SENATE STATE OF MINNESOTA NINETY-FIRST SESSION

S0278-5

S.F. No. 278

(SENATE AUTHORS: JENSEN, Dahms, Wiklund, Draheim and Benson)					
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		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				
	4518	Secretary of State Chapter 39 05/17/2019			
		Effective date 07/01/19			

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

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2.1	(3) both clau	use (1) and clause ((2).		
2.2	<u>Subd. 4.</u> Co	mmissioner. "Con	nmissioner" me	eans the commissioner	of commerce.
2.3	<u>Subd. 5.</u> En	rollee. "Enrollee"	means a natura	l person covered by a h	nealth plan and
2.4	includes an insu	ıred, policyholder,	subscriber, con	ntract holder, member,	covered person, or
2.5	certificate holde	<u>er.</u>			
2.6	Subd. 6. He	alth carrier. "Hea	lth carrier" has	the meaning given in s	section 62A.011,
2.7	subdivision 2.				
2.8	<u>Subd. 7.</u> <u>He</u>	<mark>alth plan.</mark> "Health	plan" means a	policy, contract, certifi	cate, or agreement
2.9	defined in section	on 62A.011, subdiv	vision 3.		
2.10	<u>Subd. 8.</u> Ma	il order pharmac	y. "Mail order	pharmacy" means a ph	armacy whose
2.11	primary busines	ss is to receive pres	criptions by ma	ail, fax, or through elect	ronic submissions,
2.12	dispense prescri	ption drugs to enr	ollees through	the use of the United S	tates mail or other
2.13	common carrier	services, and prov	vide consultation	on with patients electro	nically rather than
2.14	face-to-face.				
2.15	<u>Subd. 9.</u> Ma	ximum allowable	e cost price. "N	Aaximum allowable cos	st price" means the
2.16	maximum amou	int that a pharmacy	y benefit mana	ger will reimburse a pha	armacy for a group
2.17	of therapeutical	ly and pharmaceut	ically equivale	ent multiple source drug	gs. The maximum
2.18	allowable cost p	price does not inclu	ude a dispensir	ng or professional fee.	
2.19	<u>Subd. 10.</u> M	ultiple source dru	ugs. "Multiple	source drugs" means a	therapeutically
2.20	equivalent drug	that is available fr	rom at least two	o manufacturers.	
2.21	<u>Subd. 11.</u> No.	etwork pharmacy	v. "Network ph	armacy" means a retail	or other licensed
2.22	pharmacy provi	der that directly co	ontracts with a	pharmacy benefit mana	ager.
2.23	<u>Subd. 12.</u> O	ther prescription	drug or devic	e services. "Other pres	cription drug or
2.24	device services'	' means services of	ther than claim	s processing services, p	rovided directly or
2.25	indirectly, wheth	her in connection w	ith or separate	from claims processing	services, including:
2.26	(1) negotiati	ng rebates, discou	nts, or other fi	nancial incentives and a	arrangements with
2.27	drug manufactu	rers;			
2.28	(2) disbursir	ng or distributing r	ebates;		
2.29	(3) managin	g or participating i	in incentive pro	ograms or arrangements	s for pharmacy
2.30	services;				
2.31	(4) negotiati	ng or entering into	contractual arra	ingements with pharmad	cists or pharmacies,
2.32	or both;				

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3.1	(5) develo	pping prescription dr	ug formularies;				
3.2	(6) design	ing prescription ben	efit programs; o	<u>r</u>			
3.3	<u>(7)</u> advert	ising or promoting s	ervices.				
3.4	Subd. 13.	Pharmacist. "Pharm	nacist" means ar	individual with a va	lid license issued by		
3.5	the Board of	Pharmacy under cha	pter 151.				
3.6	Subd. 14.	Pharmacy. "Pharm	acy" or "pharma	cy provider" means a	a place of business		
3.7	licensed by the Board of Pharmacy under chapter 151 in which prescription drugs are prepared, compounded, or dispensed under the supervision of a pharmacist.						
3.8	prepared, cor	npounded, or dispen	sed under the su	pervision of a pharm	acist.		
3.9	Subd. 15.	Pharmacy benefit r	nanager. (a) "Ph	armacy benefit manag	ger" 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 li	mited to:				
3.12	<u>(1) contra</u>	cting directly or ind	irectly with phar	macies to provide pro	escription drugs to		
3.13	enrollees or o	other covered individ	luals;				
3.14	(2) administering a prescription drug benefit;						
3.15	<u>(3) proces</u>	ssing or paying phar	macy claims;				
3.16	(4) creating or updating prescription drug formularies;						
3.17	<u>(5) makin</u>	g or assisting in mal	king prior author	ization determinatior	ns on prescription		
3.18	drugs;						
3.19	<u>(6)</u> admin	istering rebates on p	rescription drug	s; or			
3.20	(7) establ	ishing a pharmacy n	etwork.				
3.21	(b) Pharm	acy benefit manager	r does not includ	e the Department of	Human Services.		
3.22	<u>Subd. 16.</u>	Plan sponsor. "Plan	n sponsor" mean	s a group purchaser a	us defined under		
3.23	section 62J.0	3; an employer in th	e case of an emp	loyee health benefit	plan established or		
3.24	maintained b	y a single employer;	or an employee	organization in the c	ase of a health plan		
3.25	established or	maintained by an er	mployee organiz	ation, an association,	joint board trustees,		
3.26	<u>a committee,</u>	or other similar grou	up that establishe	es or maintains the he	ealth plan. This term		
3.27	includes a pe	rson or entity acting	for a pharmacy	benefit manager in a	contractual or		
3.28	employment	elationship in the pe	rformance of pha	rmacy benefit manag	ement. Plan sponsor		
3.29	does not inclu	ude the Department	of Human Servio	ces.			
3.30	Subd. 17.	Specialty drug. "Sp	pecialty drug" m	eans a prescription d	rug that:		
3.31	<u>(1)</u> canno	t be routinely dispen	sed at a majority	of retail pharmacies	<u>;</u>		

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4.1	<u>(2) is use</u>	ed to treat chronic and	l complex, or 1	are medical conditions	• 2		
4.2	<u>(3) has s</u>	pecial storage, handli	ng, or distribu	ion requirements that t	ypically cannot be		
4.3	met by a ret	ail pharmacy; and					
4.4	<u>(4) meet</u>	s at least three of the	following crite	ria:			
4.5	(i) requi	res complex and exter	nded patient ec	ucation and counseling	<u></u>		
4.6	(ii) requi	ires intensive monitor	ring;				
4.7	(iii) requ	ires clinical oversigh	t; and				
4.8	(iv) requ	ires product support s	services.				
4.9	Subd. 18	<u>. Retail pharmacy. "</u>	Retail pharma	cy" means a chain pharr	nacy, a supermarket		
4.10	pharmacy, a	n independent pharm	acy, or a netwo	ork of independent phar	macies, licensed		
4.11	under chapt	er 151, that dispenses	prescription d	rugs to the public.			
4.12	Subd. 19	. Rebates. "Rebates"	means all pric	e concessions paid by a	drug manufacturer		
4.13	to a pharma	cy benefit manager or	r plan sponsor,	including discounts an	d other price		
4.14	concessions	that are based on the	actual or estin	nated utilization of a pr	escription drug.		
4.15	Rebates also include price concessions based on the effectiveness of a prescription drug as						
4.16	in a value-b	ased or performance-	based contract	<u>.</u>			
4.17	Subd. 20	. Specialty pharmacy	y. "Specialty pl	armacy" means a pharn	nacy that specializes		
4.18	in dispensin	g specialty drugs for	patients with se	erious health conditions	s requiring complex		
4.19	therapies an	d high cost biotech ar	nd injectable m	edications. A pharmac	y benefit manager		
4.20							
4.21							
4.22	<u>(1) Utiliz</u>	zation Review Accred	litation Comm	ission (URAC);			
4.23	<u>(2) Accr</u>	editation Commissior	ner for Health	Care, Inc.; or			
4.24	(3) Joint	Accreditation Comm	iission.				
4.25	Sec. 3. [62	2W.03] LICENSE TO	O DO BUSINI	ESS.			
4.26	Subdivis	ion 1. General. (a) B	eginning Janu	ary 1, 2020, no person	shall perform, act,		
4.27	or do busine	ess in this state as a pl	narmacy benef	t manager unless the p	erson has a valid		
4.28	license issue	ed under this chapter	by the commis	sioner of commerce.			
4.29	<u>(b)</u> A lic	ense issued in accord	ance with this	chapter is nontransferal	ble.		

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5.1	Subd. 2.	Application. (a) A p	oharmacy benefit	manager seeking a li	cense shall apply to
5.2	the commiss	sioner of commerce of	on a form prescril	bed by the commission	ner. The application
5.3	form must i	nclude at a minimum	the following in	formation:	
5.4	<u>(1) the n</u>	ame, address, and tel	lephone number	of the pharmacy bene	fit manager;
5.5	<u>(2) the n</u>	ame and address of t	he pharmacy ber	efit manager agent fo	or service of process
5.6	in this state;	and			
5.7	<u>(3) the n</u>	ame, address, officia	l position, and p	ofessional qualificati	ons of each person
5.8	responsible	for the conduct of affa	irs of the pharma	cy benefit manager, in	cluding all members
5.9	of the board	of directors, board of	of trustees, execu	tive committee, or oth	her governing board
5.10	or committe	e; the principal office	ers in the case of	a corporation; or the p	partners or members
5.11	in the case of	of a partnership or as	sociation.		
5.12	(b) Each	application for licens	ure must be accor	mpanied by a nonrefur	ndable fee of \$8,500.
5.13	The fees col	lected under this sub	division shall be	deposited in the gene	eral fund.
5.14	(c) With	in 30 days of receivin	g an application,	the commissioner ma	y require additional
5.15	information	or submissions from	an applicant and	may obtain any docu	ment or information
5.16	reasonably 1	necessary to verify th	e information con	ntained in the applicat	tion. Within 90 days
5.17	after receipt	of a completed appli	cation, the netwo	rk adequacy report rec	quired under section
5.18	62W.05, and	the applicable licen	se fee, the comm	issioner shall review	the application and
5.19	issue a licen	se if the applicant is	deemed qualifie	d under this section. I	f the commissioner
5.20	determines t	the applicant is not q	ualified, the com	missioner shall notify	the applicant and
5.21	shall specify	the reason or reason	ns for the denial.		
5.22	<u>Subd. 3.</u>	Renewal. (a) A licer	nse issued under t	his chapter is valid for	r one year. To renew
5.23	<u>a license, an</u>	applicant must subr	nit a completed r	enewal application or	<u>n a form prescribed</u>
5.24	by the comm	nissioner, the networ	k adequacy repo	rt required under sect	ion 62W.05, and a
5.25	renewal fee	of \$8,500. The fees	collected under the	his paragraph shall be	e deposited in the
5.26	general func	l. The commissioner	may request a re	enewal applicant to su	bmit additional
5.27	information	to clarify any new in	nformation preser	nted in the renewal ap	plication.
5.28	<u>(b)</u> A ren	ewal application sub	mitted after the re	newal deadline date m	nust be accompanied
5.29	by a nonrefu	undable late fee of \$5	500. The fees col	lected under this para	graph shall be
5.30	deposited in	the general fund.			
5.31	<u>(c)</u> The c	ommissioner may de	ny the renewal of	a license for any of th	e following reasons:
5.32	<u>(1) the p</u>	harmacy benefit mar	nager has been de	etermined by the com	missioner to be in
5.33	violation or	noncompliance with	federal or state l	aw; or	

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6.1	(2) the phar	macy benefit man	ager has failed t	o timely submit a renew	val application and
6.2	<u> </u>	required under pa			
6.3	In lieu of a den	ial of a renewal a	oplication, the c	ommissioner may perm	it the pharmacy
6.4				corrective action plan	
6.5	deficiencies.			•	
6.6	Subd. 4. Ov	v ersight. (a) The c	commissioner m	ay suspend, revoke, or	place on probation
6.7				r this chapter for any of	
6.8	circumstances:				
6.9	(1) the phar	macy benefit man	ager has engage	ed in fraudulent activity	that constitutes a
6.10	violation of stat	te or federal law;			
6.11	(2) the com	missioner has rece	eived consumer	complaints that justify a	n action under this
6.12		protect the safety a			
6.13	(3) the pharm	macy benefit man	ager fails to pay	an application license of	or renewal fee; and
6.14	(4) the phar	macy benefit man	ager fails to con	nply with a requiremen	t set forth in this
6.15	chapter.				
6.16	(b) The com	missioner may iss	sue a license sub	ject to restrictions or lim	nitations, including
6.17	<u> </u>			activities in which the	
6.18	manager may b	e engaged.			
6.19	Subd. 5. Pe	nalty. If a pharma	cy benefit mana	ager acts without a licer	ise, the pharmacy
6.20	benefit manage	r may be subject t	to a fine of \$5,0	00 per day for the perio	d the pharmacy
6.21	benefit manage	r is found to be in	violation. Any	penalties collected und	er this subdivision
6.22	shall be deposit	ted in the general	fund.		
6.23	<u>Subd. 6.</u> En	forcement. The co	ommissioner sha	all enforce this chapter u	nder the provisions
6.24	of chapter 45.				
6.25		-	Y BENEFIT M	ANAGER GENERAL	<u> BUSINESS</u>
6.26	PRACTICES.				
6.27	(a) A pharm	acy benefit mana	ger must exerci	se good faith and fair de	ealing in the
6.28	performance of	its contractual du	ties. A provision	n in a contract between a	a pharmacy benefit
6.29	manager and a	health carrier or a	network pharm	acy that attempts to wa	ive or limit this
6.30	obligation is vo	vid.			

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7.1	(b) A pl	narmacy benefit mana	ger must notify	a health carrier in wri	ting of any activity,
7.2	policy, or p	ractice of the pharma	cy benefit mana	ager that directly or ind	directly presents a
7.3	conflict of	interest with the duties	s imposed in th	is section.	
7.4	Sec. 5. <u>[6</u>	2W.05] PHARMACY	Y BENEFIT N	IANAGER NETWO	RK ADEQUACY.
7.5	Subdivi	sion 1. Requirements	. (a) A pharmac	y benefit manager must	provide an adequate
7.6	and accessi	ble pharmacy network	c for the provis	ion of prescription dru	gs that meet the
7.7	relevant rec	juirements in section	62K.10. Mail o	rder pharmacies must	not be included in
7.8	the calculat	tions of determining th	ne adequacy of	the pharmacy benefit	manager's pharmacy
7.9	network un	der section 62K.10.			
7.10	<u>(b) A pł</u>	narmacy benefit manag	ger must submi	t to the commissioner	a pharmacy network
7.11	adequacy re	eport describing the pl	harmacy netwo	rk and pharmacy acces	ssibility in this state,
7.12	with the pha	armacy benefit manage	er's license appl	ication and renewal, in	a manner prescribed
7.13	by the com	missioner.			
7.14	Subd. 2	. Network adequacy	waiver. A phar	macy benefit manager	may apply for a
7.15	waiver from	n the commissioner of	f health if the pl	narmacy benefit manag	ger is unable to meet
7.16	the network	adequacy requirements	nts under subdi	vision 1. A waiver app	plication must be
7.17	submitted to	o the commissioner of	health on a forr	n prescribed by the con	nmissioner of health
7.18	and must:				
7.19	<u>(1) dem</u>	onstrate with specific	data why the ph	armacy benefit manag	er is not able to meet
7.20	the require	ments; and			
7.21	<u>(2) inclu</u>	ude information as to	the steps that w	rere and will be taken	to address network
7.22	adequacy.				
7.23	If a waiver	is granted by the com	missioner of he	alth, the waiver shall a	automatically expire
7.24	after three	years. If a renewal of	the waiver is so	ought, the commission	er of health shall
7.25	consider ste	eps that the pharmacy	benefit manage	er has taken over the pa	ast three-year period
7.26	to address 1	network adequacy.			
7.27	Subd. 3	. Accreditation stand	lards. A pharm	acy benefit manager n	nust not require
7.28	pharmacy a	ccreditation standards	or recertificati	on requirements to par	ticipate in a network
7.29	that are inco	onsistent with, more str	ringent than, or	in addition to federal ar	nd state requirements
7.30	for licensur	e as a pharmacy in the	is state unless a	uthorized under this c	hapter.

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8.1	Sec. 6. [6	2W.06] PHARMACY	Y BENEFIT M	ANAGER TRANSPA	ARENCY.
8.2	Subdivi	sion 1. Transparency	y to plan sponso	o rs. (a) Beginning in th	he second quarter
8.3	after the eff	ective date of a contrac	ct between a pha	macy benefit manager	and a plan sponsor,
8.4	the pharma	cy benefit manager m	ust disclose, upo	on the request of the p	lan sponsor, the
8.5	following in	nformation with respec	ct to prescription	drug benefits specific	to the plan sponsor:
8.6	(1) the a	aggregate wholesale a	cquisition costs	from a drug manufact	urer or wholesale
8.7	drug distrib	outor for each theraped	utic category of	prescription drugs;	
8.8	(2) the a	aggregate wholesale a	equisition costs	from a drug manufact	urer or wholesale
8.9	drug distrib	outor for each theraped	utic category of	prescription drugs ava	ilable to the plan
8.10	sponsor's er	nrollees;			
8.11	(3) the a	aggregate amount of r	ebates received	by the pharmacy bene	fit manager by
8.12	therapeutic	category of prescripti	ion drugs. The a	ggregate amount of re	bates must include
8.13	any utilizat	ion discounts the phar	macy benefit ma	anager receives from a	u drug manufacturer
8.14	or wholesal	le drug distributor;			
8.15	<u>(4) any</u>	other fees received fro	om a drug manu	facturer or wholesale	drug distributor;
8.16	(5) whet	ther the pharmacy bene	efit manager has a	a contract, agreement, o	or other arrangement
8.17	with a drug	manufacturer to excl	usively dispense	or provide a drug to a	a plan sponsor's
8.18	enrollees, a	nd the application of a	ll consideration	or economic benefits c	ollected or received
8.19	pursuant to	the arrangement;			
8.20	<u>(6) pres</u>	cription drug utilization	on information f	or the plan sponsor's e	enrollees;
8.21	<u>(7) de-ic</u>	lentified claims level in	nformation in ele	ctronic format that allo	ows the plan sponsor
8.22	to sort and	analyze the following	information for	each claim:	
8.23	(i) whet	her the claim required	l prior authoriza	tion;	
8.24	<u>(ii) the a</u>	amount paid to the pha	armacy for each	prescription, net of th	e aggregate amount
8.25	of fees or ot	her assessments impos	sed on the pharm	acy, including point-of	-sale and retroactive
8.26	charges;				
8.27	<u>(iii)</u> any	spread between the ne	et amount paid to	the pharmacy in item	(ii) and the amount
8.28	charged to	the plan sponsor;			
8.29	(iv) whe	ether the pharmacy is,	or is not, under	common control or ov	wnership with the
8.30	pharmacy b	enefit manager;			
8.31	<u>(v) whe</u>	ther the pharmacy is,	or is not, a prefe	rred pharmacy under	the plan;

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9.1	(vi) who	ether the pharmacy is,	or is not, a mail	order pharmacy; and	
9.2	<u>(vii)</u> wh	ether enrollees are req	uired by the pla	n to use the pharmacy;	
9.3	<u>(8)</u> the a	aggregate amount of pa	ayments made b	y the pharmacy benefi	t manager to
9.4	pharmacies	owned or controlled b	y the pharmacy	benefit manager on beh	alf of the sponsor's
9.5	<u>plan;</u>				
9.6	(9) the a	aggregate amount of pa	ayments made b	by the pharmacy benefi	t manager to
9.7	pharmacies	not owned or controll	ed by the pharn	nacy benefit manager o	n behalf of the
9.8	sponsor's p	lan; and			
9.9	(10) the	aggregate amount of th	e fees imposed	on, or collected from, n	etwork pharmacies
9.10	or other ass	essments against netwo	rk pharmacies, i	ncluding point-of-sale	fees and retroactive
9.11	charges, an	d the application of the	ose amounts col	lected pursuant to the	contract with the
9.12	plan sponse	<u>or.</u>			
9.13	<u>(b)</u> A pł	narmacy benefit manag	er may require	a plan sponsor to agree	to a nondisclosure
9.14	agreement	that specifies that the i	nformation repo	orted under this section	is proprietary
9.15	information	1. The pharmacy benef	it manager is no	ot required to disclose t	he information to
9.16	the plan spo	onsor until the plan spor	nsor has execute	d the nondisclosure agr	eement, if required
9.17	by the phar	macy benefit manager	<u>.</u>		
9.18	Subd. 2	. <u>Transparency repor</u>	t to the commi	ssioner. (a) Beginning	June 1, 2020, and
9.19	annually th	ereafter, each pharmac	y benefit manag	ger must submit to the	commissioner a
9.20	transparenc	y report containing data	a from the prior o	calendar year as it pertai	ns to plan sponsors
9.21	doing busin	ness in Minnesota. The	report must co	ntain the following info	ormation:
9.22	(1) the a	aggregate wholesale ac	equisition costs	from a drug manufactu	rer or wholesale
9.23	drug distrib	outor for each therapeu	tic category of 1	prescription drugs for a	ll of the pharmacy
9.24	benefit mai	nager's plan sponsor cli	ients, and these	costs net of all rebates	and other fees and
9.25	payments,	direct or indirect, from	all sources;		
9.26	(2) the a	aggregate amount of all	rebates that the	pharmacy benefit man	ager received from
9.27	all drug ma	unufacturers for all of the	he pharmacy be	nefit manager's plan sp	oonsor clients. The
9.28	aggregate a	mount of rebates must	include any uti	lization discounts the p	pharmacy benefit
9.29	manager re	ceives from a drug ma	nufacturer or w	holesale drug distribute	or;
9.30	(3) the a	aggregate of all fees fro	m all sources, d	irect or indirect, that the	e pharmacy benefit
9.31	manager re	ceived for all of the ph	armacy benefit	manager's plan sponso	or clients;

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10.1 10.2	<u></u>	aggregate retained reb nager received from a			· · · · · ·	
10.3	to plan spor	•			<u>8_</u>	
10.4	(5) the a	aggregate retained rel	bate and fees perc	entage;		
10.5	(6) the l	nighest, lowest, and n	nean aggregate re	tained rebate and fee	s percentage for all	
10.6	of the pharm	macy benefit manage	r's plan sponsor c	lients; and		
10.7	(7) de-ie	dentified claims level	l information in el	ectronic format that	allows the	
10.8	commission	ner to sort and analyz	the following ir	nformation for each c	elaim:	
10.9	<u>(i) the d</u>	rug and quantity for	each prescription;			
10.10	<u>(ii) whe</u>	ther the claim require	ed prior authoriza	tion;		
10.11	(iii) pati	ient cost-sharing paid	l on each prescrip	tion. This data is clas	ssified pursuant to	
10.12	paragraph (<u>d);</u>				
10.13	(iv) the	amount paid to the pl	narmacy for each	prescription, net of th	ne aggregate amount	
10.14	of fees or ot	her assessments impo	osed on the pharma	cy, including point-or	f-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. Thi	s data is classified	l pursuant to paragra	ph (d);	
10.18	(vi) ider	ntity of the pharmacy	for each prescrip	tion;		
10.19	<u>(vii) wh</u>	ether the pharmacy is	s, or is not, under	common control or	ownership with the	
10.20	pharmacy b	enefit manager;				
10.21	(viii) wl	hether the pharmacy	is, or is not, a pret	ferred pharmacy und	er the plan;	
10.22	<u>(ix) whe</u>	ether the pharmacy is	, or is not, a mail	order pharmacy; and	<u>l</u>	
10.23	(\mathbf{x}) whe	ther enrollees are req	uired by the plan	to use the pharmacy.		
10.24	(b) With	nin 60 days upon rece	eipt of the transpa	rency report, the con	nmissioner shall	
10.25	publish the	report from each pha	rmacy benefit ma	nager on the Departr	ment of Commerce's	
10.26	website, wi	th the exception of da	ta considered trad	le secret information	under section 13.37.	
10.27	The transpa	arency report must be	published in sucl	h a way as to not disc	close the identity of	
10.28	a specific p	lan sponsor, the price	es charged for a sp	pecific prescription d	rug or classes of	
10.29	drugs, or th	e amount of any reba	ates provided for a	a specific prescription	n drug or classes of	
10.30	drugs.					

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11.1	(c) For p	ourposes of this subdiv	vision, the aggre	egate retained rebate a	nd fee percentage		
11.2	must be cal	culated for each plan	sponsor for reba	tes and fees in the pre	vious calendar year		
11.3	as follows:						
11.4	(1) the s	um total dollar amour	nt of rebates and	l fees from all drug ma	anufacturers for all		
11.5	utilization of	of enrollees of a plan s	ponsor that was	s not passed through to	the plan sponsor;		
11.6	and						
11.7	<u>(2) divid</u>	led by the sum total d	ollar amount of	all rebates and fees re	ceived from all		
11.8	sources, dir	ect or indirect, for all	enrollees of a p	lan sponsor.			
11.9	<u>(</u> d) Data	, documents, material	s, or other infor	mation in the possessi	on or control of the		
11.10	commission	er of commerce that a	re obtained by, cr	reated by, or disclosed	to the commissioner		
11.11	pursuant to	paragraph (a), clause	(7), items (iii), (iv), and (v), are classi	fied as confidential,		
11.12	protected no	onpublic, or both. The	ose data, docum	ents, materials, or othe	er information are		
11.13	not subject	to subpoena, and are 1	not subject to di	scovery or admissible	in evidence in any		
11.14	private civi	action. However, the	commissioner	may use the data, doci	uments, materials,		
11.15	or other info	ormation in the furthe	rance of a regul	atory or legal action b	rought 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 b	enefit manager. Neith	er the commissi	ioner nor any person v	vho received data,		
11.19	documents,	materials, or other ini	formation while	acting under the auth	ority of the		
11.20	commission	er are permitted or rec	quired to testify	in any private civil acti	on concerning data,		
11.21	documents,	materials, or informa	tion subject to t	his paragraph that are	classified as		
11.22	confidential	, protected nonpublic	, or both.				
11.23	Subd. 3.	Penalty. The commis	ssioner may imp	ose civil penalties of n	ot more than \$1,000		
11.24	per day per	violation of this section	on.				
11.25	Sec. 7. [62	W.07] PHARMACY	<u>OWNERSHIP</u>	INTEREST; PHARN	IACY SERVICES.		
11.26	<u>(a)</u> A pha	armacy benefit manage	er that has an ow	nership interest either c	lirectly or indirectly,		
11.27	or through a	an affiliate or subsidia	ry, in a pharma	ey must disclose to a p	blan sponsor that		
11.28	contracts w	ith the pharmacy bene	efit manager any	v difference between the	he amount paid to		
11.29	that pharma	cy and the amount ch	arged to the pla	n sponsor.			
11.30	<u>(b)</u> A ph	armacy benefit manag	er or health carri	er is prohibited from p	enalizing, requiring,		
11.31	or providing	financial incentives, in	ncluding variation	ons in premiums, deduc	tibles, co-payments,		
11.32	or coinsurat	ice, to an enrollee as a	n incentive to us	se a retail pharmacy, m	ail order pharmacy,		
11.33	specialty ph	armacy, or other netw	vork pharmacy p	provider in which a ph	armacy benefit		

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12.1	manager h	as an ownership intere	st or in which th	e pharmacy provider	has an ownership	
12.2	interest in	the pharmacy benefit r	nanager.			
12.3	(c) Para	agraph (b) does not app	lv if the pharma	cy benefit manager or	health carrier offers	
12.4	<u> </u>	the same financial inc				
12.5		specialty pharmacy, or				
12.6	manager ha	as no ownership interes	st and the netwo	rk pharmacy has agree	d to accept the same	
12.7	pricing ter	ms, conditions, and rec	uirements relat	ed to the cost of the p	rescription drug and	
12.8	the cost of	dispensing the prescri	ption drug that a	are in the agreement w	vith a network	
12.9	pharmacy	in which the pharmacy	v benefit manage	er has an ownership in	iterest.	
12.10	(d) A p	harmacy benefit mana	ger or health ca	rrier is prohibited fror	n imposing limits,	
12.11		quantity limits or refill				
12.12	that differ	based solely on wheth	er the health car	rier or pharmacy bene	fit manager has an	
12.13	ownership	interest in a pharmacy	or the pharmacy	has an ownership inte	rest in the pharmacy	
12.14	benefit ma	nager.				
12.15	<u>(e) Not</u>	hing in paragraph (d) s	hall be construe	d to prohibit a pharma	acy benefit manager	
12.16	from impo	sing different limits, ir	cluding quantit	y limits or refill frequ	ency limits on an	
12.17	enrollee's a	access to medication ba	ased on whether	the enrollee uses a m	ail order pharmacy	
12.18	or retail ph	armacy so long as the	enrollee has the	option to use a mail	order pharmacy or	
12.19	retail pharm	nacy with the same lin	nits imposed in	which the pharmacy b	benefit manager or	
12.20	health carrier does not have an ownership interest.					
12.21	<u>(f)</u> A pl	narmacy benefit manag	ger or health car	rier must not prohibit	an entity authorized	
12.22	to participa	ate in the federal 340B	Drug Pricing P	rogram under section	340B of the Public	
12.23	Health Ser	vice Act, United States	s Code, title 42,	chapter 6A, or a pharm	macy under contract	
12.24	with such a	n entity to provide pha	rmacy services	from participating in t	he pharmacy benefit	
12.25	manager's	or health carrier's provi	der network. A j	pharmacy benefit mana	ager or health carrier	
12.26	must not re	eimburse an entity or a	pharmacy under	contract with such ar	entity participating	
12.27	in the feder	al 340B Drug Pricing P	rogram different	ly than other similarly	situated pharmacies.	
12.28	A pharmac	ey benefit manager that	t contracts with	a managed care plan	or county-based	
12.29	purchasing	g plan under contract w	vith the commiss	sioner of human servio	ces under chapter	
12.30	256B or 25	56L must comply with	this paragraph	only if the entity or co	ntracted pharmacy	
12.31	can identif	y all claims eligible for	340B drugs at	the time of initial clair	ns submission at the	
12.32	point of sa	le. This paragraph doe	s not preclude a	pharmacy benefit ma	nager that contracts	
12.33	with a mar	aged care plan or cour	nty-based purch	asing plan under cont	ract with the	
12.34	commissio	ner of human services	under chapter 2	56B or 256L from rei	mbursing an entity	

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13.1	or pharmac	y identified in this par	agraph at a lowe	er rate for any prescrip	tion drug purchased
13.2	by the entity	y or pharmacy throug	h the federal 34	0B Drug Pricing Prog	ram.
13.3	Sec. 8. [6]	2W.075] THERAPE	UTIC ALTER	NATIVE PRESCRIP	TION DRUG.
13.4	A pharm	nacy benefit manager	or health carrie	r must not require, or	demonstrate a
13.5	preference	for, a pharmacy to dis	pense a therape	utically equivalent or	therapeutically
13.6	alternative of	drug that costs the enr	ollee more out-	of-pocket than the pre	scribed drug, unless
13.7	the substitu	tion is made for medi-	cal reasons that	benefit the patient. Be	efore a substitution
13.8	is made und	ler this section, the ph	narmacy must of	otain approval from th	e prescribing
13.9	practitioner	and must inform the	enrollee of the 1	eason for the substitut	tion.
13.10	Sec. 9. [62	2W.076] SPECIALT	Y PHARMAC	<u>Y.</u>	
13.11	A pharm	nacy benefit manager	that contracts w	vith a specialty pharma	acy must disclose to
13.12	an enrollee,	upon request, the enr	ollee's out-of-p	ocket costs at the spec	ialty pharmacy for
13.13	the prescrip	tion drug referenced	by the enrollee	and the enrollee's out-	of-pocket cost at a
13.14	network ret	ail pharmacy that is id	lentified by the	enrollee that is within	the enrollee's health
13.15	plan networ	<u>rk.</u>			
13.16	Sec. 10. [0	62W.077] PREFERR	RED NETWOR	<u>RK.</u>	
13.17	A pharm	nacy benefit manager	that uses a prefe	rred network of pharm	nacies must disclose
13.18	to an enroll	ee upon request the er	nrollee's out-of-	pocket cost at the pref	Ferred pharmacy for
13.19	the prescrip	tion drug referenced	by the enrollee	and the enrollee's out-	of-pocket cost at a
13.20	nonpreferre	d pharmacy identified	l by the enrollee	e that is within the enr	ollee's health plan
13.21	network.				
13.22	Sec. 11. [62W.08] MAXIMUN	1 ALLOWABI	E COST PRICING.	
13.23	<u>(a)</u> With	respect to each contr	act and contract	renewal between a pl	narmacy benefit
13.24	manager an	d a pharmacy, the pha	armacy benefits	manager must:	
13.25	<u>(1) prov</u>	ide to the pharmacy, a	t the beginning	of each contract and c	ontract renewal, the
13.26	sources util	ized to determine the	maximum allov	vable cost pricing of th	ne pharmacy benefit
13.27	manager;				
13.28	<u>(2) upda</u>	ite any maximum allo	wable cost price	e list at least every sev	ven business days,
13.29	noting any	price changes from th	e previous list,	and provide a means b	y which network
13.30	pharmacies	may promptly review	current prices i	n an electronic, print, o	or telephonic format
13.31	within one	business day at no cos	st to the pharma	<u>cy;</u>	

Sec. 11.

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14.1	(3) mai	ntain a procedure to eli	minate products	from the list of drugs s	subject to maximum
14.2	<u> </u>		-	r to remain consistent	
14.3	marketplac	e;			
14.4	(4) ensi	are that the maximum	allowable cost r	rices are not set below	sources utilized by
14.5		cy benefits manager;	•		
14.6				loss the sources utilize	ad for acting
14.6 14.7	<u> </u>			lose the sources utilize	
14.7	-	•		llowable cost price list	•
14.9				must make the list of	
14.10		· • ·		ey in a format that is rea	
14.11		ne network pharmacy.			
17.11					
14.12	<u> </u>			ace a prescription drug	
14.13	allowable of	cost list unless the drug	g is available for	purchase by pharmaci	es in this state from
14.14	<u>a national o</u>	or regional drug whole	esaler and is not	obsolete.	
14.15	(c) Eacl	h contract between a p	harmacy benefi	t manager and a pharm	nacy must include a
14.16	process to	appeal, investigate, an	d resolve disput	es regarding maximun	n allowable cost
14.17	pricing that	t includes:			
14.18	<u>(1) a 15</u>	5-business-day limit or	n the right to app	beal following the initi	al claim;
14.19	<u>(2) a re</u>	quirement that the app	eal be investiga	ted and resolved withi	n seven business
14.20	days after t	the appeal is received;	and		
14.21	<u>(3) a rec</u>	quirement that a pharm	acy benefit man	ager provide a reason fo	or any appeal denial
14.22	and identif	y the national drug co	de of a drug that	t may be purchased by	the pharmacy at a
14.23	price at or l	below the maximum al	llowable cost pr	ice as determined by th	e pharmacy benefit
14.24	manager.				
14.25	<u>(d) If a</u>	n appeal is upheld, the	pharmacy bene	fit manager must make	e an adjustment to
14.26	the maxim	um allowable cost pric	e no later than	one business day after	the date of
14.27	determinat	ion. The pharmacy ber	nefit manager m	ust make the price adj	ustment applicable
14.28	to all simil	arly situated network	pharmacy provi	ders as defined by the	plan sponsor.
14.29	Sec. 12.]	[62W.09] PHARMAC	CY AUDITS.		
14.30	Subdivi	ision 1. Procedure an	d process for c	onducting and report	ing an audit. (a)
14.31	Unless othe	erwise prohibited by f	ederal requirem	ents or regulations, any	y entity conducting
14.32	a pharmacy	y audit must follow the	e following proc	edures:	

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15.1	<u>(1) a ph</u>	armacy must be given	notice 14 days	before an initial on-site	audit is conducted;
15.2	(2) an a	udit that involves clin	ical or profession	onal judgment must be	conducted by or in
15.3		n with a licensed phar			
15.4	(3) each	nharmacy shall be an	idited under the	same standards and pa	arameters as other
15.5		tuated pharmacies.	lanca under the	same standards and p	
			11 6 1 1	· , 1,.	C
15.6	~ /	<u> </u>	•	quirements or regulation	ons, for any entity
15.7	conducting	a pharmacy audit the	following item	s apply:	
15.8	(1) the	period covered by the	audit may not e	exceed 24 months from	the date that the
15.9	<u>claim was s</u>	submitted to or adjudic	ated by the enti	ty, unless a longer perio	od is required under
15.10	state or fed	eral law;			
15.11	(2) if an	entity uses random sa	ampling as a me	ethod for selecting a se	t of claims for
15.12	examinatio	n, the sample size mu	st be appropriat	e for a statistically reli	able sample.
15.13	Notwithsta	nding section 151.69,	the auditing en	tity shall provide the p	harmacy a masked
15.14	list that pro	vides a prescription n	umber or date r	ange that the auditing	entity is seeking to
15.15	<u>audit;</u>				
15.16	<u>(3)</u> an o	n-site audit may not ta	ake place during	g the first five business	s days of the month
15.17	unless cons	sented to by the pharm	acy;		
15.18	<u>(</u> 4) audi	tors may not enter the	pharmacy area	unless escorted where	patient-specific
15.19	information	n is available and to th	e extent possib	le must be out of sight	and hearing range
15.20	of the pharm	macy customers;			
15.21	(5) any 1	recoupment will not be	e deducted agair	st future remittances u	ntil after the appeals
15.22	process and	l both parties have rec	eived the result	s of the final audit;	
15.23	<u>(</u> 6) a ph	armacy benefit manag	ger may not req	uire information to be	written on a
15.24	prescription	n unless the information	on is required to	be written on the pres	scription by state or
15.25	federal law	. Recoupment may be	assessed for ite	ems not written on the	prescription if:
15.26	(i) addit	tional information is re	equired in the p	rovider manual; or	
15.27	<u>(ii) the</u>	information is required	d by the Food a	nd Drug Administratic	on (FDA); or
15.28	<u>(iii) the</u>	information is require	d by the drug m	anufacturer's product	safety program; and
15.29	(iv) the	information in item (i), (ii), or (iii) is	not readily available f	or the auditor at the
15.30	time of the	audit; and			

Sec. 12.

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16.1	(7) the	auditing company or a	gent may not re	ceive payment based	on a percentage of
16.2		t recovered. This section			
16.3	charging o	r assessing the responsi	ble party, directl	y or indirectly, based of	on amounts recouped
16.4	if both of t	the following condition	is are met:		
16.5	(i) the	plan sponsor and the er	ntity conducting	the audit have a cont	tract that explicitly
16.6	states the p	percentage charge or as	ssessment to the	plan sponsor; and	
16.7	<u>(ii) a co</u>	ommission to an agent o	or employee of t	he entity conducting t	he audit is not based,
16.8	directly or	indirectly, on amounts	recouped.		
16.9	<u>(c)</u> An	amendment to pharma	cy audit terms i	n a contract between	a pharmacy benefit
16.10	manager a	nd a pharmacy must be	e disclosed to th	e pharmacy at least 6	0 days prior to the
16.11	effective d	late of the proposed cha	ange.		
16.12	Subd. 2	2. Requirement for rec	coupment or ch	argeback. For recoup	oment or chargeback,
16.13	the follow	ing criteria apply:			
16.14	<u>(1)</u> aud	it parameters must cons	sider consumer-o	priented parameters ba	used on manufacturer
16.15	listings;				
16.16	<u>(2) a pl</u>	harmacy's usual and cu	stomary price for	or compounded medio	cations is considered
16.17	the reimbu	ursable cost unless the p	pricing methodo	logy is outlined in the	e pharmacy provider
16.18	contract;				
16.19	<u>(3)</u> a fin	nding of overpayment of	or underpaymen	t must be based on the	actual overpayment
16.20	or underpa	ayment and not a project	ction based on t	he number of patients	served having a
16.21	similar dia	ignosis or on the numb	er of similar ord	lers or refills for simi	lar drugs;
16.22	(4) the	entity conducting the a	udit shall not u	se extrapolation in ca	lculating the
16.23	recoupmen	nt or penalties for audit	s unless require	d by state or federal l	aw or regulations;
16.24	<u>(5) cale</u>	culations of overpayme	ents must not inc	lude dispensing fees	unless a prescription
16.25	was not ac	tually dispensed, the p	rescriber denied	l authorization, the pr	escription dispensed
16.26	was a med	lication error by the pha	armacy, or the i	dentified overpaymer	t is solely based on
16.27	an extra di	ispensing fee;			
16.28	<u>(6)</u> an e	entity may not consider a	any clerical or re	cord-keeping error, su	ch as a typographical
16.29	error, scriv	vener's error, or comput	er error regardin	ng a required docume	nt or record as fraud,
16.30	however s	uch errors may be subj	ect to recoupme	ent;	
16.31	<u>(7) in t</u>	he case of errors that h	ave no actual fi	nancial harm to the pa	atient or plan, the
16.32	pharmacy	benefit manager must	not assess any c	hargebacks. Errors th	at are a result of the

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17.1	pharmacy fail	ing to comply with	a formal correct	ive action plan may be	subject to recovery;
17.2	and				
17.3	(8) interes	t may not accrue du	uring the audit p	eriod for either party,	beginning with the
17.4	notice of the	audit and ending wi	ith the final audi	t report.	
17.5	<u>Subd. 3.</u>	Ocumentation. (a)	To validate the p	harmacy record and de	livery, the pharmacy
17.6	may use authe	entic and verifiable	statements or red	cords including medic	ation administration
17.7	records of a n	ursing home, assist	ed living facility	y, hospital, physician,	or other authorized
17.8	practitioner o	r additional audit de	ocumentation pa	rameters located in th	e provider manual.
17.9	(b) Any le	gal prescription that	at meets the requ	irements in this chapt	ter may be used to
17.10	validate claim	s in connection with	prescriptions, re	efills, or changes in pre	escriptions, including
17.11	medication ac	lministration record	ls, faxes, e-prese	criptions, or document	ted telephone calls
17.12	from the pres	criber or the prescri	iber's agents.		
17.13	<u>Subd. 4.</u>	Appeals process. The second se	he entity conduc	ting the audit must es	tablish a written
17.14	appeals proce	ess which must inclu	ude appeals of p	reliminary reports and	l final reports.
17.15	<u>Subd. 5.</u> <u>A</u>	udit information a	nd reports. (a) A	A preliminary audit rep	ort must be delivered
17.16	to the pharma	acy within 60 days a	after the conclus	ion of the audit.	
17.17	<u>(b)</u> A pha	rmacy must be allow	wed at least 45 d	lays following receipt	of the preliminary
17.18	audit to provi	de documentation t	o address any di	screpancy found in th	e audit.
17.19	(c) A fina	l audit report must l	be delivered to the	he pharmacy within 12	20 days after receipt
17.20	of the prelimi	inary audit report or	final appeal, w	hichever is later.	
17.21	(d) An ent	tity shall remit any	money due to a	pharmacy or pharmac	ist as a result of an
17.22	underpaymen	t of a claim within	45 days after the	e appeals process has	been exhausted and
17.23	the final audi	t report has been iss	sued.		
17.24	<u>Subd. 6.</u> I	Disclosure to plan s	sponsor. Where	contractually required	l, an auditing entity
17.25	must provide	a copy to the plan	sponsor of its cla	aims that were include	ed in the audit, and
17.26	any recouped	money shall be ret	urned to the plan	n sponsor.	
17.27	<u>Subd. 7.</u>	Applicability of oth	er laws and reg	gulations. This section	n does not apply to
17.28	any investiga	tive audit that invol	ves suspected fr	aud, willful misrepres	sentation, abuse, or
17.29	any audit con	npleted by Minneso	ta health care pi	ograms.	
17.30	<u>Subd. 8.</u> I	Definitions. For pur	poses of this sec	ction, "entity" means a	a pharmacy benefit
17.31	manager or a	ny person or organi	zation that repre	esents a pharmacy ben	efit manager.

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18.1	Sec. 13.	62W.10] SYNCHRO	NIZATION.			
18.2	<u>(a)</u> For	ourposes of this sectior	n, "synchronizati	on" means the coordir	nation of prescription	
18.3	drug refills	for a patient taking tw	o or more medic	ations for one or more	e 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	<u>(b)</u> A co	ontract between a pha	rmacy benefit m	anager and a pharma	cy must allow for	
18.7	synchroniz	ation of prescription d	rug refills for a	patient on at least one	e occasion per year,	
18.8	if the follow	wing criteria are met:				
18.9	<u>(1) the</u>	prescription drugs are	covered under t	he patient's health pla	in or have been	
18.10	approved b	y a formulary exception	ons process;			
18.11	(2) the	prescription drugs are	maintenance me	edications as defined	by the health plan	
18.12	and have or	ne or more refills avai	lable at the time	of synchronization;		
18.13	(3) the	prescription drugs are	not Schedule II,	III, or IV controlled	substances;	
18.14	(4) the p	patient meets all utiliza	ation management	nt criteria relevant to t	the prescription drug	
18.15	at the time	of synchronization;				
18.16	(5) the	prescription drugs are	of a formulation	n that can be safely sp	lit into short-fill	
18.17	periods to a	achieve synchronizatio	on; and			
18.18	(6) the	prescription drugs do	not have special	handling or sourcing	needs that require a	
18.19	single, desi	gnated pharmacy to fi	ll or refill the p	escription.		
18.20	<u>(c) Whe</u>	en necessary to permit	synchronization,	the pharmacy benefit	manager must apply	
18.21	a prorated,	daily patient cost-shar	ing rate to any p	rescription drug dispe	ensed by a pharmacy	
18.22	under this s	section. The dispensin	g fee must not b	e prorated, and all dis	spensing fees shall	
18.23	be based or	n the number of preser	riptions filled or	refilled.		
18.24	<u>(d) Syn</u>	chronization may be r	equested by the	patient or by the pation	ent's parent or legal	
18.25	guardian if	the patient is under th	e age of 18 or is	s incapacitated as defi	ned in section	
18.26	<u>524.5-102,</u>	or by the patient's hea	alth care agent as	s defined in chapter 1	<u>45C.</u>	
18.27	Sec. 14.]	62W.11] GAG CLAU	JSE PROHIBI	<u>FION.</u>		
18.28	<u>(a) No c</u>	contract between a pha	armacy benefit r	nanager or health car	rier and a pharmacy	
18.29	or pharmac	ist shall prohibit, restr	rict, or penalize a	a pharmacy or pharma	acist from disclosing	
18.30	to an enroll	ee any health care info	rmation that the p	pharmacy or pharmaci	st deems appropriate	
18.31	regarding t	he nature of treatment	; the risks or alto	ernatives; the availab	ility of alternative	
18.32	therapies, c	consultations, or tests;	the decision of	utilization reviewers of	or similar persons to	
	Sec. 14.		18			

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- authorize or deny services; the process that is used to authorize or deny health care services
 or benefits; or information on financial incentives and structures used by the health carrier
 or pharmacy benefit manager.
- 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 <u>carrier or pharmacy benefit manager, in accordance with section 151.214, subdivision 1.</u>
- 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 <u>the prescription drug under the enrollee's health plan.</u>
- 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 <u>lesser of:</u>
- 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 <u>the prescription drug without using a health plan or any other source of prescription drug</u>

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.

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Sec. 17. [62W.14] PROMPT FILLING FOR SPECIALTY DRUGS. 20.1 (a) A health carrier or pharmacy benefit manager that requires or provides financial 20.2 incentives for enrollees to use a mail order pharmacy to fill a prescription for a specialty 20.3 drug must ensure through contract and other means that the mail order pharmacy dispenses 20.4 the prescription drug to the enrollee in a timely manner, such that the enrollee receives the 20.5 filled prescription within seven business days of the date of transmittal to the mail order 20.6 pharmacy. The health carrier or pharmacy benefit manager may grant to a mail order 20.7 20.8 pharmacy an exemption from this requirement if the mail order pharmacy can document that the specialty drug was out of stock due to a delay in shipment by the specialty drug 20.9 manufacturer or wholesaler. If an exemption is granted, the health carrier or pharmacy 20.10 benefit manager must notify the enrollee within 24 hours of granting the exemption and, if 20.11 medically necessary, must provide the enrollee with an emergency supply of the specialty 20.12 20.13 drug. (b) For purposes of this section, "health carrier" includes managed care plans and 20.14 county-based purchasing plans participating in a public health care program under chapter 20.15 256B or 256L, and integrated health partnerships established under section 256B.0755. 20.16 Sec. 18. Minnesota Statutes 2018, section 151.21, subdivision 7, is amended to read: 20.17 Subd. 7. Drug formulary. This section Subdivision 3 does not apply when a pharmacist 20.18 is dispensing a prescribed drug to persons covered under a managed health care plan that 20.19 maintains a mandatory or closed drug formulary. 20.20 Sec. 19. Minnesota Statutes 2018, section 151.21, is amended by adding a subdivision to 20.21 20.22 read: Subd. 7a. Coverage by substitution. (a) When a pharmacist receives a prescription 20.23 order by paper or hard copy, by electronic transmission, or by oral instruction from the 20.24 prescriber, in which the prescriber has not expressly indicated that the prescription is to be 20.25 dispensed as communicated and the drug prescribed is not covered under the purchaser's 20.26 20.27 health plan or prescription drug plan, the pharmacist may dispense a therapeutically equivalent and interchangeable prescribed drug or biological product that is covered under 20.28 the purchaser's plan, if the pharmacist has a written protocol with the prescriber that outlines 20.29 the class of drugs of the same generation and designed for the same indication that can be 20.30 substituted and the required communication between the pharmacist and the prescriber. 20.31

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- 21.1 (b) The pharmacist must inform the purchaser if the pharmacist is dispensing a drug or
- 21.2 <u>biological product other than the specific drug or biological product prescribed and the</u>
- 21.3 reason for the substitution.
- 21.4 (c) The pharmacist must communicate to the prescriber the name and manufacturer of
- the substituted drug that was dispensed and the reason for the substitution, in accordance
- 21.6 with the written protocol.

21.7 Sec. 20. <u>RULEMAKING AUTHORITY.</u>

- 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 <u>62W. The commissioner must not adopt rules to implement Minnesota Statutes, chapter</u>
- 21.12 <u>62W, under any other grant of rulemaking authority. If the commissioner of commerce does</u>
- 21.13 <u>not adopt rules by January 1, 2022, rulemaking authority under this section is repealed.</u>
- 21.14 <u>Rulemaking authority under this section is not continuing authority to amend or repeal rules.</u>
- 21.15 Notwithstanding Minnesota Statutes, section 14.125, any additional action on rules after
- 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. <u>REPEALER.</u>

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

21.29 <u>151.63; 151.64; 151.65; 151.66; 151.67; 151.68; 151.69; 151.70; and 151.71, are repealed.</u>

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.

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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.