the name and address of the pharmacy benefit manager agent for service of process in this state; and

(3) the name, address, official position, and professional qualifications of each person responsible for the conduct of affairs of the pharmacy benefit manager, including all members of the board of directors, board of trustees, executive committee, or other governing board or committee; the principal officers in the case of a corporation; or the partners or members in the case of a partnership or association.

(b) Each application for licensure must be accompanied by a nonrefundable fee of $3,000 and evidence of financial responsibility in the amount of $1,000,000.

(c) Within 30 days of receiving an application, the commissioner may require additional information or submissions from an applicant and may obtain any document or information reasonably necessary to verify the information contained in the application. Within 90 days after receipt of a completed application, evidence of financial responsibility, the network adequacy report required under section 62W.05, and the applicable license fee, the commissioner shall review the application and issue a license if the applicant is deemed qualified under this section. If the commissioner determines the applicant is not qualified, the commissioner shall notify the applicant and shall specify the reason or reasons for the denial.

Subd. 3. **Renewal.** (a) A license issued under this chapter is valid for a period of three years. To renew a license, an applicant must submit a completed renewal application on a form prescribed by the commissioner, the network adequacy report required under section 62W.05, and a renewal fee of $3,000. The commissioner may request a renewal applicant to submit additional information to clarify any new information presented in the renewal application.

(b) A renewal application submitted after the renewal deadline date must be accompanied by a nonrefundable late fee of $500.

Subd. 4. **Oversight.** (a) The commissioner may suspend, revoke, or place on probation a pharmacy benefit manager license issued under this chapter for any of the following circumstances:

(1) the pharmacy benefit manager has engaged in fraudulent activity that constitutes a violation of state or federal law;

(2) the commissioner has received consumer complaints that justify an action under this subdivision to protect the safety and interests of consumers;

(3) the pharmacy benefit manager fails to pay an application license or renewal fee; and

(4) the pharmacy benefit manager fails to comply with a requirement set forth in this section.

(b) The commissioner may issue a license subject to restrictions or limitations, including the types of services that may be supplied or the activities in which the pharmacy benefit manager may be engaged.

Subd. 5. **Penalty.** If a pharmacy benefit manager acts without a license, the pharmacy benefit manager may be subject to a fine of $5,000 per day for the period the pharmacy benefit manager is found to be in violation.

Subd. 6. **Rulemaking.** The commissioner may adopt rules to implement this section.

Sec. 4. **[62W.04] PHARMACY BENEFIT MANAGER GENERAL BUSINESS PRACTICES.**

(a) A pharmacy benefit manager has a fiduciary duty to a health carrier and must discharge that duty in accordance with the provisions of state and federal law.

(b) A pharmacy benefit manager must perform its duties with care, skill, prudence, diligence, and professionalism. A pharmacy benefit manager must exercise good faith and fair dealing in the performance of its contractual duties. A provision in a contract between a pharmacy benefit manager and a health carrier or a network pharmacy that attempts to waive or limit this obligation is void.

(c) A pharmacy benefit manager must notify a health carrier in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents a conflict of interest with the duties imposed in this section.

Sec. 5. **[62W.05] PHARMACY BENEFIT MANAGER NETWORK ADEQUACY.**

(a) A pharmacy benefit manager must provide an adequate and accessible pharmacy network for the provision of prescription drugs that provides access to pharmacies within a reasonable distance from an enrollee's residence. The network must include a sufficient number of pharmacies to ensure that pharmacy services are available to all enrollees without unreasonable delay. A mail order pharmacy must not be included in the calculations of determining the adequacy of the pharmacy benefit manager's pharmacy network.

(b) A pharmacy benefit manager must submit to the commissioner a pharmacy network adequacy report describing the pharmacy network and pharmacy accessibility in this state, with the pharmacy benefit manager's license application and renewal, in a manner prescribed by the commissioner.

Sec. 6. **[62W.06] PHARMACY BENEFIT MANAGER TRANSPARENCY.**

Subdivision 1. **Transparency to plan sponsors.** (a) Beginning in the second quarter after the effective date of a contract between a pharmacy benefit manager and a plan sponsor,

the pharmacy benefit manager must disclose, upon the request of the plan sponsor, the following information with respect to prescription drug benefits specific to the plan sponsor:

(1) the aggregate wholesale acquisition costs from a drug manufacturer or wholesale drug distributor for each therapeutic category of prescription drugs;

(2) the aggregate amount of rebates received by the pharmacy benefit manager by therapeutic category of prescription drugs. The aggregate amount of rebates must include any utilization discounts the pharmacy benefit manager receives from a drug manufacturer or wholesale drug distributor;

(3) any other fees received from a drug manufacturer or wholesale drug distributor;

(4) whether the pharmacy benefit manager has a contract, agreement, or other arrangement with a drug manufacturer to exclusively dispense or provide a drug to a plan sponsor's employees or enrollees, and the application of all consideration or economic benefits collected or received pursuant to the arrangement;

(5) prescription drug utilization information for the plan sponsor's employees or enrollees that is not specific to any individual employee or enrollee;

(6) de-identified claims level information in electronic format that allows the plan sponsor to sort and analyze the following information for each claim:

(i) the drug and quantity for each prescription;

(ii) whether the claim required prior authorization;

(iii) patient cost-sharing paid on each prescription;

(iv) the amount paid to the pharmacy for each prescription, net of the aggregate amount of fees or other assessments imposed on the pharmacy, including point-of-sale and retroactive charges;

(v) any spread between the net amount paid to the pharmacy in item (iv) and the amount charged to the plan sponsor;

(vi) identity of the pharmacy for each prescription;

(vii) whether the pharmacy is, or is not, under common control or ownership with the pharmacy benefit manager;

(viii) whether the pharmacy is, or is not, a preferred pharmacy under the plan;

(ix) whether the pharmacy is, or is not, a mail order pharmacy; and

(x) whether enrollees are required by the plan to use the pharmacy;

(7) the aggregate amount of payments made by the pharmacy benefit manager to pharmacies owned or controlled by the pharmacy benefit manager;

(8) the aggregate amount of payments made by the pharmacy benefit manager to pharmacies not owned or controlled by the pharmacy benefit manager; and

(9) the aggregate amount of the fees imposed on, or collected from, network pharmacies or other assessments against network pharmacies, including point-of-sale fees and retroactive charges, and the application of those amounts collected pursuant to the contract with the plan sponsor.

Subd. 2. **Transparency report to the commissioner.** (a) Beginning June 1, 2020, and annually thereafter, each pharmacy benefit manager must submit to the commissioner of commerce a transparency report containing data from the prior calendar year. The report must contain the following information:

(1) the aggregate wholesale acquisition costs from a drug manufacturer or wholesale drug distributor for each therapeutic category of prescription drugs for all of the pharmacy benefit manager's health carrier clients and for each health carrier client, and these costs net of all rebates and other fees and payments, direct or indirect, from all sources;

(2) the aggregate amount of all rebates that the pharmacy benefit manager received from all drug manufacturers for all of the pharmacy benefit manager's health carrier clients and for each health carrier client. The aggregate amount of rebates must include any utilization discounts the pharmacy benefit manager receives from a drug manufacturer or wholesale drug distributor;

(3) the aggregate of all fees from all sources, direct or indirect, that the pharmacy benefit manager received for all of the pharmacy benefit manager's health carrier clients, and the amount of these fees for each health carrier client separately;

(4) the aggregate retained rebates and other fees, as listed in clause (3), that the pharmacy benefit manager received from all sources, direct or indirect, that were not passed through to the health carrier;

(5) the aggregate retained rebate and fees percentage;

(6) the highest, lowest, and mean aggregate retained rebate and fees percentage for all of the pharmacy benefit manager's health carrier clients and for each health carrier client; and

(7) de-identified claims level information in electronic format that allows the commissioner to sort and analyze the following information for each claim:

(i) the drug and quantity for each prescription;

(ii) whether the claim required prior authorization;

(iii) patient cost-sharing paid on each prescription;

(iv) the amount paid to the pharmacy for each prescription, net of the aggregate amount of fees or other assessments imposed on the pharmacy, including point-of-sale and retroactive charges;

(v) any spread between the net amount paid to the pharmacy in item (iv) and the amount charged to the plan sponsor;

(vi) identity of the pharmacy for each prescription;

(vii) whether the pharmacy is, or is not, under common control or ownership with the pharmacy benefit manager;

(viii) whether the pharmacy is, or is not, a preferred pharmacy under the plan;

(ix) whether the pharmacy is, or is not, a mail order pharmacy; and

(x) whether enrollees are required by the plan to use the pharmacy.

(b) Within 60 days upon receipt of the transparency report, the commissioner shall publish the report from each pharmacy benefit manager on the Department of Commerce's website, with the exception of data considered trade secret information under section 13.37.

(c) For purposes of this subdivision, the aggregate retained rebate and fee percentage must be calculated for each health carrier for rebates and fees in the previous calendar year as follows:

(1) the sum total dollar amount of rebates and fees from all drug manufacturers for all utilization of enrollees of a health carrier that was not passed through to the health carrier; and

(2) divided by the sum total dollar amount of all rebates and fees received from all sources, direct or indirect, for all enrollees of a health carrier.

Subd. 3. **Penalty.** The commissioner may impose civil penalties of not more than $1,000 per day per violation of this section.

Sec. 7. **[62W.07] PHARMACY OWNERSHIP INTEREST; SPECIALTY PHARMACY SERVICES.**

(a) A pharmacy benefit manager that has an ownership interest either directly or indirectly, or through an affiliate or subsidiary, in a pharmacy must disclose to a plan sponsor that contracts with the pharmacy benefit manager any difference between the amount paid to a pharmacy and the amount charged to the plan sponsor.

(b) A pharmacy benefit manager or a pharmacy benefit manager's affiliates or subsidiaries must not own or have an ownership interest in a patient assistance program or a mail order specialty pharmacy, unless the pharmacy benefit manager, affiliate, or subsidiary agrees to fair competition, no self-dealing, and no interference with prospective economic advantage, and establishes a firewall between the administrative functions and the mail order pharmacy.

(c) A pharmacy benefit manager or health carrier is prohibited from penalizing, requiring, or providing financial incentives, including variations in premiums, deductibles, co-payments, or coinsurance, to an enrollee as an incentive to use a retail pharmacy, mail order pharmacy, specialty pharmacy, or other network pharmacy provider in which a pharmacy benefit manager has an ownership interest or that has an ownership interest in a pharmacy benefit manager.

(d) A pharmacy benefit manager or health carrier is prohibited from imposing limits, including quantity limits or refill frequency limits, on a patient's access to medication that differ based solely on whether the health carrier or pharmacy benefit manager has an ownership interest in a pharmacy or the pharmacy has an ownership in the pharmacy benefit manager.

(e) A pharmacy benefit manager must not require 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 in this state.

Sec. 8. **[62W.08] MAXIMUM ALLOWABLE COST PRICING.**

(a) With respect to each contract and contract renewal between a pharmacy benefit manager and a pharmacy, the pharmacy benefits manager must:

(1) provide to the pharmacy, at the beginning of each contract and contract renewal, the sources utilized to determine the maximum allowable cost pricing of the pharmacy benefit manager;

(2) update any maximum allowable cost price list at least every seven business days, noting any price changes from the previous list, and provide a means by which network pharmacies may promptly review current prices in an electronic, print, or telephonic format within one business day at no cost to the pharmacy;

(3) maintain a procedure to eliminate products from the list of drugs subject to maximum allowable cost pricing in a timely manner in order to remain consistent with changes in the marketplace;

(4) ensure that the maximum allowable cost prices are not set below sources utilized by the pharmacy benefits manager; and

(5) upon request of a network pharmacy, disclose the sources utilized for setting maximum allowable cost price rates on each maximum allowable cost price list included under the contract and identify each maximum allowable cost price list that applies to the network pharmacy. A pharmacy benefit manager must make the list of the maximum allowable costs available to a contracted pharmacy in a format that is readily accessible and usable to the network pharmacy.

(b) A pharmacy benefit manager must not place a prescription drug on a maximum allowable cost list unless the drug is available for purchase by pharmacies in this state from a national or regional drug wholesaler and is not obsolete.

(c) Each contract between a pharmacy benefit manager and a pharmacy must include a process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing that includes:

(1) a 15-business-day limit on the right to appeal following the initial claim;

(2) a requirement that the appeal be investigated and resolved within seven business days after the appeal is received; and

(3) a requirement that a pharmacy benefit manager provide a reason for any appeal denial and identify the national drug code of a drug that may be purchased by the pharmacy at a price at or below the maximum allowable cost price as determined by the pharmacy benefit manager.

(d) If an appeal is upheld, the pharmacy benefit manager must make an adjustment to the maximum allowable cost price no later than one business day after the date of determination. The pharmacy benefit manager must make the price adjustment applicable to all similarly situated network pharmacy providers as defined by the plan sponsor.

Sec. 9. **[62W.09] PHARMACY AUDITS.**

Subdivision 1. **Procedure and process for conducting and reporting an audit.** (a) Unless otherwise prohibited by federal requirements or regulations, any entity conducting a pharmacy audit must follow the following procedures:

(1) a pharmacy must be given notice 14 days before an initial on-site audit is conducted;

(2) an audit that involves clinical or professional judgment must be conducted by or in consultation with a licensed pharmacist; and

(3) each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies.

(b) Unless otherwise prohibited by federal requirements or regulations, for any entity conducting a pharmacy audit the following items apply:

(1) the period covered by the audit may not exceed 24 months from the date that the claim was submitted to or adjudicated by the entity, unless a longer period is required under state or federal law;

(2) if an entity uses random sampling as a method for selecting a set of claims for examination, the sample size must be appropriate for a statistically reliable sample. Notwithstanding section 151.69, the auditing entity shall provide the pharmacy a masked list that provides a prescription number or date range that the auditing entity is seeking to audit;

(3) an on-site audit may not take place during the first five business days of the month unless consented to by the pharmacy;

(4) auditors may not enter the pharmacy area unless escorted where patient-specific information is available and to the extent possible must be out of sight and hearing range of the pharmacy customers;

(5) any recoupment will not be deducted against future remittances until after the appeals process and both parties have received the results of the final audit;

(6) a pharmacy benefit manager may not require information to be written on a prescription unless the information is required to be written on the prescription by state or federal law. Recoupment may be assessed for items not written on the prescription if:

(i) additional information is required in the provider manual; or

(ii) the information is required by the Food and Drug Administration (FDA); or

(iii) the information is required by the drug manufacturer's product safety program; and

(iv) the information in item (i), (ii), or (iii) is not readily available for the auditor at the time of the audit; and

(7) the auditing company or agent may not receive payment based on a percentage of the amount recovered. This section does not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:

(i) the plan sponsor and the entity conducting the audit have a contract that explicitly states the percentage charge or assessment to the plan sponsor; and

(ii) a commission to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

(c) An amendment to pharmacy audit terms in a contract between a pharmacy benefit manager and a pharmacy must be disclosed to the pharmacy at least 60 days prior to the effective date of the proposed change.

Subd. 2. **Requirement for recoupment or chargeback.** For recoupment or chargeback, the following criteria apply:

(1) audit parameters must consider consumer-oriented parameters based on manufacturer listings;

(2) a pharmacy's usual and customary price for compounded medications is considered the reimbursable cost unless the pricing methodology is outlined in the pharmacy provider contract;

(3) a finding of overpayment or underpayment must be based on the actual overpayment or underpayment and not a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs;

(4) the entity conducting the audit shall not use extrapolation in calculating the recoupment or penalties for audits unless required by state or federal law or regulations;

(5) calculations of overpayments must not include dispensing fees unless a prescription was not actually dispensed, the prescriber denied authorization, the prescription dispensed was a medication error by the pharmacy, or the identified overpayment is solely based on an extra dispensing fee;

(6) an entity may not consider any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error regarding a required document or record as fraud, however such errors may be subject to recoupment;

(7) in the case of errors that have no actual financial harm to the patient or plan, the pharmacy benefit manager must not assess any chargebacks. Errors that are a result of the pharmacy failing to comply with a formal corrective action plan may be subject to recovery; and

(8) interest may not accrue during the audit period for either party, beginning with the notice of the audit and ending with the final audit report.

Subd. 3. **Documentation.** (a) To validate the pharmacy record and delivery, the pharmacy may use authentic and verifiable statements or records including medication administration records of a nursing home, assisted living facility, hospital, physician, or other authorized practitioner or additional audit documentation parameters located in the provider manual.

(b) Any legal prescription that meets the requirements in this chapter may be used to validate claims in connection with prescriptions, refills, or changes in prescriptions, including medication administration records, faxes, e-prescriptions, or documented telephone calls from the prescriber or the prescriber's agents.

Subd. 4. **Appeals process.** The entity conducting the audit must establish a written appeals process which must include appeals of preliminary reports and final reports.

Subd. 5. **Audit information and reports.** (a) A preliminary audit report must be delivered to the pharmacy within 60 days after the conclusion of the audit.

(b) A pharmacy must be allowed at least 45 days following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit.

(c) A final audit report must be delivered to the pharmacy within 120 days after receipt of the preliminary audit report or final appeal, whichever is later.

(d) An entity shall remit any money due to a pharmacy or pharmacist as a result of an underpayment of a claim within 45 days after the appeals process has been exhausted and the final audit report has been issued.

Subd. 6. **Disclosure to plan sponsor.** Where contractually required, an auditing entity must provide a copy to the plan sponsor of its claims that were included in the audit, and any recouped money shall be returned to the plan sponsor.

Subd. 7. **Applicability of other laws and regulations.** This section does not apply to any investigative audit that involves suspected fraud, willful misrepresentation, abuse, or any audit completed by Minnesota health care programs.

Subd. 8. **Definitions.** For purposes of this section, "entity" means a pharmacy benefits manager or any person or organization that represents these companies, groups, or organizations.

Sec. 10. **[62W.10] SYNCHRONIZATION.**

(a) For purposes of this section, "synchronization" means the coordination of prescription drug refills for a patient taking two or more medications for one or more chronic conditions, to allow the patient's medications to be refilled on the same schedule for a given period of time.

(b) A contract between a pharmacy benefit manager and a pharmacy must allow for synchronization of prescription drug refills for a patient on at least one occasion per year, if the following criteria are met:

(1) the prescription drugs are covered under the patient's health plan or have been approved by a formulary exceptions process;

(2) the prescription drugs are maintenance medications as defined by the health plan and have one or more refills available at the time of synchronization;

(3) the prescription drugs are not Schedule II, III, or IV controlled substances;

(4) the patient meets all utilization management criteria relevant to the prescription drug at the time of synchronization;

(5) the prescription drugs are of a formulation that can be safely split into short-fill periods to achieve synchronization; and

(6) the prescription drugs do not have special handling or sourcing needs that require a single, designated pharmacy to fill or refill the prescription.

(c) When necessary to permit synchronization, the pharmacy benefit manager must apply a prorated, daily patient cost-sharing rate to any prescription drug dispensed by a pharmacy under this section. The dispensing fee must not be prorated, and all dispensing fees shall be based on the number of prescriptions filled or refilled.

Sec. 11. **[62W.11] GAG CLAUSE PROHIBITION.**

(a) No contract between a pharmacy benefit manager or health carrier and a pharmacy or pharmacist shall prohibit, restrict, or penalize a pharmacy or pharmacist from disclosing to an enrollee any health care information that the pharmacy or pharmacist deems appropriate regarding the nature of treatment; the risks or alternatives; the availability of alternative therapies, consultations, or tests; the decision of utilization reviewers or similar persons to authorize or deny services; the process that is used to authorize or deny health care services or benefits; or information on financial incentives and structures used by the health carrier or pharmacy benefit manager.

(b) A pharmacy or pharmacist must provide to an enrollee information regarding the enrollee's total cost for each prescription drug dispensed where part or all of the cost of the prescription is being paid or reimbursed by the employer-sponsored plan or by a health carrier or pharmacy benefit manager, in accordance with section 151.214, subdivision 1.

(c) A pharmacy benefit manager or health carrier must not prohibit a pharmacist or pharmacy from discussing information regarding the total cost for pharmacy services for a prescription drug, including the patient's co-payment amount, the pharmacy's own usual and customary price of the prescription, and the net amount the pharmacy will receive from all sources for dispensing the prescription drug, once the claim has been completed by the pharmacy benefit manager or the patient's health carrier.

(d) A pharmacy benefit manager or health carrier must not prohibit a pharmacist or pharmacy from discussing the availability of any therapeutically equivalent alternative prescription drugs or alternative methods for purchasing the prescription drug, including but not limited to paying out-of-pocket the pharmacy's usual and customary price when that amount is less expensive to the enrollee than the amount the enrollee is required to pay for the prescription drug under the enrollee's health plan.

Sec. 12. **[62W.12] POINT OF SALE.**

No pharmacy benefit manager or health carrier shall require 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 co-payment for the prescription drug;

(2) the allowable claim amount for the prescription drug;

(3) the amount an enrollee would pay for the prescription drug if the enrollee purchased the prescription drug without using a health plan or any other source of prescription drug benefits or discounts; or

(4) the amount the pharmacy will be reimbursed for the prescription drug from the pharmacy benefit manager or health carrier.

Sec. 13. Minnesota Statutes 2018, section 151.21, subdivision 7, is amended to read:

Subd. 7. **Drug formulary.** ~~This section~~ Subdivision 3 does not apply when a pharmacist is dispensing a prescribed drug to persons covered under a managed health care plan that maintains a mandatory or closed drug formulary.

Sec. 14. Minnesota Statutes 2018, section 151.21, is amended by adding a subdivision to read:

Subd. 7a. **Coverage by substitution.** (a) When a pharmacist receives a prescription order by paper or hard copy, by electronic transmission, or by oral instruction from the prescriber, in which the prescriber has not expressly indicated that the prescription is to be dispensed as communicated and the drug prescribed is not covered under the purchaser's health plan or prescription drug plan, the pharmacist may 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 that outlines the class of drugs of the same generation and designed for the same indication that can be substituted and the required communication between the pharmacist and the prescriber.

(b) The pharmacist must inform the purchaser if the pharmacist is dispensing a drug or biological product other than the specific drug or biological product prescribed and the reason for the substitution.

(c) The pharmacist must communicate to the prescriber the name and manufacturer of the substituted drug that was dispensed and the reason for the substitution, in accordance with the written protocol.

Sec. 15. **SEVERABILITY.**

If any provision of this act is held invalid or unenforceable, the remainder of this act is not affected and the provisions of this act are severable.

Sec. 16. **REPEALER.**

Minnesota Statutes 2018, sections 151.214, subdivision 2; 151.60; 151.61; 151.62; 151.63; 151.64; 151.65; 151.66; 151.67; 151.68; 151.69; 151.70; and 151.71, are repealed.

151.214 PAYMENT DISCLOSURE.

Subd. 2. **No prohibition on disclosure.** No contracting agreement between an employer-sponsored health plan or health plan company, or its contracted pharmacy benefit manager, and a resident or nonresident pharmacy registered under this chapter, may prohibit the pharmacy from disclosing to patients information a pharmacy is required or given the option to provide under subdivision 1.

151.60 PHARMACY AUDIT INTEGRITY PROGRAM.

The pharmacy audit integrity program is established to provide standards for an audit of pharmacy records carried out by a pharmacy benefits manager or any entity that represents pharmacy benefits managers.

151.61 DEFINITIONS.

Subdivision 1. **Scope.** For the purposes of sections 151.60 to 151.70, the following terms have the meanings given.

Subd. 2. **Entity.** "Entity" means a pharmacy benefits manager or any person or organization that represents these companies, groups, or organizations.

Subd. 3. **Pharmacy benefits manager or PBM.** "Pharmacy benefits manager" or "PBM" means a person, business, or other entity that performs pharmacy benefits management. The term includes a person or entity acting for a PBM in a contractual or employment relationship in the performance of pharmacy benefits management.

Subd. 4. **Plan sponsor.** "Plan sponsor" means the employer in the case of an employee benefit plan established or maintained by a single employer, a group purchaser as defined in section 62J.03, subdivision 6, or the employee organization in the case of a plan established or maintained by an employee organization, an association, joint board trustees, a committee, or other similar group that establishes or maintains the plan.

151.62 PHARMACY BENEFIT MANAGER CONTRACT.

An amendment to pharmacy audit terms in a contract between a PBM and a pharmacy must be disclosed to the pharmacy at least 60 days prior to the effective date of the proposed change.

151.63 PROCEDURE AND PROCESS FOR CONDUCTING AND REPORTING AN AUDIT.

Subdivision 1. **Audit procedures.** Unless otherwise prohibited by federal requirements or regulations, any entity conducting a pharmacy audit must follow the following procedures.

(1) A pharmacy must be given notice 14 days before an initial on-site audit is conducted.

(2) An audit that involves clinical or professional judgment must be conducted by or in consultation with a licensed pharmacist.

(3) Each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies.

Subd. 2. **Audit process.** Unless otherwise prohibited by federal requirements or regulations, for any entity conducting a pharmacy audit the following audit items apply.

(1) The period covered by the audit may not exceed 24 months from the date that the claim was submitted to or adjudicated by the entity, unless a longer period is required under state or federal law.

(2) If an entity uses random sampling as a method for selecting a set of claims for examination, the sample size must be appropriate for a statistically reliable sample. Notwithstanding section 151.69, the auditing entity shall provide the pharmacy a masked list that provides a prescription number or date range that the auditing entity is seeking to audit.

(3) An on-site audit may not take place during the first five business days of the month unless consented to by the pharmacy.

(4) Auditors may not enter the pharmacy area unless escorted where patient-specific information is available and to the extent possible must be out of sight and hearing range of the pharmacy customers.

(5) Any recoupment will not be deducted against future remittances until after the appeals process and both parties have received the results of the final audit.

(6) A PBM may not require information to be written on a prescription unless the information is required to be written on the prescription by state or federal law. Recoupment may be assessed for items not written on the prescription if:

(i) additional information is required in the provider manual; or

(ii) the information is required by the Food and Drug Administration (FDA); or

(iii) the information is required by the drug manufacturer's product safety program; and

(iv) the information in clause (i), (ii), or (iii) is not readily available for the auditor at the time of the audit.

(7) The auditing company or agent may not receive payment based on a percentage of the amount recovered. This section does not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:

(i) the plan sponsor and the entity conducting the audit have a contract that explicitly states the percentage charge or assessment to the plan sponsor; and

(ii) a commission to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

151.64 REQUIREMENTS FOR RECOUPMENT OR CHARGEBACK.

For recoupment or chargeback, the following criteria apply.

(1) Audit parameters must consider consumer-oriented parameters based on manufacturer listings.

(2) A pharmacy's usual and customary price for compounded medications is considered the reimbursable cost unless the pricing methodology is outlined in the provider contract.

(3) A finding of overpayment or underpayment must be based on the actual overpayment or underpayment and not a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.

(4) The entity conducting the audit shall not use extrapolation in calculating the recoupment or penalties for audits unless required by state or federal law or regulations.

(5) Calculations of overpayments must not include dispensing fees unless a prescription was not actually dispensed, the prescriber denied authorization, the prescription dispensed was a medication error by the pharmacy, or the identified overpayment is solely based on an extra dispensing fee.

(6) An entity may not consider any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error regarding a required document or record as fraud, however such errors may be subject to recoupment.

(7) In the case of errors that have no actual financial harm to the patient or plan, the PBM must not assess any chargebacks. Errors that are a result of the pharmacy failing to comply with a formal corrective action plan may be subject to recovery.

(8) Interest may not accrue during the audit period for either party, beginning with the notice of the audit and ending with the final audit report.

151.65 DOCUMENTATION.

(a) To validate the pharmacy record and delivery, the pharmacy may use authentic and verifiable statements or records including medication administration records of a nursing home, assisted living facility, hospital, physician, or other authorized practitioner or additional audit documentation parameters located in the provider manual.

(b) Any legal prescription that meets the requirements in this chapter may be used to validate claims in connection with prescriptions, refills, or changes in prescriptions, including medication administration records, faxes, e-prescriptions, or documented telephone calls from the prescriber or the prescriber's agents.

151.66 APPEALS PROCESS.

The entity conducting the audit must establish a written appeals process which must include appeals of preliminary reports and final reports.

151.67 AUDIT INFORMATION AND REPORTS.

(a) A preliminary audit report must be delivered to the pharmacy within 60 days after the conclusion of the audit.

(b) A pharmacy must be allowed at least 45 days following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit.

(c) A final audit report must be delivered to the pharmacy within 120 days after receipt of the preliminary audit report or final appeal, whichever is later.

(d) An entity shall remit any money due to a pharmacy or pharmacist as a result of an underpayment of a claim within 45 days after the appeals process has been exhausted and the final audit report has been issued.

151.68 DISCLOSURES TO PLAN SPONSOR.

Where contractually required, an auditing entity must provide a copy to the plan sponsor of its claims that were included in the audit, and any recouped money shall be returned to the plan sponsor.

151.69 APPLICABILITY OF OTHER LAWS AND REGULATIONS.

Sections 151.62 to 151.67 do not apply to any investigative audit that involves suspected fraud, willful misrepresentation, abuse, or any audit completed by Minnesota health care programs.

151.70 VIOLATIONS.

Violations of sections 151.62 to 151.68 may be grounds for action, but are not deemed misdemeanors as described in section 151.29.

151.71 MAXIMUM ALLOWABLE COST PRICING.

Subdivision 1. **Definitions.** (a) For purposes of this section, the following definitions apply.

(b) "Health plan company" has the meaning provided in section 62Q.01, subdivision 4.

(c) "Pharmacy benefit manager" means an entity doing business in this state that contracts to administer or manage prescription drug benefits on behalf of any health plan company that provides prescription drug benefits to residents of this state.

Subd. 2. **Pharmacy benefit manager contracts with pharmacies; maximum allowable cost pricing.** (a) In each contract between a pharmacy benefit manager and a pharmacy, the pharmacy shall be given the right to obtain from the pharmacy benefit manager a current list of the sources used to determine maximum allowable cost pricing. The pharmacy benefit manager shall update the pricing information at least every seven business days and provide a means by which contracted pharmacies may promptly review current prices in an electronic, print, or telephonic format within one business day at no cost to the pharmacy. A pharmacy benefit manager shall maintain a procedure to eliminate products from the list of drugs subject to maximum allowable cost pricing in a timely manner in order to remain consistent with changes in the marketplace.

(b) In order to place a prescription drug on a maximum allowable cost list, a pharmacy benefit manager shall ensure that the drug is generally available for purchase by pharmacies in this state from a national or regional wholesaler and is not obsolete.

(c) Each contract between a pharmacy benefit manager and a pharmacy must include a process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing that includes:

(1) a 15-business day limit on the right to appeal following the initial claim;

(2) a requirement that the appeal be investigated and resolved within seven business days after the appeal is received; and

(3) a requirement that a pharmacy benefit manager provide a reason for any appeal denial and identify the national drug code of a drug that may be purchased by the pharmacy at a price at or below the maximum allowable cost price as determined by the pharmacy benefit manager.

(d) If an appeal is upheld, the pharmacy benefit manager shall make an adjustment to the maximum allowable cost price no later than one business day after the date of determination. The

pharmacy benefit manager shall make the price adjustment applicable to all similarly situated network pharmacy providers as defined by the plan sponsor.