01/05/23 REVISOR SGS/KA 23-00996 as introduced

SENATE STATE OF MINNESOTA NINETY-THIRD SESSION

A bill for an act

relating to health care; modifying pharmacy benefit manager business practices;

establishing pharmacy benefit manager general reimbursement practices; modifying

S.F. No. 246

(SENATE AUTHORS: DRAHEIM)

DATE D-PG 01/12/2023

1.1

1 2

1.3

OFFICIAL STATUS

01/12/2023 Introduction and first reading Referred to Health and Human Services

maximum allowable cost pricing requirements; amending Minnesota Statutes 2022, 1.4 sections 62W.02, by adding subdivisions; 62W.04; 62W.08; 62W.09, subdivision 1.5 1; 62W.13; proposing coding for new law in Minnesota Statutes, chapter 62W. 1.6 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA: 1.7 Section 1. Minnesota Statutes 2022, section 62W.02, is amended by adding a subdivision 1.8 to read: 1.9 Subd. 13a. Pharmacy acquisition cost. "Pharmacy acquisition cost" means the amount 1.10 that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the 1.11 pharmacy's invoice. 1.12 Sec. 2. Minnesota Statutes 2022, section 62W.02, is amended by adding a subdivision to 1.13 read: 1.14 Subd. 15a. Pharmacy benefit manager affiliate. "Pharmacy benefit manager affiliate" 1.15 or "affiliate" means a pharmacy that directly or indirectly through one or more intermediaries 1.16 owns or controls, is owned or controlled by, or is under common ownership or control with 1.17 a pharmacy benefit manager. 1.18 Sec. 3. Minnesota Statutes 2022, section 62W.02, is amended by adding a subdivision to 1.19 read: 1.20 Subd. 15b. **Pharmaceutical wholesaler.** "Pharmaceutical wholesaler" means a person 1.21 or entity that sells and distributes prescription pharmaceutical products, including but not 1.22

Sec. 3. 1

2.1 limited to brand name, generic, and over-the-counter drugs, and offers regular and private

delivery to a pharmacy.

2.4

2.5

2.6

2.7

2.8

2.9

2.10

2.11

2.12

2.13

2.14

2.15

2.16

2.21

2.22

2.23

2.24

2.25

2.26

2.27

2.28

Sec. 4. Minnesota Statutes 2022, section 62W.04, is amended to read:

62W.04 PHARMACY BENEFIT MANAGER GENERAL BUSINESS PRACTICES.

- (a) A pharmacy benefit manager must exercise good faith and fair dealing in the performance of its contractual duties. A provision in a contract between a pharmacy benefit manager and a health carrier or a network pharmacy that attempts to waive or limit this obligation is void.
- (b) A pharmacy benefit manager must notify a health carrier in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents a conflict of interest with the duties imposed in this section.
 - (c) A pharmacy benefit manager must not cause or knowingly permit the use of advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading.
- (d) A pharmacy benefit manager must not charge a pharmacy a fee related to the adjudication of a claim, including but not limited to:
- 2.17 (1) the receipt and processing of a pharmacy claim;
- 2.18 (2) the development or management of claims processing services in a pharmacy benefit
 2.19 manager network; or
- 2.20 (3) participation in a pharmacy benefit network.
 - (e) A pharmacy benefit manager must not amend or change the terms of an existing contract between the pharmacy benefit manager and the pharmacy unless: (1) the change is disclosed to the pharmacy at least 45 days before the effective date of the change and the change is agreed to in writing by the pharmacy or the pharmacy's representative; or (2) the change is required to be made under state or federal law or by a governmental regulatory authority. If the change is required by law or regulatory authority, the pharmacy benefit manager must provide the pharmacy with the specific statute or regulation requiring the change.

Sec. 4. 2

Sec. 5. [62W.045] PHARMACY BENEFIT MANAGER GENERAL

REIMBURSEMENT	PRACTICES
---------------	------------------

3.1

3.2

3.3

3.4

3.5

3.6

3.7

3.8

3.9

3.10

3.11

3.12

3.13

3.14

3.15

3.16

3.17

3.18

3.19

3.20

3.21

3.22

3.23

3.24

3.25

3.26

3.27

3.28

3.29

3.32

(a) A pharmacy benefit manager must not reimburse a pharmacy in an amount less than
the amount the pharmacy benefit manager reimburses a pharmacy benefit manager affiliate
or subsidiary for providing the same prescription drug. The amount must be calculated on
a per unit basis using the same generic product identifier or generic code number.

- (b) A pharmacy benefit manager must not pay or reimburse a pharmacy for the ingredient drug product component less than the national average drug acquisition cost or, if the national drug acquisition cost is unavailable, the wholesale acquisition cost.
- (c) A pharmacy benefit manager must not make or permit any reduction of payment for a prescription drug or service either directly or indirectly to a pharmacy under a reconciliation process to an effective rate of reimbursement, direct or indirect remuneration fees, or any other reduction or aggregate reduction of payment, unless the reduction is a result of an audit performed under section 62W.09 and complies with section 62W.13.
- (d) Termination of a pharmacy from the pharmacy benefit manager network does not release the pharmacy benefit manager from the obligation to make any payment due to the pharmacy for drugs or services rendered.
- Sec. 6. Minnesota Statutes 2022, section 62W.08, is amended to read:

62W.08 MAXIMUM ALLOWABLE COST PRICING.

- (a) With respect to each contract and contract renewal between a pharmacy benefit manager and a pharmacy, the pharmacy benefits manager must:
- (1) provide to the pharmacy, at the beginning of each contract and before entering into the initial contract and before contract renewal, the maximum allowable cost price list and the sources utilized to determine the maximum allowable cost pricing of the pharmacy benefit manager;
- (2) update any maximum allowable cost price list at least every seven business days, noting any price changes from the previous list, and within seven calendar days from:
- (i) an increase of ten percent or more in the pharmacy acquisition cost from 60 percent or more of the pharmaceutical wholesalers doing business in the state;
- 3.30 (ii) a change in the methodology on which the maximum allowable cost price list is
 3.31 based; or
 - (iii) a change in the value of a variable involved in the methodology.

Sec. 6. 3

4.1

4.2

4.3

4.4

4.5

4.6

4.7

4.8

4.9

4.10

4.11

4.12

4.13

4.14

4.15

4.16

4.17

4.18

4.19

4.20

4.21

4.22

4.23

4.24

4.25

4.26

4.27

4.28

4.29

4.30

The pharmacy benefit manager must provide a means by which network pharmacies ma	ıy
promptly review current prices in an electronic, print, or telephonic format within one	
business day at no cost to the pharmacy;	
(3) maintain a procedure to eliminate products from the list of drugs subject to maximu	ım
allowable cost pricing in a timely manner in order to remain consistent with changes in t	he
marketplace;	
(4) ensure that the maximum allowable cost prices are not set below sources utilized	by
the pharmacy benefits manager and not set below the pharmacy acquisition cost; and	
(5) upon request of a network pharmacy, identify each maximum allowable cost price	<u>:e</u>
list that applies to the network pharmacy, and disclose the sources utilized for setting	
maximum allowable cost price rates on each maximum allowable cost price list included	d
under the contract and identify each maximum allowable cost price list that applies to the	1e
network pharmacy., including the following:	
(i) average acquisition cost, including national average drug acquisition cost;	
(ii) average manufacturer price;	
(iii) average wholesale price;	
(iv) brand effective rate or generic effective rate;	
(v) discount indexing;	
(vi) federal upper limits;	
(vii) wholesale acquisition cost; and	
(viii) any other term that a pharmacy benefit manager or plan sponsor may use to establi	<u>ish</u>
the maximum allowable cost price for a prescription drug.	
A The pharmacy benefit manager must make the list of the maximum allowable costs co	<u>ost</u>
price list available to a contracted network pharmacy in a format that is readily accessib	le
and usable to the network pharmacy.	
(b) A pharmacy benefit manager must not place a prescription drug on a maximum	
allowable cost list unless the drug is available for purchase by pharmacies in this state from	m
a national or regional drug wholesaler and is not obsolete.	
(c) Each contract between a pharmacy benefit manager and a pharmacy must include	e
provide a process to appeal, investigate, and resolve disputes regarding maximum allowable	ole

Sec. 6. 4

cost pricing that includes the ability of a pharmacy to challenge the maximum allowable 5.1 cost price if the price: 5.2 (1) a 15-business-day limit on the right to appeal following the initial claim does not 5.3 meet the requirements of this chapter; or 5.4 (2) a requirement that the appeal be investigated and resolved within seven business 5.5 days after the appeal is received; and is below the pharmacy acquisition cost. 5.6 (3) a requirement that a pharmacy benefit manager provide a reason for any appeal denial 5.7 and identify the national drug code of a drug that may be purchased by the pharmacy at a 5.8 price at or below the maximum allowable cost price as determined by the pharmacy benefit 5.9 manager. 5.10 (d) If an appeal is upheld, the pharmacy benefit manager must make an adjustment to 5.11 the maximum allowable cost price no later than one business day after the date of 5.12 determination. The pharmacy benefit manager must make the price adjustment applicable 5.13 to all similarly situated network pharmacy providers as defined by the plan sponsor. The 5.14 appeal process must include: 5.15 (1) a dedicated telephone number and e-mail address or website for the purpose of 5.16 submitting an appeal; and 5.17 (2) the option to submit an appeal directly to the pharmacy benefit manager regarding 5.18 the pharmacy benefit plan or program or through a pharmacy service administrative program. 5.19 (e) Any appeal must be submitted to the pharmacy benefit manager within 30 business 5.20 days from the date of the initial claim. The pharmacy benefit manager must notify the 5.21 challenging pharmacy within three business days that the appeal was received. The pharmacy 5.22 benefit manager must investigate and resolve the appeal within 30 business days from the 5.23 date the appeal is received. 5.24 (f) If the appeal is upheld, or the pharmacy benefit manager fails to resolve the appeal 5.25 within the time period established in paragraph (e), the pharmacy benefit manager must: 5.26 5.27 (1) make an adjustment to the maximum allowable cost price list to at least the pharmacy acquisition cost no later than one business day after the date of determination and make the 5.28 price adjustment applicable to all similarly situated network pharmacy providers as defined 5.29 by the plan sponsor; 5.30

(2) permit the challenging pharmacy to reverse and rebill the claim in question; and

Sec. 6. 5

5.31

(3) provide to the pharmacy the National Drug Code number on which the adjustment 6.1 is based. 6.2 (g) If the appeal is denied, the pharmacy benefit manager must provide the challenging 6.3 pharmacy with the reason for the denial, and: 6.4 6.5 (1) identify the National Drug Code number and the names of the national or regional pharmaceutical wholesalers operating in this state that have the drug currently in stock at 6.6 a price below the maximum allowable cost price; or 6.7 (2) if the National Drug Code number provided by the pharmacy benefit manager is not 6.8 available below the pharmacy acquisition cost from the pharmaceutical wholesaler from 6.9 which the pharmacy purchases the majority of prescription drugs for resale, then the 6.10 pharmacy benefit manager must adjust the maximum allowable cost price above the 6.11 challenging pharmacy's pharmacy acquisition cost and permit the pharmacy to reverse and 6.12 rebill each claim affected by the inability to procure the drug at a cost that is equal to or 6.13 less than the previously challenged maximum allowable cost price. 6.14 (h) A pharmacy may decline to provide a prescription drug or services to a patient or 6.15 pharmacy benefit manager if, as a result of a maximum allowable cost pricing, a pharmacy 6.16 is to be paid less than the pharmacy acquisition cost of the pharmacy dispensing the 6.17 prescription drug or providing the pharmacy services. 6.18 Sec. 7. Minnesota Statutes 2022, section 62W.09, subdivision 1, is amended to read: 6.19 Subdivision 1. Procedure and process for conducting and reporting an audit. (a) 6.20 Unless otherwise prohibited by federal requirements or regulations, any entity conducting 6.21 a pharmacy audit must follow the following procedures: 6.22 (1) a pharmacy must be given notice 14 days before an initial on-site audit is conducted; 6.23 (2) an audit that involves clinical or professional judgment must be conducted by or in 6.24 consultation with a licensed pharmacist; and 6.25 (3) each pharmacy shall be audited under the same standards and parameters as other 6.26 similarly situated pharmacies. 6.27 (b) Unless otherwise prohibited by federal requirements or regulations, for any entity 6.28 conducting a pharmacy audit the following items apply: 6.29 (1) the period covered by the audit may not exceed 24 six months from the date that the 6.30 claim was submitted to or adjudicated by the entity, unless a longer period is required under 6.31 state or federal law; 6.32

Sec. 7. 6

7.1

7.2

7.3

7.4

7.5

7.6

7.7

7.8

7.9

7.10

7.11

7.12

7.13

7.14

7.15

7.16

7.17

7.18

7.19

7.20

7.21

7.22

7.23

7.24

7.25

7.26

7.27

7.28

7.29

7.30

(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. The auditing entity shall provide the pharmacy a masked list that provides a prescription number or date range that the auditing entity is seeking to audit;

- (3) an on-site audit may not take place during the first five business days of the month unless consented to by the pharmacy;
- (4) auditors may not enter the pharmacy area unless escorted where patient-specific information is available and to the extent possible must be out of sight and hearing range of the pharmacy customers;
- (5) any recoupment will not be deducted against future remittances until after the appeals process and both parties have received the results of the final audit;
- (6) a pharmacy benefit manager may not require information to be written on a prescription unless the information is required to be written on the prescription by state or federal law. Recoupment may be assessed for items not written on the prescription if:
 - (i) additional information is required in the provider manual; or
 - (ii) the information is required by the Food and Drug Administration (FDA); or
 - (iii) the information is required by the drug manufacturer's product safety program; and
- (iv) the information in item (i), (ii), or (iii) is not readily available for the auditor at the time of the audit; and
- (7) the auditing company or agent may not receive payment based on a percentage of the amount recovered. This section does not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:
- (i) the plan sponsor and the entity conducting the audit have a contract that explicitly states the percentage charge or assessment to the plan sponsor; and
- (ii) a commission to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.
- (c) An amendment to pharmacy audit terms in a contract between a pharmacy benefit manager and a pharmacy must be disclosed to the pharmacy at least 60 days prior to the effective date of the proposed change.

Sec. 7. 7

01/05/23 REVISOR SGS/KA 23-00996 as introduced Sec. 8. Minnesota Statutes 2022, section 62W.13, is amended to read: 62W.13 RETROACTIVE ADJUSTMENTS. No pharmacy benefit manager shall directly or indirectly retroactively adjust deny or reduce a claim or aggregate of claims for reimbursement submitted by a pharmacy for a prescription drug, more than 30 days after the original claim was submitted, unless the adjustment is a result of a: (1) pharmacy audit conducted in accordance with section 62W.09; or and it was determined that: (1) the original claim was submitted fraudulently; (2) technical billing error. the original claim payment was incorrect because the pharmacy 8.10

(3) the prescription drug or service was not dispensed or rendered by the pharmacy or

was already paid for the prescription drug or service; or

8.1

8.2

8.3

8.4

8.5

8.6

8.7

8.8

8.9

8.11

8.12

8.13

pharmacist.

Sec. 8.

8