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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
- 03/04/2019 Adoption of Report: Amended and re-referred to the Committee on Government Operations
- 03/13/2019 Adoption of Report: Re-referred to the Committee on Ways and Means

1.1 A bill for an act

1.2 relating to health care; creating licensure and regulations for pharmacy benefit

1.3 managers; authorizing rulemaking; amending Minnesota Statutes 2018, section

1.4 151.21, subdivision 7, by adding a subdivision; proposing coding for new law as

1.5 Minnesota Statutes, chapter 62W; repealing Minnesota Statutes 2018, sections

1.6 151.214, subdivision 2; 151.60; 151.61; 151.62; 151.63; 151.64; 151.65; 151.66;

1.7 151.67; 151.68; 151.69; 151.70; 151.71.

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

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

1.10 This chapter may be cited as the "Minnesota Pharmacy Benefit Manager Licensure and

1.11 Regulation Act."

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

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

1.14 given.

1.15 Subd. 2. Aggregate retained rebate. "Aggregate retained rebate" means the percentage

1.16 of all rebates received by a pharmacy benefit manager from a drug manufacturer for drug

1.17 utilization that is not passed on to the pharmacy benefit manager's health carrier's clients.

1.18 Subd. 3. Claims processing service. "Claims processing service" means the

1.19 administrative services performed in connection with the processing and adjudicating of

1.20 claims relating to pharmacy services that includes:

- 1.21 (1) receiving payments for pharmacy services;
- 1.22 (2) making payments to pharmacists or pharmacies for pharmacy services; or

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

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

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

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

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

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

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

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

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

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

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

2.28 (2) disbursing or distributing rebates;

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

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

3.1 (5) developing prescription drug formularies;

3.2 (6) designing prescription benefit programs; or

3.3 (7) advertising or promoting services.

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

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

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

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

3.14 (2) administering a prescription drug benefit;

3.15 (3) processing or paying pharmacy claims;

3.16 (4) creating or updating prescription drug formularies;

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

3.19 (6) administering rebates on prescription drugs; or

3.20 (7) establishing a pharmacy network.

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

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

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

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

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

4.2 (3) meets a majority of the following criteria:

4.3 (i) requires special handling or storage;

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

4.5 (iii) requires intensive monitoring;

4.6 (iv) requires clinical oversight; and

4.7 (v) requires product support services.

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

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

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

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

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

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

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

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

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

5.1 (b) Each application for licensure must be accompanied by a nonrefundable fee of \$3,000
5.2 and evidence of financial responsibility in the amount of \$1,000,000 to be maintained at all
5.3 times by the pharmacy benefit manager during its licensure period.

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

5.13 Subd. 3. **Renewal.** (a) A license issued under this chapter is valid for a period of three
5.14 years. To renew a license, an applicant must submit a completed renewal application on a
5.15 form prescribed by the commissioner, the network adequacy report required under section
5.16 62W.05, and a renewal fee of \$3,000. The commissioner may request a renewal applicant
5.17 to submit additional information to clarify any new information presented in the renewal
5.18 application.

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

5.21 (c) The commissioner shall deny the renewal of a license for any of the following reasons:

5.22 (1) the pharmacy benefit manager is operating in a financially hazardous condition
5.23 relative to its financial condition and the services it administers for health carriers;

5.24 (2) the pharmacy benefit manager has been determined by the commissioner to be in
5.25 violation or noncompliance with the requirements of state law or the rules promulgated
5.26 under this chapter; or

5.27 (3) the pharmacy benefit manager has failed to timely submit a renewal application and
5.28 the information required under paragraph (a).

5.29 In lieu of a denial of a renewal application, the commissioner may permit the pharmacy
5.30 benefit manager to submit to the commissioner a corrective action plan to cure or correct
5.31 deficiencies.

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

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

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

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

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

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

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

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

6.18 Subd. 7. **Enforcement.** The commissioner shall enforce this chapter under the provisions
6.19 of chapter 45.

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

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

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

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

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

7.2 (a) A pharmacy benefit manager must provide an adequate and accessible pharmacy
7.3 network for the provision of prescription drugs that provides access to pharmacies within
7.4 a reasonable distance from an enrollee's residence. The network must include a sufficient
7.5 number of pharmacies to ensure that pharmacy services are available to all enrollees without
7.6 unreasonable delay. In determining network adequacy, the commissioner shall ensure that
7.7 the maximum travel distance or time requirement to the nearest pharmacy equals the
7.8 requirement applied under section 62K.10 for pharmacy services. A mail order pharmacy
7.9 must not be included in the calculations of determining the adequacy of the pharmacy benefit
7.10 manager's pharmacy network.

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

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

7.16 Subdivision 1. **Transparency to plan sponsors.** (a) Beginning in the second quarter
7.17 after the effective date of a contract between a pharmacy benefit manager and a plan sponsor,
7.18 the pharmacy benefit manager must disclose, upon the request of the plan sponsor, the
7.19 following information with respect to prescription drug benefits specific to the plan sponsor:

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

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

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

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

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

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

8.3 (i) the drug and quantity for each prescription;

8.4 (ii) whether the claim required prior authorization;

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

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

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

8.11 (vi) identity of the pharmacy for each prescription;

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

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

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

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

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

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

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

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

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

9.1 benefit manager's health carrier clients and for each health carrier client, and these costs net
9.2 of all rebates and other fees and payments, direct or indirect, from all sources;

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

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

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

9.14 (5) the aggregate retained rebate and fees percentage;

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

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

9.20 (i) the drug and quantity for each prescription;

9.21 (ii) whether the claim required prior authorization;

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

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

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

9.28 (vi) identity of the pharmacy for each prescription;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11.6 (e) A pharmacy benefit manager must not require pharmacy accreditation standards or
11.7 recertification requirements to participate in a network that are inconsistent with, more
11.8 stringent than, or in addition to federal and state requirements for licensure as a pharmacy
11.9 in this state.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12.29 (2) if an entity uses random sampling as a method for selecting a set of claims for
12.30 examination, the sample size must be appropriate for a statistically reliable sample.

12.31 Notwithstanding section 151.69, the auditing entity shall provide the pharmacy a masked

13.1 list that provides a prescription number or date range that the auditing entity is seeking to
13.2 audit;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16.30 (d) A pharmacy benefit manager or health carrier must not prohibit a pharmacist or
16.31 pharmacy from discussing the availability of any therapeutically equivalent alternative
16.32 prescription drugs or alternative methods for purchasing the prescription drug, including
16.33 but not limited to paying out-of-pocket the pharmacy's usual and customary price when that

17.1 amount is less expensive to the enrollee than the amount the enrollee is required to pay for
17.2 the prescription drug under the enrollee's health plan.

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

17.4 No pharmacy benefit manager or health carrier shall require an enrollee to make a
17.5 payment at the point of sale for a covered prescription drug in an amount greater than the
17.6 lesser of:

17.7 (1) the applicable co-payment for the prescription drug;

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

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

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

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

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

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

17.20 Subd. 7a. **Coverage by substitution.** (a) When a pharmacist receives a prescription
17.21 order by paper or hard copy, by electronic transmission, or by oral instruction from the
17.22 prescriber, in which the prescriber has not expressly indicated that the prescription is to be
17.23 dispensed as communicated and the drug prescribed is not covered under the purchaser's
17.24 health plan or prescription drug plan, the pharmacist may dispense a therapeutically
17.25 equivalent and interchangeable prescribed drug or biological product that is covered under
17.26 the purchaser's plan, if the pharmacist has a written protocol with the prescriber that outlines
17.27 the class of drugs of the same generation and designed for the same indication that can be
17.28 substituted and the required communication between the pharmacist and the prescriber.

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

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

18.4 Sec. 15. **SEVERABILITY.**

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

18.7 Sec. 16. **REPEALER.**

18.8 Minnesota Statutes 2018, sections 151.214, subdivision 2; 151.60; 151.61; 151.62;
18.9 151.63; 151.64; 151.65; 151.66; 151.67; 151.68; 151.69; 151.70; and 151.71, are repealed.

151.214 PAYMENT DISCLOSURE.

No active language found for: 151.214.2

No active language found for: 151.60

No active language found for: 151.61

No active language found for: 151.62

No active language found for: 151.63

No active language found for: 151.64

No active language found for: 151.65

No active language found for: 151.66

No active language found for: 151.67

No active language found for: 151.68

No active language found for: 151.69

No active language found for: 151.70

No active language found for: 151.71