SGS

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

## S.F. No. 1098

(SENATE AUTHORS: ROSEN, Dahms, Klein, Wiklund and Benson)						
DATE	TE D-PG OFFICIAL STATUS					
02/11/2019	332	Introduction and first reading				
		Referred to Health and Human Services Finance and Policy				
03/27/2019	1380a	Comm report: To pass as amended and re-refer to Judiciary and Public Safety Finance and Policy				
02/20/2020	4812a	Comm report: To pass as amended and re-refer to Finance				
03/11/2020	5401a	Comm report: To pass as amended				
	5402	Second reading				
04/20/2020	5800a	Special Order: Amended				
	5810	Third reading Passed				
05/11/2020	6447	Returned from House				
		Presentment date 05/12/2020				
05/15/2020	7048	Governor's action Approval 05/12/2020				
	7048	Secretary of State Chapter 78 05/12/2020				
		Effective date 07/01/20				

1.1	A bill for an act
1.2 1.3 1.4 1.5	relating to health; establishing the Prescription Drug Price Transparency Act; requiring drug manufacturers to submit drug price information to the commissioner of health; providing civil penalties; requiring a report; modifying appropriations; proposing coding for new law in Minnesota Statutes, chapter 62J.
1.6	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:
1.7	Section 1. [62J.84] PRESCRIPTION DRUG PRICE TRANSPARENCY.
1.8	Subdivision 1. Short title. This section may be cited as the "Prescription Drug Price
1.9	Transparency Act."
1.10	Subd. 2. Definitions. (a) For purposes of this section, the terms defined in this subdivision
1.11	have the meanings given.
1.12	(b) "Biosimilar" means a drug that is produced or distributed pursuant to a biologics
1.13	license application approved under United States Code, title 42, section 262(K)(3).
1.14	(c) "Brand name drug" means a drug that is produced or distributed pursuant to:
1.15	(1) an original, new drug application approved under United States Code, title 21, section
1.16	355(c), except for a generic drug as defined under Code of Federal Regulations, title 42,
1.17	section 447.502; or
1.18	(2) a biologics license application approved under United States Code, title 45, section
1.19	<u>262(a)(c).</u>
1.20	(d) "Commissioner" means the commissioner of health.
1.21	(e) "Generic drug" means a drug that is marketed or distributed pursuant to:

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Section 1.

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2.1	(1) an abbr	reviated new drug a	pplication app	roved under United Sta	ates Code, title 21,
2.2	section 355(j)				
2.3	<u>(2) an auth</u>	orized generic as de	fined under Co	ode of Federal Regulati	ons, title 45, section
2.4	447.502; or				
2.5	<u>(3) a drug t</u>	that entered the mar	ket the year be	fore 1962 and was not	originally marketed
2.6	under a new d	rug application.			
2.7	<u>(f)</u> "Manuf	acturer" means a dr	rug manufactur	er licensed under secti	on 151.252.
2.8	<u>(g)</u> "New p	prescription drug" of	r "new drug" n	neans a prescription dr	ug approved for
2.9	marketing by	the United States Fo	ood and Drug A	Administration for whi	ch no previous
2.10	wholesale acq	uisition cost has been	en established	for comparison.	
2.11	(h) "Patient	t assistance program	" means a prog	ram that a manufacture	er offers to the public
2.12	in which a con	sumer may reduce	the consumer's	out-of-pocket costs fo	or prescription drugs
2.13	by using coup	ons, discount cards,	prepaid gift ca	ards, manufacturer deb	oit cards, or by other
2.14	means.				
2.15	(i) "Prescri	ption drug" or "drug	" has the meani	ng provided in section 1	151.441, subdivision
2.16	<u>8.</u>				
2.17	<u>(j)</u> "Price"	means the wholesal	le acquisition c	ost as defined in Unite	ed States Code, title
2.18	42, section 13	95w-3a(c)(6)(B).			
2.19	<u>Subd. 3.</u> P	rescription drug p	rice increases	<b>reporting.</b> (a) Beginni	ng October 1, 2021,
2.20	a drug manufa	cturer must submit to	o the commission	oner the information de	scribed in paragraph
2.21	(b) for each pr	escription drug for	which the pric	e was \$100 or greater	for a 30-day supply
2.22	or for a course	e of treatment lastin	g less than 30 o	days and:	
2.23	(1) for bran	nd name drugs wher	e there is an in	crease of ten percent of	r greater in the price
2.24	over the previous	ous 12-month perio	d or an increas	e of 16 percent or grea	ter in the price over
2.25	the previous 2	4-month period; and	d		
2.26	(2) for gen	eric drugs where the	ere is an increas	se of 50 percent or grea	ater in the price over
2.27	the previous 1	2-month period.			
2.28	(b) For eac	h of the drugs desc	ribed in paragr	aph (a), the manufactu	rer shall submit to
2.29	the commission	oner no later than 60	days after the	price increase goes int	o effect, in the form
2.30	and manner pr	rescribed by the con	nmissioner, the	e following information	n, if applicable:
2.31	(1) the nan	ne and price of the o	drug and the ne	et increase, expressed a	as a percentage;
2.32	(2) the fact	ors that contributed	l to the price in	icrease;	

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3.1	(3) the r	name of any generic ve	ersion of the pre	escription drug availa	ble on the market;		
3.2	(4) the introductory price of the prescription drug when it was approved for marketing						
3.3	by the Food	l and Drug Administra	ation and the ne	t yearly increase, by c	calendar year, in the		
3.4	price of the	prescription drug dur	ing the previous	s five years;			
3.5	(5) the d	lirect costs incurred by	the manufactur	er that are associated	with the prescription		
3.6	drug, listed	separately:					
3.7	<u>(i) to ma</u>	anufacture the prescrip	otion drug;				
3.8	<u>(ii) to m</u>	arket the prescription	drug, including	advertising costs; an	d		
3.9	<u>(iii) to d</u>	listribute the prescripti	ion drug;				
3.10	(6) the to	otal sales revenue for the	he prescription of	lrug during the previo	ous 12-month period;		
3.11	(7) the n	nanufacturer's net prof	it attributable to	the prescription drug	during the previous		
3.12	12-month p	period;					
3.13	(8) the to	otal amount of financia	l assistance the	manufacturer has prov	vided through patient		
3.14	prescription	n assistance programs,	if applicable;				
3.15	<u>(9) any a</u>	agreement between a n	nanufacturer and	d another entity contir	igent upon any delay		
3.16	in offering	to market a generic ve	rsion of the pre	scription drug;			
3.17	(10) the	patent expiration date	of the prescrip	tion drug if it is under	r patent;		
3.18	<u>(11) the</u>	name and location of	the company th	at manufactured the o	drug; and		
3.19	<u>(12) if a</u>	brand name prescript	ion drug, the ter	n highest prices paid	for the prescription		
3.20	drug during	g the previous calendar	r year in any co	untry other than the U	United States.		
3.21	<u>(c)</u> The 1	manufacturer may subr	nit any documer	tation necessary to sup	pport the information		
3.22	reported un	der this subdivision.					
3.23	<u>Subd. 4</u> .	<u>New prescription di</u>	rug price repor	<b>ting.</b> (a) Beginning (	Detober 1, 2021, no		
3.24	later than 6	0 days after a manufac	cturer introduce	s a new prescription of	drug for sale in the		
3.25	United State	es that is a new brand n	ame drug with a	price that is greater the	han the tier threshold		
3.26	established	by the Centers for Me	edicare and Med	licaid Services for spo	ecialty drugs in the		
3.27		eart D program for a 30					
3.28	price that is	greater than the tier t	hreshold establi	shed by the Centers f	for Medicare and		
3.29		ervices for specialty d					
3.30	and is not a	t least 15 percent lowe	er than the refer	enced brand name dr	ug when the generic		

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4.1	or biosimila	ar drug is launched, the	e manufacturer	must submit to the co	mmissioner, in the		
4.2	form and manner prescribed by the commissioner, the following information, if applicable:						
4.3	(1) the p	price of the prescription	n drug;				
4.4	(2) when	ther the Food and Drug	g Administratio	on granted the new pre	scription drug a		
4.5	breakthroug	gh therapy designation	or a priority re	eview;			
4.6	(3) the d	lirect costs incurred by	the manufactu	rer that are associated v	vith the prescription		
4.7	drug, listed	separately:					
4.8	<u>(i) to ma</u>	anufacture the prescrip	tion drug;				
4.9	<u>(ii) to m</u>	arket the prescription of	drug, including	g advertising costs; and	1		
4.10	<u>(iii) to d</u>	listribute the prescription	on drug; and				
4.11	(4) the p	patent expiration date o	of the drug if it	is under patent.			
4.12	<u>(b)</u> The	manufacturer may sub	mit documenta	ntion necessary to supp	oort the information		
4.13	reported un	der this subdivision.					
4.14	Subd. 5.	Newly acquired pres	cription drug	price reporting. (a) I	Beginning October		
4.15	1, 2021, the	e acquiring drug manuf	acturer must su	ıbmit to the commissio	oner the information		
4.16	described in paragraph (b) for each newly acquired prescription drug for which the price						
4.17	was \$100 or greater for a 30-day supply or for a course of treatment lasting less than 30						
4.18	days and:						
4.19	(1) for a	newly acquired brand	name drug wl	nere there is an increas	e of ten percent or		
4.20	greater in th	ne price over the previou	us 12-month pe	eriod or an increase of 1	6 percent or greater		
4.21	in price ove	er the previous 24-mon	th period; and				
4.22	(2) for a	newly acquired generi	c drug where t	here is an increase of 5	0 percent or greater		
4.23	in the price	over the previous 12-r	nonth period.				
4.24	(b) For (	each of the drugs descr	ibed in paragr	aph (a), the acquiring 1	nanufacturer shall		
4.25	submit to th	ne commissioner no lat	er than 60 day	s after the acquiring m	anufacturer begins		
4.26	to sell the n	ewly acquired drug, in	the form and	manner prescribed by	the commissioner,		
4.27	the following	ng information, if appli	cable:				
4.28	(1) the p	price of the prescription	n drug at the ti	me of acquisition and i	n the calendar year		
4.29	prior to acq	uisition;					
4.30	(2) the r	name of the company f	rom which the	prescription drug was	acquired, the date		
4.31	acquired, an	nd the purchase price;					

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5.1	(3) the y	ear the prescription d	rug was introdu	ced to market and the	price of the	
5.2	<u> </u>	drug at the time of in			·	
5.3	<u>(4) the p</u>	rice of the prescriptio	n drug for the p	revious five years;		
5.4	(5) any a	greement between a n	nanufacturer and	l another entity contin	gent upon any delay	
5.5	in offering t	o market a generic ve	rsion of the ma	nufacturer's drug; and		
5.6	<u>(6) the p</u>	atent expiration date of	of the drug if it	is under patent.		
5.7	<u>(c)</u> The n	nanufacturer may subn	nit any documer	tation necessary to sup	port the information	
5.8	reported und	der this subdivision.				
5.9	Subd. 6.	Public posting of pre	escription drug	price information. (a	) The commissioner	
5.10	shall post or	1 the department's we	bsite, or may co	ontract with a private e	entity or consortium	
5.11	that satisfies	s the standards of sect	tion 62U.04, sub	odivision 6, to meet th	is requirement, the	
5.12	following in	formation:				
5.13	(1) a list	of the prescription dr	ugs reported un	der subdivisions 3, 4,	and 5, and the	
5.14	manufacture	ers of those prescription	on drugs; and			
5.15	(2) infor	mation reported to the	e commissioner	under subdivisions 3,	, 4, and 5.	
5.16	<u>(b)</u> The i	nformation must be p	oublished in an o	easy-to-read format ar	nd in a manner that	
5.17	identifies th	e information that is c	lisclosed on a p	er-drug basis and mus	st not be aggregated	
5.18	in a manner that prevents the identification of the prescription drug.					
5.19	(c) The c	commissioner shall no	ot post to the de	partment's website or	a private entity	
5.20	contracting	with the commissione	er shall not post	any information desc	ribed in this section	
5.21	if the inform	nation is not public da	ta under section	n 13.02, subdivision 8	a; or is trade secret	
5.22	information	under section 13.37, s	subdivision 1, pa	aragraph (b); or is trad	e secret information	
5.23	pursuant to	the Defend Trade Sec	erets Act of 201	6, United States Code	, title 18, section	
5.24	<u>1836, as am</u>	ended. If a manufactu	arer believes inf	formation should be w	ithheld from public	
5.25	disclosure p	ursuant to this paragra	ph, the manufac	turer must clearly and	specifically identify	
5.26	that informa	tion and describe the	legal basis in w	riting when the manu	facturer submits the	
5.27	information	under this section. If the	he commissione	r disagrees with the ma	anufacturer's request	
5.28	to withhold	information from pub	olic disclosure, 1	he commissioner shal	ll provide the	
5.29	manufacture	er written notice that t	the information	will be publicly poste	d 30 days after the	
5.30	date of the r	notice.				
5.31	<u>(d) If the</u>	commissioner withh	olds any inform	ation from public dise	closure pursuant to	
5.32	this subdivis	sion, the commissione	r shall post to th	e department's website	e a report describing	

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6.1	the nature of	the information and	the commission	er's basis for withhold	ing the information			
6.2	from disclosu				<u> </u>			
6.3	Subd. 7. <b>(</b>	Subd. 7. Consultation. (a) The commissioner may consult with a private entity or						
6.4				62U.04, subdivision 6				
6.5	Minnesota, or	r the commissioner o	f commerce, as a	ppropriate, in issuing	the form and format			
6.6	of the inform	ation reported under	this section; in p	osting information pure	suant to subdivision			
6.7	6; and in taki	ng any other action	for the purpose	of implementing this s	ection.			
6.8	(b) The co	ommissioner may coi	nsult with repres	entatives of the manufa	acturers to establish			
6.9	a standard for	mat for reporting inf	formation under	his section and may us	e existing reporting			
6.10	methodologie	es to establish a stand	lard format to m	nimize administrative	burdens to the state			
6.11	and manufact	turers.						
6.12	<u>Subd. 8.</u>	Enforcement and p	enalties. (a) A n	nanufacturer may be s	ubject to a civil			
6.13	penalty, as pr	ovided in paragraph	(b), for:					
6.14	<u>(1) failing</u>	g to submit timely re	ports or notices	as required by this sec	etion;			
6.15	(2) failing	g to provide informat	tion required un	der this section; or				
6.16	<u>(3) provid</u>	ling inaccurate or in	complete inform	nation under this section	on.			
6.17	<u>(b)</u> The co	ommissioner shall ac	lopt a schedule	of civil penalties, not t	to exceed \$10,000			
6.18	per day of vio	olation, based on the	severity of eacl	n violation.				
6.19	(c) The co	ommissioner shall in	npose civil pena	lties under this section	as provided in			
6.20	section 144.9	9, subdivision 4.						
6.21	(d) The co	ommissioner may rer	nit or mitigate ci	vil penalties under this	section upon terms			
6.22	and condition	ns the commissioner	considers prope	er and consistent with	public health and			
6.23	safety.							
6.24	(e) Civil p	enalties collected un	der this section	shall be deposited in th	e health care access			
6.25	fund.							
6.26	<u>Subd. 9.</u> I	Legislative report. (a	a) No later than J	anuary 15 of each year	, beginning January			
6.27	15, 2022, the	commissioner shall	report to the ch	airs and ranking minor	rity members of the			
6.28	legislative co	mmittees with juriso	liction over con	merce and health and	human services			
6.29	policy and fin	nance on the implem	entation of this	section, including but	not limited to the			
6.30	effectiveness	in addressing the fo	llowing goals:					
6.31	<u>(1)</u> promo	oting transparency in	pharmaceutical	pricing for the state a	nd other payers;			
6.32	<u>(2) enhan</u>	cing the understandi	ng on pharmace	utical spending trends	; and			

Section 1.

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7.1	<u>(3) assis</u>	ting the state and othe	er payers in the	management of pharm	aceutical costs.
7.2	<u>(b) The</u>	report must include a s	ummary of the i	nformation submitted	to the commissioner
7.3	under subdi	visions 3, 4, and 5.			
7.4	Sec. 2. <u>Al</u>	PPROPRIATION.			
7.5	<u>(a) In fis</u>	scal year 2021, the tota	al appropriation	and the general fund	appropriation to the
7.6	commission	ner of health in Laws 2	2019, First Spec	ial Session chapter 9,	article 14, section
7.7	3, subdivisi	on 1, are reduced by \$	6655,000.		
7.8	<u>(b)</u> In fis	scal year 2021, the ger	neral fund appro	priation to the commis	ssioner of health for
7.9	health impr	ovement in Laws 2019	9, First Special	Session chapter 9, arti	cle 14, section 3,
7.10	subdivision	2, is reduced by \$655	<u>,000.</u>		
7.11	(c) The	general fund base leve	el adjustment fo	r the commissioner of	health for health
7.12	improvemen	nt in Laws 2019, First	Special Session	chapter 9, article 14, se	ection 3, subdivision
7.13	2, paragrap	h (j), is increased by \$	98,000 in fiscal	year 2022 and increa	sed by \$68,000 in
7.14	fiscal year 2	2023.			