SGS

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

## S.F. No. 1098

(SENATE AUTHORS: ROSEN, Dahms, Klein, Wiklund and Benson)						
DATE	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				
		Second reading				

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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2.1	(1) an abbrev	viated new drug a	pplication appr	oved under United Sta	ates Code, title 21,
2.2	section 355(j);				
2.3	(2) an author	ized generic as de	fined under Co	de of Federal Regulati	ions, title 45, section
2.4	447.502; or				
2.5	(3) a drug that	at entered the mar	ket the year bet	fore 1962 and was not	originally marketed
2.6	under a new dru	g application.			
2.7	(f) "Manufac	turer" means a dr	rug manufactur	er licensed under sect	ion 151.252.
2.8	(g) "New pre	escription drug" o	r "new drug" m	eans a prescription dr	ug approved for
2.9	marketing by the	e United States Fo	ood and Drug A	dministration for whi	ich no previous
2.10	wholesale acqui	sition cost has be	en established f	for comparison.	
2.11	(h) "Patient a	ssistance program	n" means a prog	ram that a manufacture	er offers to the public
2.12	in which a consu	imer may reduce	the consumer's	out-of-pocket costs fo	or prescription drugs
2.13	by using coupon	s, discount cards	, prepaid gift ca	urds, manufacturer deb	oit cards, or by other
2.14	means.				
2.15	(i) "Prescripti	ion drug" or "drug	" has the meaning	ng provided in section	151.441, subdivision
2.16	<u>8.</u>				
2.17	(j) "Price" m	eans the wholesa	le acquisition c	ost as defined in Unite	ed States Code, title
2.18	42, section 1395	w-3a(c)(6)(B).			
2.19	Subd. 3. Pre	scription drug p	rice increases I	<b>reporting.</b> (a) Beginni	ing October 1, 2021,
2.20	a drug manufact	urer must submit t	o the commissio	oner the information de	escribed in paragraph
2.21	(b) for each pres	cription drug for	which the price	e was \$100 or greater	for a 30-day supply
2.22	or for a course o	of treatment lastin	g less than 30 c	lays and:	
2.23	(1) for brand	name drugs when	re there is an inc	crease of ten percent o	r greater in the price
2.24	over the previou	s 12-month perio	d or an increase	e of 16 percent or grea	ater in the price over
2.25	the previous 24-	month period; an	<u>d</u>		
2.26	(2) for gener	ic drugs where the	ere is an increas	e of 50 percent or grea	ater in the price over
2.27	the previous 12-	month period.			
2.28	(b) For each	of the drugs desc	ribed in paragra	aph (a), the manufactu	urer shall submit to
2.29	the commission	er no later than 60	) days after the	price increase goes int	to effect, in the form
2.30	and manner pres	scribed by the cor	nmissioner, the	following information	n, if applicable:
2.31	(1) the name	and price of the	drug and the ne	t increase, expressed a	as a percentage;
2.32	(2) the factor	rs that contributed	to the price in	crease;	

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3.1	(3) the r	name of any generic ve	ersion of the pre	escription drug availal	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 duri	ing the previous	five years;				
3.5	(5) the d	irect 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; and	d			
3.9	<u>(iii)</u> to d	istribute the prescripti	ion drug;					
3.10	(6) the to	otal sales revenue for th	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	eriod;						
3.13	(8) the to	otal amount of financia	l assistance the	manufacturer has prov	vided through patient			
3.14	prescription	assistance programs,	if applicable;					
3.15	<u>(9)</u> any a	ngreement between a m	nanufacturer and	l another entity contin	ngent upon any delay			
3.16	in offering	to market a generic ve	rsion of the pre	scription drug;				
3.17	<u>(10) the</u>	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 c	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	the previous calendar	r year in any co	untry other than the U	United States.			
3.21	<u>(c)</u> The r	nanufacturer may subn	nit any documen	tation necessary to sup	pport the information			
3.22	reported un	der this subdivision.						
3.23	<u>Subd. 4</u> .	New prescription dr	rug price repor	<b>ting.</b> (a) Beginning C	Detober 1, 2021, no			
3.24	later than 6	0 days after a manufac	cturer introduce	s a new prescription of	lrug 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		by the Centers for Me						
3.27		art D program for a 30						
3.28	-	greater than the tier th						
3.29		ervices for specialty d						
3.30	and is not a	t least 15 percent lowe	er than the refer	enced brand name dru	ug when the generic			

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4.1	or biosimila	r drug is launched, the	e manufacturer	must submit to the co	ommissioner, in the			
4.2	form and manner prescribed by the commissioner, the following information, if applicable:							
4.3	<u>(1) the p</u>	rice of the prescription	n drug;					
4.4	(2) whet	her the Food and Drug	g Administratio	on granted the new pro	escription drug a			
4.5	breakthroug	h therapy designation	or a priority re	eview;				
4.6	(3) the di	irect costs incurred by	the manufactur	er that are associated	with the prescription			
4.7	drug, listed	separately:						
4.8	(i) to ma	nufacture the prescrip	tion drug;					
4.9	(ii) to ma	arket the prescription	drug, including	advertising costs; and	<u>d</u>			
4.10	(iii) to di	istribute the prescripti	on drug; and					
4.11	(4) the p	atent expiration date of	of the drug if it	is under patent.				
4.12	<u>(b)</u> The 1	manufacturer may sub	mit documenta	tion necessary to sup	port the information			
4.13	reported und	der this subdivision.						
4.14	Subd. 5. Newly acquired prescription drug price reporting. (a) Beginning October							
4.15	1, 2021, the acquiring drug manufacturer must submit to the commissioner 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	<u>(1) for a</u>	newly acquired brand	name drug wł	here there is an increas	se of ten percent or			
4.20	greater in the	e price over the previo	us 12-month pe	eriod or an increase of	16 percent or greater			
4.21	in price over	r the previous 24-mon	th period; and					
4.22	(2) for a	newly acquired gener	ic drug where t	here is an increase of :	50 percent or greater			
4.23	in the price	over the previous 12-1	nonth period.					
4.24	<u>(b)</u> For e	each of the drugs prese	cribed in parag	caph (a), the acquiring	manufacturer shall			
4.25	submit to th	e commissioner no lat	er than 60 day	s after the acquiring m	nanufacturer begins			
4.26	to sell the ne	ewly acquired drug, in	the form and	manner prescribed by	the commissioner,			
4.27	the followin	g information, if appl	icable:					
4.28	(1) the p	rice of the prescription	n drug at the ti	ne of acquisition and	in the calendar year			
4.29	prior to acqu	uisition;						
4.30	(2) the name of the company from which the prescription drug was acquired, the date							
4.31	acquired, an	d 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	prescription	drug at the time of in	troduction;		<u> </u>		
5.3	<u>(4) the p</u>	rice of the prescriptio	n drug for the p	revious five years;			
5.4	<u>(</u> 5) any a	greement between a n	nanufacturer and	l another entity contin	igent upon any delay		
5.5	in offering t	o market a generic ve	rsion of the mar	nufacturer's drug; and	<u> </u>		
5.6	(6) the p	atent expiration date of	of the drug if it	is under patent.			
5.7	<u>(c) The n</u>	nanufacturer may subn	nit any documen	tation necessary to sup	oport the information		
5.8	reported und	der this subdivision.					
5.9	Subd. 6.	Public posting of pre	escription drug	price information. (a	a) The commissioner		
5.10	shall post or	n the department's we	bsite, or may co	ntract with a private	entity or consortium		
5.11	that satisfies	s the standards of sect	ion 62U.04, sub	division 6, to meet th	nis 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) information reported to the commissioner under subdivisions 3, 4, and 5.						
5.16	<u>(b)</u> The i	information must be p	oublished in an e	easy-to-read format an	nd in a manner that		
5.17	identifies th	e information that is c	disclosed on a po	er-drug basis and mu	st not be aggregated		
5.18	in a manner that prevents the identification of the prescription drug.						
5.19	(c) The c	(c) The commissioner shall not post to the department'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	13.02, subdivision 8	a; or is trade secret		
5.22	information	under section 13.37, s	subdivision 1, pa	uragraph (b); or is trad	le secret information		
5.23	pursuant to	the Defend Trade Sec	erets Act of 2016	6, United States Code	, title 18, section		
5.24	<u>1836, as am</u>	ended. If a manufactu	arer believes inf	ormation should be w	vithheld from public		
5.25	disclosure p	ursuant to this paragra	ph, the manufac	turer must clearly and	specifically identify		
5.26	that information	tion and describe the	legal basis in w	riting when the manu	facturer submits the		
5.27	information	under this section. If the	he commissioner	r disagrees with the m	anufacturer's request		
5.28	to withhold	information from pub	olic disclosure, t	he commissioner sha	ll provide the		
5.29	manufacture	er written notice that t	the information	will be publicly poste	ed 30 days after the		
5.30	date of the r	notice.					
5.31	<u>(d) If the</u>	e commissioner withh	olds any inform	ation from public dis	closure pursuant to		
5.32	this subdivis	sion, the commissione	r shall post to th	e department's websit	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								
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 information	ation reported under	this section; in pe	osting information pur	suant to subdivision				
6.7	6; and in taki	ng any other action	for the purpose	of implementing this s	section.				
6.8	<u>(b)</u> The co	ommissioner may con	nsult with repres	entatives of the manuf	acturers to establish				
6.9	a standard for	mat for reporting inf	ormation under t	his section and may us	se existing reporting				
6.10	methodologie	es to establish a stand	ard format to mi	nimize administrative	burdens to the state				
6.11	and manufact	turers.							
6.12	<u>Subd. 8.</u>	Enforcement and po	e <b>nalties.</b> (a) A n	nanufacturer may be s	ubject to a civil				
6.13	penalty, as pr	ovided in paragraph	(b), for:						
6.14	(1) failing	to submit timely re	ports or notices	as required by this see	ction;				
6.15	(2) failing	g to provide informat	tion required un	der this section; or					
6.16	<u>(3) provid</u>	ling inaccurate or ind	complete inform	ation under this section	on.				
6.17	<u>(b)</u> The co	ommissioner shall ac	lopt a schedule	of civil penalties, not	to exceed \$10,000				
6.18	per day of vio	per day of violation, based on the severity of each violation.							
6.19	(c) The co	ommissioner shall in	pose civil pena	lties under this section	n as provided in				
6.20	section 144.99, subdivision 4.								
6.21	(d) The co	ommissioner may ren	nit or mitigate ci	vil penalties under this	s section upon terms				
6.22	and condition	ns the commissioner	considers prope	r and consistent with	public health and				
6.23	safety.								
6.24	(e) Civil p	enalties collected un	der this section s	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 cha	airs and ranking mino	rity members of the				
6.28	legislative co	mmittees with jurise	liction over com	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) prome</u>	oting transparency in	pharmaceutical	pricing for the state a	and other payers;				
6.32	<u>(2) enhan</u>	cing the understandi	ng on pharmace	utical spending trends	s; and				

Section 1.

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7.1	<u>(3) assis</u>	ting the state and othe	er payers in the	management of pharn	naceutical 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	(a) In fis	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	vial 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 commi	ssioner of health for
7.9	health impr	ovement in Laws 201	9, First Special	Session chapter 9, art	icle 14, section 3,
7.10	subdivision	2, is reduced by \$655	<u>5,000.</u>		
7.11	<u>(c)</u> The	general fund base leve	el adjustment fo	r the commissioner of	f 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 fisca	l year 2022 and increa	sed by \$68,000 in
7.14	fiscal year 2	2023.			