

**SENATE**  
**STATE OF MINNESOTA**  
**NINETY-FIRST SESSION**

**S.F. No. 278**

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DATE	D-PG	OFFICIAL STATUS
01/17/2019	118	Introduction and first reading
		Referred to Health and Human Services Finance and Policy
03/11/2019	745a	Comm report: To pass as amended and re-refer to Commerce and Consumer Protection Finance and Policy
03/21/2019	1072a	Comm report: To pass as amended and re-refer to Finance
04/03/2019	2144a	Comm report: To pass as amended
	2152	Second reading
04/04/2019	2160a	Special Order: Amended
	2165	Third reading Passed
05/09/2019	4254	Returned from House with amendment
	4254	Senate not concur, conference committee of 3 requested
	4268	Senate conferees Jensen; Benson; Klein
05/13/2019	4272	House conferees Mann; Morrison; Munson
05/16/2019	4307c	Conference committee report, delete everything
		Senate adopted CC report and repassed bill
	4325	Third reading
05/17/2019	4347	House adopted SCC report and repassed bill
		Presentment date 05/17/2019
05/20/2019	4518	Governor's action Approval 05/17/2019
	4518	Secretary of State Chapter 39 05/17/2019
		Effective date 08/01/19

1.1 A bill for an act

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

1.3 managers; appropriating money; 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 client.

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 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 benefit 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;

4.2 (3) has special storage, handling, or distribution requirements that typically cannot be  
4.3 met by a retail pharmacy; and

4.4 (4) meets at least three of the following criteria:

4.5 (i) requires complex and extended patient education and counseling;

4.6 (ii) requires intensive monitoring;

4.7 (iii) requires clinical oversight; and

4.8 (iv) requires product support services.

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

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

4.17 Subd. 20. **Specialty pharmacy.** "Specialty pharmacy" means a pharmacy that specializes  
4.18 in dispensing specialty drugs for patients with serious health conditions requiring complex  
4.19 therapies and high cost biotech and injectable medications. A pharmacy benefit manager  
4.20 or health carrier may require a specialty pharmacy to be accredited as a specialty pharmacy  
4.21 from one of the following accrediting organizations:

4.22 (1) Utilization Review Accreditation Commission (URAC);

4.23 (2) Accreditation Commissioner for Health Care, Inc.; or

4.24 (3) Joint Accreditation Commission.

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

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

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

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

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

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

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

5.12 (b) Each application for licensure must be accompanied by a nonrefundable fee of \$8,500.  
5.13 The fees collected under this subdivision shall be deposited in the general fund.

5.14 (c) Within 30 days of receiving an application, the commissioner may require additional  
5.15 information or submissions from an applicant and may obtain any document or information  
5.16 reasonably necessary to verify the information contained in the application. Within 90 days  
5.17 after receipt of a completed application, the network adequacy report required under section  
5.18 62W.05, and the applicable license fee, the commissioner shall review the application and  
5.19 issue a license if the applicant is deemed qualified under this section. If the commissioner  
5.20 determines the applicant is not qualified, the commissioner shall notify the applicant and  
5.21 shall specify the reason or reasons for the denial.

5.22 Subd. 3. **Renewal.** (a) A license issued under this chapter is valid for one year. To renew  
5.23 a license, an applicant must submit a completed renewal application on a form prescribed  
5.24 by the commissioner, the network adequacy report required under section 62W.05, and a  
5.25 renewal fee of \$8,500. The fees collected under this paragraph shall be deposited in the  
5.26 general fund. The commissioner may request a renewal applicant to submit additional  
5.27 information to clarify any new information presented in the renewal application.

5.28 (b) A renewal application submitted after the renewal deadline date must be accompanied  
5.29 by a nonrefundable late fee of \$500. The fees collected under this paragraph shall be  
5.30 deposited in the general fund.

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

5.32 (1) the pharmacy benefit manager has been determined by the commissioner to be in  
5.33 violation or noncompliance with federal or state law; or

6.1 (2) the pharmacy benefit manager has failed to timely submit a renewal application and  
6.2 the information required under paragraph (a).

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

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

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

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

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

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

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

6.19 Subd. 5. **Penalty.** If a pharmacy benefit manager acts without a license, the pharmacy  
6.20 benefit manager may be subject to a fine of \$5,000 per day for the period the pharmacy  
6.21 benefit manager is found to be in violation. Any penalties collected under this subdivision  
6.22 shall be deposited in the general fund.

6.23 Subd. 6. **Enforcement.** The commissioner shall enforce this chapter under the provisions  
6.24 of chapter 45.

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

6.27 (a) A pharmacy benefit manager must exercise good faith and fair dealing in the  
6.28 performance of its contractual duties. A provision in a contract between a pharmacy benefit  
6.29 manager and a health carrier or a network pharmacy that attempts to waive or limit this  
6.30 obligation is void.

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

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

7.5 Subdivision 1. **Requirements.** (a) A pharmacy benefit manager must provide an adequate  
7.6 and accessible pharmacy network for the provision of prescription drugs that meet the  
7.7 relevant requirements in section 62K.10. Mail order pharmacies must not be included in  
7.8 the calculations of determining the adequacy of the pharmacy benefit manager's pharmacy  
7.9 network under section 62K.10.

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

7.14 Subd. 2. **Network adequacy waiver.** A pharmacy benefit manager may apply for a  
7.15 waiver from the commissioner of health if the pharmacy benefit manager is unable to meet  
7.16 the network adequacy requirements under subdivision 1. A waiver application must be  
7.17 submitted to the commissioner of health on a form prescribed by the commissioner of health  
7.18 and must:

7.19 (1) demonstrate with specific data why the pharmacy benefit manager is not able to meet  
7.20 the requirements; and

7.21 (2) include information as to the steps that were and will be taken to address network  
7.22 adequacy.

7.23 If a waiver is granted by the commissioner of health, the waiver shall automatically expire  
7.24 after three years. If a renewal of the waiver is sought, the commissioner of health shall  
7.25 consider steps that the pharmacy benefit manager has taken over the past three-year period  
7.26 to address network adequacy.

7.27 Subd. 3. **Accreditation standards.** A pharmacy benefit manager must not require  
7.28 pharmacy accreditation standards or recertification requirements to participate in a network  
7.29 that are inconsistent with, more stringent than, or in addition to federal and state requirements  
7.30 for licensure as a pharmacy in this state unless authorized under this chapter.

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

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

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

8.8 (2) the aggregate wholesale acquisition costs from a drug manufacturer or wholesale  
8.9 drug distributor for each therapeutic category of prescription drugs available to the plan  
8.10 sponsor's enrollees;

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

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

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

8.20 (6) prescription drug utilization information for the plan sponsor's enrollees;

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

8.23 (i) whether the claim required prior authorization;

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

8.27 (iii) any spread between the net amount paid to the pharmacy in item (ii) and the amount  
8.28 charged to the plan sponsor;

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

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



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

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

9.3 (8) the aggregate amount of payments made by the pharmacy benefit manager to  
 9.4 pharmacies owned or controlled by the pharmacy benefit manager on behalf of the sponsor's  
 9.5 plan;

9.6 (9) the aggregate amount of payments made by the pharmacy benefit manager to  
 9.7 pharmacies not owned or controlled by the pharmacy benefit manager on behalf of the  
 9.8 sponsor's plan; and

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

9.13 (b) A pharmacy benefit manager may require a plan sponsor to agree to a nondisclosure  
 9.14 agreement that specifies that the information reported under this section is proprietary  
 9.15 information. The pharmacy benefit manager is not required to disclose the information to  
 9.16 the plan sponsor until the plan sponsor has executed the nondisclosure agreement, if required  
 9.17 by the pharmacy benefit manager.

9.18 Subd. 2. **Transparency report to the commissioner.** (a) Beginning June 1, 2020, and  
 9.19 annually thereafter, each pharmacy benefit manager must submit to the commissioner a  
 9.20 transparency report containing data from the prior calendar year as it pertains to plan sponsors  
 9.21 doing business in Minnesota. The report must contain the following information:

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

9.26 (2) the aggregate amount of all rebates that the pharmacy benefit manager received from  
 9.27 all drug manufacturers for all of the pharmacy benefit manager's plan sponsor clients. The  
 9.28 aggregate amount of rebates must include any utilization discounts the pharmacy benefit  
 9.29 manager receives from a drug manufacturer or wholesale drug distributor;

9.30 (3) the aggregate of all fees from all sources, direct or indirect, that the pharmacy benefit  
 9.31 manager received for all of the pharmacy benefit manager's plan sponsor clients;

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

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

10.5 (6) the highest, lowest, and mean aggregate retained rebate and fees percentage for all  
10.6 of the pharmacy benefit manager's plan sponsor clients; and

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

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

10.10 (ii) whether the claim required prior authorization;

10.11 (iii) patient cost-sharing paid on each prescription. This data is classified pursuant to  
10.12 paragraph (d);

10.13 (iv) the amount paid to the pharmacy for each prescription, net of the aggregate amount  
10.14 of fees or other assessments imposed on the pharmacy, including point-of-sale and retroactive  
10.15 charges. This data is classified pursuant to paragraph (d);

10.16 (v) any spread between the net amount paid to the pharmacy in item (iv) and the amount  
10.17 charged to the plan sponsor. This data is classified pursuant to paragraph (d);

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

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

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

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

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

10.24 (b) Within 60 days upon receipt of the transparency report, the commissioner shall  
10.25 publish the report from each pharmacy benefit manager on the Department of Commerce's  
10.26 website, with the exception of data considered trade secret information under section 13.37.  
10.27 The transparency report must be published in such a way as to not disclose the identity of  
10.28 a specific plan sponsor, the prices charged for a specific prescription drug or classes of  
10.29 drugs, or the amount of any rebates provided for a specific prescription drug or classes of  
10.30 drugs.

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

11.4 (1) the sum total dollar amount of rebates and fees from all drug manufacturers for all  
 11.5 utilization of enrollees of a plan sponsor that was not passed through to the plan sponsor;  
 11.6 and

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

11.9 (d) Data, documents, materials, or other information in the possession or control of the  
 11.10 commissioner of commerce that are obtained by, created by, or disclosed to the commissioner  
 11.11 pursuant to paragraph (a), clause (7), items (iii), (iv), and (v), are classified as confidential,  
 11.12 protected nonpublic, or both. Those data, documents, materials, or other information are  
 11.13 not subject to subpoena, and are not subject to discovery or admissible in evidence in any  
 11.14 private civil action. However, the commissioner may use the data, documents, materials,  
 11.15 or other information in the furtherance of a regulatory or legal action brought as a part of  
 11.16 the commissioner's official duties. The commissioner shall not otherwise make the data,  
 11.17 documents, materials, or other information public without the prior written consent of the  
 11.18 pharmacy benefit manager. Neither the commissioner nor any person who received data,  
 11.19 documents, materials, or other information while acting under the authority of the  
 11.20 commissioner are permitted or required to testify in any private civil action concerning data,  
 11.21 documents, materials, or information subject to this paragraph that are classified as  
 11.22 confidential, protected nonpublic, or both.

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

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

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

11.30 (b) A pharmacy benefit manager or health carrier is prohibited from penalizing, requiring,  
 11.31 or providing financial incentives, including variations in premiums, deductibles, co-payments,  
 11.32 or coinsurance, to an enrollee as an incentive to use a retail pharmacy, mail order pharmacy,  
 11.33 specialty pharmacy, or other network pharmacy provider in which a pharmacy benefit

12.1 manager has an ownership interest or in which the pharmacy provider has an ownership  
12.2 interest in the pharmacy benefit manager.

12.3 (c) Paragraph (b) does not apply if the pharmacy benefit manager or health carrier offers  
12.4 an enrollee the same financial incentives for using a network retail pharmacy, mail order  
12.5 pharmacy, specialty pharmacy, or other network pharmacy in which the pharmacy benefit  
12.6 manager has no ownership interest and the network pharmacy has agreed to accept the same  
12.7 pricing terms, conditions, and requirements related to the cost of the prescription drug and  
12.8 the cost of dispensing the prescription drug that are in the agreement with a network  
12.9 pharmacy in which the pharmacy benefit manager has an ownership interest.

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

12.15 (e) Nothing in paragraph (d) shall be construed to prohibit a pharmacy benefit manager  
12.16 from imposing different limits, including quantity limits or refill frequency limits on an  
12.17 enrollee's access to medication based on whether the enrollee uses a mail order pharmacy  
12.18 or retail pharmacy so long as the enrollee has the option to use a mail order pharmacy or  
12.19 retail pharmacy with the same limits imposed in which the pharmacy benefit manager or  
12.20 health carrier does not have an ownership interest.

12.21 (f) A pharmacy benefit manager or health carrier must not prohibit an entity authorized  
12.22 to participate in the federal 340B Drug Pricing Program under section 340B of the Public  
12.23 Health Service Act, United States Code, title 42, chapter 6A, or a pharmacy under contract  
12.24 with such an entity to provide pharmacy services from participating in the pharmacy benefit  
12.25 manager's or health carrier's provider network. A pharmacy benefit manager or health carrier  
12.26 must not reimburse an entity or a pharmacy under contract with such an entity participating  
12.27 in the federal 340B Drug Pricing Program differently than other similarly situated pharmacies.  
12.28 A pharmacy benefit manager that contracts with a managed care plan or county-based  
12.29 purchasing plan under contract with the commissioner of human services under chapter  
12.30 256B or 256L must comply with this paragraph only if the entity or contracted pharmacy  
12.31 can identify all claims eligible for 340B drugs at the time of initial claims submission at the  
12.32 point of sale. This paragraph does not preclude a pharmacy benefit manager that contracts  
12.33 with a managed care plan or county-based purchasing plan under contract with the  
12.34 commissioner of human services under chapter 256B or 256L from reimbursing an entity

13.1 or pharmacy identified in this paragraph at a lower rate for any prescription drug purchased  
13.2 by the entity or pharmacy through the federal 340B Drug Pricing Program.

13.3 **Sec. 8. [62W.075] THERAPEUTIC ALTERNATIVE PRESCRIPTION DRUG.**

13.4 A pharmacy benefit manager or health carrier must not require, or demonstrate a  
13.5 preference for, a pharmacy to dispense a therapeutically equivalent or therapeutically  
13.6 alternative drug that costs the enrollee more out-of-pocket than the prescribed drug, unless  
13.7 the substitution is made for medical reasons that benefit the patient. Before a substitution  
13.8 is made under this section, the pharmacy must obtain approval from the prescribing  
13.9 practitioner and must inform the enrollee of the reason for the substitution.

13.10 **Sec. 9. [62W.076] SPECIALTY PHARMACY.**

13.11 A pharmacy benefit manager that contracts with a specialty pharmacy must disclose to  
13.12 an enrollee, upon request, the enrollee's out-of-pocket costs at the specialty pharmacy for  
13.13 the prescription drug referenced by the enrollee and the enrollee's out-of-pocket cost at a  
13.14 network retail pharmacy that is identified by the enrollee that is within the enrollee's health  
13.15 plan network.

13.16 **Sec. 10. [62W.077] PREFERRED NETWORK.**

13.17 A pharmacy benefit manager that uses a preferred network of pharmacies must disclose  
13.18 to an enrollee upon request the enrollee's out-of-pocket cost at the preferred pharmacy for  
13.19 the prescription drug referenced by the enrollee and the enrollee's out-of-pocket cost at a  
13.20 nonpreferred pharmacy identified by the enrollee that is within the enrollee's health plan  
13.21 network.

13.22 **Sec. 11. [62W.08] MAXIMUM ALLOWABLE COST PRICING.**

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

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

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

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

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

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

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

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

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

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

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

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

14.29 **Sec. 12. [62W.09] PHARMACY AUDITS.**

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

- 15.1 (1) a pharmacy must be given notice 14 days before an initial on-site audit is conducted;
- 15.2 (2) an audit that involves clinical or professional judgment must be conducted by or in
- 15.3 consultation with a licensed pharmacist; and
- 15.4 (3) each pharmacy shall be audited under the same standards and parameters as other
- 15.5 similarly situated pharmacies.
- 15.6 (b) Unless otherwise prohibited by federal requirements or regulations, for any entity
- 15.7 conducting a pharmacy audit the following items apply:
- 15.8 (1) the period covered by the audit may not exceed 24 months from the date that the
- 15.9 claim was submitted to or adjudicated by the entity, unless a longer period is required under
- 15.10 state or federal law;
- 15.11 (2) if an entity uses random sampling as a method for selecting a set of claims for
- 15.12 examination, the sample size must be appropriate for a statistically reliable sample.
- 15.13 Notwithstanding section 151.69, the auditing entity shall provide the pharmacy a masked
- 15.14 list that provides a prescription number or date range that the auditing entity is seeking to
- 15.15 audit;
- 15.16 (3) an on-site audit may not take place during the first five business days of the month
- 15.17 unless consented to by the pharmacy;
- 15.18 (4) auditors may not enter the pharmacy area unless escorted where patient-specific
- 15.19 information is available and to the extent possible must be out of sight and hearing range
- 15.20 of the pharmacy customers;
- 15.21 (5) any recoupment will not be deducted against future remittances until after the appeals
- 15.22 process and both parties have received the results of the final audit;
- 15.23 (6) a pharmacy benefit manager may not require information to be written on a
- 15.24 prescription unless the information is required to be written on the prescription by state or
- 15.25 federal law. Recoupment may be assessed for items not written on the prescription if:
- 15.26 (i) additional information is required in the provider manual; or
- 15.27 (ii) the information is required by the Food and Drug Administration (FDA); or
- 15.28 (iii) the information is required by the drug manufacturer's product safety program; and
- 15.29 (iv) the information in item (i), (ii), or (iii) is not readily available for the auditor at the
- 15.30 time of the audit; and

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

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

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

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

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

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

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

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

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

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

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

16.31 (7) in the case of errors that have no actual financial harm to the patient or plan, the  
16.32 pharmacy benefit manager must not assess any chargebacks. Errors that are a result of the



17.1 pharmacy failing to comply with a formal corrective action plan may be subject to recovery;  
17.2 and

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

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

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

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

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

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

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

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

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

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

17.30 Subd. 8. **Definitions.** For purposes of this section, "entity" means a pharmacy benefit  
17.31 manager or any person or organization that represents a pharmacy benefit manager.

18.1 Sec. 13. [62W.10] SYNCHRONIZATION.

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

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

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

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

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

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

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

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

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

18.24 (d) Synchronization may be requested by the patient or by the patient's parent or legal  
18.25 guardian if the patient is under the age of 18 or is incapacitated as defined in section  
18.26 524.5-102, or by the patient's health care agent as defined in chapter 145C.

18.27 Sec. 14. [62W.11] GAG CLAUSE PROHIBITION.

18.28 (a) No contract between a pharmacy benefit manager or health carrier and a pharmacy  
18.29 or pharmacist shall prohibit, restrict, or penalize a pharmacy or pharmacist from disclosing  
18.30 to an enrollee any health care information that the pharmacy or pharmacist deems appropriate  
18.31 regarding the nature of treatment; the risks or alternatives; the availability of alternative  
18.32 therapies, consultations, or tests; the decision of utilization reviewers or similar persons to

19.1 authorize or deny services; the process that is used to authorize or deny health care services  
 19.2 or benefits; or information on financial incentives and structures used by the health carrier  
 19.3 or pharmacy benefit manager.

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

19.8 (c) A pharmacy benefit manager or health carrier must not prohibit a pharmacist or  
 19.9 pharmacy from discussing information regarding the total cost for pharmacy services for a  
 19.10 prescription drug, including the patient's co-payment amount and the pharmacy's own usual  
 19.11 and customary price of the prescription.

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

19.18 Sec. 15. **[62W.12] POINT OF SALE.**

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

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

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

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

19.27 Sec. 16. **[62W.13] RETROACTIVE ADJUSTMENTS.**

19.28 No pharmacy benefit manager shall retroactively adjust a claim for reimbursement  
 19.29 submitted by a pharmacy for a prescription drug, unless the adjustment is a result of a:

19.30 (1) pharmacy audit conducted in accordance with section 62W.09; or

19.31 (2) technical billing error.

20.1 Sec. 17. [62W.14] PROMPT FILLING FOR SPECIALTY DRUGS.

20.2 (a) A health carrier or pharmacy benefit manager that requires or provides financial  
 20.3 incentives for enrollees to use a mail order pharmacy to fill a prescription for a specialty  
 20.4 drug must ensure through contract and other means that the mail order pharmacy dispenses  
 20.5 the prescription drug to the enrollee in a timely manner, such that the enrollee receives the  
 20.6 filled prescription within seven business days of the date of transmittal to the mail order  
 20.7 pharmacy. The health carrier or pharmacy benefit manager may grant to a mail order  
 20.8 pharmacy an exemption from this requirement if the mail order pharmacy can document  
 20.9 that the specialty drug was out of stock due to a delay in shipment by the specialty drug  
 20.10 manufacturer or wholesaler. If an exemption is granted, the health carrier or pharmacy  
 20.11 benefit manager must notify the enrollee within 24 hours of granting the exemption and, if  
 20.12 medically necessary, must provide the enrollee with an emergency supply of the specialty  
 20.13 drug.

20.14 (b) For purposes of this section, "health carrier" includes managed care plans and  
 20.15 county-based purchasing plans participating in a public health care program under chapter  
 20.16 256B or 256L, and integrated health partnerships established under section 256B.0755.

20.17 Sec. 18. Minnesota Statutes 2018, section 151.21, subdivision 7, is amended to read:

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

20.21 Sec. 19. Minnesota Statutes 2018, section 151.21, is amended by adding a subdivision to  
 20.22 read:

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

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

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

21.7 **Sec. 20. RULEMAKING AUTHORITY.**

21.8 The commissioner of commerce may adopt permanent rules for license application and  
21.9 renewal requirements, forms, procedures, network adequacy, and reporting procedures and  
21.10 compliance, for pharmacy benefit manager licensing under Minnesota Statutes, chapter  
21.11 62W. The commissioner must not adopt rules to implement Minnesota Statutes, chapter  
21.12 62W, under any other grant of rulemaking authority. If the commissioner of commerce does  
21.13 not adopt rules by January 1, 2022, rulemaking authority under this section is repealed.  
21.14 Rulemaking authority under this section is not continuing authority to amend or repeal rules.  
21.15 Notwithstanding Minnesota Statutes, section 14.125, any additional action on rules after  
21.16 adoption must be under specific statutory authority to take the additional action.

21.17 **Sec. 21. INTERPRETATION.**

21.18 If an appropriation in this act is enacted more than once in the 2019 regular legislative  
21.19 session, the appropriation must be given effect only once.

21.20 **Sec. 22. APPROPRIATION.**

21.21 \$340,000 in fiscal year 2020 and \$383,000 in fiscal year 2021 are appropriated from the  
21.22 general fund to the commissioner of commerce for licensing activities under Minnesota  
21.23 Statutes, chapter 62W. The base for this appropriation is \$425,000 in fiscal year 2022 and  
21.24 \$425,000 in fiscal year 2023. \$246,000 each year shall be used solely for staff costs for two  
21.25 enforcement investigators solely for enforcement activities under Minnesota Statutes, chapter  
21.26 62W.

21.27 **Sec. 23. REPEALER.**

21.28 Minnesota Statutes 2018, sections 151.214, subdivision 2; 151.60; 151.61; 151.62;  
21.29 151.63; 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.

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(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



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