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SENATE STATE OF MINNESOTA NINETY-FIRST SESSION

S.F. No. 4084

(SENATE AUTHORS: JENSEN, Eaton, Lang, Marty and Kent)DATED-PGOFFICIAL STATUS03/05/20205265Introduction and first reading
Referred to Health and Human Services Finance and Policy

1.1	A bill for an act
1.2 1.3 1.4	relating to health; establishing the Prescription Drug Price Transparency Act; requiring a report; proposing coding for new law in Minnesota Statutes, chapter 151.
1.5	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:
1.6	Section 1. [151.80] PRESCRIPTION DRUG PRICE TRANSPARENCY ACT.
1.7	Sections 151.80 to 151.83 shall be known as the "Prescription Drug Price Transparency
1.8	Act."
1.9	Sec. 2. [151.81] DEFINITIONS.
1.10	Subdivision 1. Applicability. Only for purposes of sections 151.80 to 151.83, the terms
1.11	defined in this section have the meanings given.
1.12	Subd. 2. Commissioner. "Commissioner" means the commissioner of health.
1.13	Subd. 3. New prescription drug. "New prescription drug" means a prescription drug
1.14	approved for marketing by the United States Food and Drug Administration (FDA) for
1.15	which no previous wholesale acquisition cost has been established for comparison.
1.16	Subd. 4. Patient assistance program or program. "Patient assistance program" or
1.17	"program" means a program that a manufacturer offers to the general public in which a
1.18	consumer may reduce the out-of-pocket costs for prescription drugs paid by the consumer
1.19	by using coupons, discount cards, prepaid gift cards, manufacturer debit cards, or other
1.20	reduction in out-of-pocket costs by other means.

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2.1	<u>Subd. 5.</u>	Prescription drug	g. "Prescription dr	ug" has the meaning prov	vided in section
2.2	<u>151.44, para</u>	agraph (d).			
2.3	<u>Subd. 6.</u>	Price. "Price" mea	ans the wholesale	acquisition cost as defined	d in United States
2.4	Code, title 4	2, section 1395w-2	3a(c)(6)(B).		
2.5	<u>Subd. 7.</u>	Profit. "Profit" me	eans the total sales	revenue for a prescription	n drug during the
2.6	previous cal	endar year and the	manufacturer's p	rofit attributable to the sa	me prescription
2.7	drug during	the previous calen	dar year.		
2.8	Sec. 3. [15	51.83] REPORTIN	NG PRESCRIPT	ION DRUG PRICES.	
2.9	Subdivis	ion 1. Applicabili	ty. <u>No later than O</u>	October 1, 2019, a manufac	cturer shall report
2.10	the informat	tion described in su	ubdivisions 2, 3, a	nd 4 to the commissioner	according to the
2.11	requirement	s in subdivision 2,	3, or 4 as applica	ble.	
2.12	Subd. 2.	Prescription drug	g price increases	reporting. For every pre-	scription drug
2.13	priced more	than \$40 for a cour	rse of therapy, who	ose price increases by more	e than ten percent
2.14	<u>in a 12-mon</u>	th period or more t	han 16 percent in	a 24-month period, the m	anufacturer shall
2.15	report to the	commissioner at l	east 60 days in ad	lvance of the increase, in	the form and
2.16	manner pres	scribed by the com	missioner, the foll	owing information in a fo	orm and format
2.17	the commiss	sioner has determin	ned is appropriate	for public display:	
2.18	<u>(1) the w</u>	holesale acquisitio	on cost of the drug	for each of the last five c	alendar years, as
2.19	applicable;				
2.20	(2) the pr	rice increase as a p	ercentage of the di	rug's price for each of the	last five calendar
2.21	years, as app	plicable;			
2.22	<u>(3) the p</u>	rice of the drug at	its initial launch;		
2.23	(4) the fa	actors that contribu	ited to the price in	crease;	
2.24	<u>(5) the in</u>	ntroductory price o	f the prescription	drug when it was approve	ed for marketing
2.25	by the FDA	• <u>•</u>			
2.26	(6) the d	irect costs incurred	by the manufactu	rer that are associated wit	th the drug, listed
2.27	separately:				
2.28	<u>(i)</u> to ma	nufacture the press	cription drug;		
2.29	<u>(ii) to ma</u>	arket the prescripti	on drug, including	g advertising costs;	
2.30	(iii) to re	esearch and develo	p the prescription	drug;	
2.31	<u>(iv) to di</u>	stribute the preser	iption drug;		

Sec. 3.

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3.1	(v) other ac	lministrative cos	sts; and		
3.2	(vi) profit;				
3.3	(7) the perc	centage of the pri	ice spent on deve	loping, manufacturing, ar	nd distributing the
3.4	drug;				
3.5	<u>(8) a descri</u>	ption of the cha	nge or improvem	ent in the drug, if any, the	at necessitates the
3.6	price increase;				
3.7	(9) the tota	l amount of fina	ncial assistance t	hat the manufacturer has	provided through
3.8	any patient pre	escription assista	nce program;		
3.9	<u>(10)</u> any ag	reement between	a manufacturer a	and another party continge	ent upon any delay
3.10	in offering to r	narket a generic	version of the m	anufacturer's drug;	
3.11	(11) the pat	tent expiration d	ate of the drug if	it is under patent;	
3.12	(12) the res	earch and develo	opment costs asso	ociated with the prescripti	on drug that were
3.13	paid using pub	lic funds;			
3.14	(13) any ot	her information	that the manufac	turer deems relevant to th	ne price increase
3.15	described in th	is subdivision; a	und		
3.16	(14) the do	cumentation nec	essary to support	t the information reported	l under this
3.17	subdivision.				
3.18	<u>Subd. 3.</u> No.	ew prescription	drug price repo	rting. For every new pres	scription drug that
3.19	is a brand nam	e drug that is pri	iced over \$500 fc	or a 30-day supply or a ge	neric name drug
3.20	that is priced of	ver \$200 for a 30)-day supply, 60 o	days or less after a manufa	acturer introduces
3.21	a new prescrip	tion drug for sal	e in the United S	tates, the manufacturer sł	nall notify the
3.22	commissioner,	in the form and	manner prescribe	ed by the commissioner, o	f all the following
3.23	information in	a form and form	at the commission	ner has determined is app	ropriate for public
3.24	display:				
3.25	(1) the who	blesale acquisitio	on cost of the dru	<u>g;</u>	
3.26	(2) the pric	e of the drug at i	its initial launch;		
3.27	(3) the fact	ors that contribu	ted to the price;		
3.28	(4) the dire	ct costs incurred	by the manufactu	arer that are associated wi	th that drug, listed
3.29	separately:				
3.30	(i) to manu	facture the prese	cription drug;		
3.31	(ii) to mark	tet the prescription	on drug, includin	g advertising costs;	

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4.1	(iii) to research and develop the prescription drug;								
4.2	(iv) to distribute the prescription drug;								
4.3	(v) other administrative costs; and								
4.4	(vi) profi	(vi) profit;							
4.5	(5) the pe	ercentage of the pri	ice spent on develo	pping, manufacturing, and	d distributing the				
4.6	drug;								
4.7	<u>(6)</u> the to	tal amount of fina	ncial assistance the	at the manufacturer has p	rovided through				
4.8	any patient p	prescription assista	nce program;						
4.9	<u>(7)</u> any ag	greement between	a manufacturer and	d another party contingen	t upon any delay				
4.10	in offering to	o market a generic	version of the man	nufacturer's drug;					
4.11	(8) the pa	atent expiration da	te of the drug if it	is under patent;					
4.12	<u>(9) the re</u>	search and develo	pment costs associ	ated with the prescription	n drug that were				
4.13	paid using p	ublic funds;							
4.14	<u>(10)</u> any	other information	that the manufactu	arer deems relevant to the	e price described				
4.15	in this subdivision; and								
4.16	(11) the documentation necessary to support the information reported under this								
4.17	subdivision.								
4.18	<u>Subd. 4.</u>	Newly acquired p	rescription drug p	orice reporting. For ever	y newly acquired				
4.19	prescription	drug that is a bran	d name drug that i	s priced over \$100 for a .	30-day supply or				
4.20	a generic nar	ne drug that is pric	ed over \$50 for a 3	80-day supply, the acquiri	ng manufacturer				
4.21	shall report t	to the commission	er at least 60 days	in advance of the acquisi	tion, in the form				
4.22	and manner p	prescribed by the co	ommissioner, the f	ollowing information in a	form and format				
4.23	the commiss	ioner has determin	ned is appropriate t	for public display:					
4.24	(1) the w	holesale acquisitio	n cost at the time o	f acquisition and in the ca	lendar year prior				
4.25	to acquisition	<u>n;</u>							
4.26	(2) the na	ame of the compan	y from which the	drug was acquired, the da	ate acquired, and				
4.27	the purchase	price;							
4.28	(3) the year	ear the drug was in	troduced to marke	t and the wholesale acqui	sition cost of the				
4.29	drug at the ti	ime of introductior	<u>1;</u>						
4.30	(4) the pr	evious five calend	lar years' wholesal	e acquisition cost of the	newly acquired				
4.31	brand name	drug or newly acq	uired generic name	e drug;					

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5.1	(5) the dir	rect costs incurred	by the manufactu	rer that are associated wi	th the drug, listed			
5.2	separately:							
5.3	(i) to man	(i) to manufacture the prescription drug;						
5.4	(ii) to ma	rket the prescripti	on drug, includin	g advertising costs;				
5.5	(iii) to res	search and develop	p the prescription	drug;				
5.6	(iv) to dis	tribute the preserve	ption drug;					
5.7	(v) other	administrative cos	sts; and					
5.8	(vi) profit	<u>t;</u>						
5.9	(6) the pe	rcentage of the pr	ice projected to b	e spent on developing, m	anufacturing, and			
5.10	distributing t	he drug;						
5.11	(7) the tot	tal amount of fina	ncial assistance tl	nat the manufacturer has	provided through			
5.12	any patient p	rescription assista	ince program;					
5.13	<u>(8)</u> any ag	greement between	a manufacturer ar	nd another party continge	nt upon any delay			
5.14	in offering to	market a generic	version of the ma	anufacturer's drug;				
5.15	(9) the pa	tent expiration da	te of the drug if it	t is under patent;				
5.16	(10) the re	esearch and devel	opment costs asso	ciated with the prescripti	on drug that were			
5.17	paid using pu	ublic funds; and						
5.18	<u>(11) if ava</u>	ailable, the price a	as determined reas	sonable through effective	ness measures.			
5.19	<u>Subd. 5.</u>	Comparison data	. The commission	ner may use any publicly	available			
5.20	prescription of	drug price inform	ation the commiss	sioner deems appropriate	to verify that			
5.21	manufacture	rs have properly re	eported price incr	eases as required by subc	livision 2 of this			
5.22	section.							
5.23	<u>Subd. 6.</u>	Additional inform	nation requested	. After receiving the repo	ort or information			
5.24	described in	subdivision 2, 3, 4	4, or 5, the comm	issioner may make a writ	ten request to the			
5.25	manufacturer	for supporting do	cumentation or ac	lditional information cond	cerning the report.			
5.26	<u>Subd. 7.</u>	Public posting of J	prescription drug	<mark>g price information.</mark> (a) E	except as provided			
5.27	<u>in paragraph</u>	(c), the commissi	oner shall post to	the department's website	30 days before a			
5.28	price change	is effective the in	formation from th	e manufacturer, in an eas	y-to-read format,			
5.29	that includes	all of the following	ng information:					
5.30	<u>(1) a list c</u>	of the prescription	drugs reported u	nder subdivisions 2, 3, ar	nd 4 and the			
5.31	manufacture	rs of those prescri	ption drugs; and					

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6.1	<u>(2) inform</u>	nation reported to	the commissione	r under subdivisions 2 to (<u>5.</u>
6.2	The informati	on shall be publish	ned in a manner th	at identifies the information	n that is disclosed
6.3		-		in a manner that would no	
6.4	identification	of the drug.			
6.5	(b) The co	ommissioner may r	not post to the depa	artment's website any infor	mation described
6.6	in this section	•			
6.7	(1) the inf	formation is not n	ublic data under s	ection 13.02, subdivision	8a. and
0.7	<u> </u>				
6.8	· · ·			interest does not require c	lisclosure of the
6.9	information t	hat is unrelated to	the price of a pro	escription drug.	
6.10	<u>(c) The co</u>	mmissioner shall	publicly announc	e the posting of informatio	on required under
6.11	paragraph (a)	and shall allow the	e public to comme	ent on the posted information	on for a minimum
6.12	of 30 calenda	ur days.			
6.13	(d) If the	commissioner wit	hholds any inform	nation from public disclos	sure pursuant to
6.14	this subdivisi	on, the commissio	oner shall post to t	he department's website a	report describing
6.15	the nature of	the information a	nd the commissio	ner's basis for withholding	g the information
6.16	from disclosu	ire.			
6.17	<u>Subd. 8.</u>	C onsultation. The	e commissioner m	nay consult with a nonprot	fit dedicated to
6.18	collecting and	d reporting health	care data and the c	commissioner of commerc	e, as appropriate,
6.19	in issuing the	form and format	of the informatio	n reported under this secti	ion in posting
6.20	information c	on the department	's website pursuar	nt to subdivision 7, and in	taking any other
6.21	action for the	purpose of imple	ementing this sect	ion.	
6.22	<u>Subd. 9.</u> I	Legislative report	t. (a) No later than	January 15, 2021, and ann	ually on January
6.23	15 every year	r thereafter, the co	ommissioner shall	report to the chairs and ra	anking members
6.24	of the commi	ttees with jurisdic	ction over comme	rce, health and human ser	vices, and state
6.25	finance and o	perations on the i	mplementation of	the Prescription Drug Pri	ce Transparency
6.26	Act, includin	g but not limited	to the effectivenes	ss in addressing the follow	ving goals:
6.27	<u>(1) promo</u>	oting transparency	in pharmaceutica	al pricing for the state and	other payers;
6.28	(2) enhand	cing understandin	g about pharmace	eutical spending trends; an	nd
6.29	<u>(3) assisti</u>	ng the state and o	ther payers in ma	nagement of pharmaceution	cal costs.
6.30	(b) The re	port shall include	a summary of the	information reported to the	ne commissioner
6.31	under subdiv	isions 2 to 7 as we	ell as a summary	of any public comments r	eceived.

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7.1	(c) The rep	ort shall include	recommendations	for legislative changes,	if any, to reduce		
7.2				act of price increases on	.		
7.3	Department of	Corrections, the	State Employee (Broup Insurance Program	, the Department		
7.4	of Human Serv	vices, and health	insurance premiu	ms in the fully insured m	narkets.		
7.5	Sec. 4. [151.84] ENFORCEMENT AND PENALTIES.						
7.6	Subdivision	n 1. <mark>Civil monet</mark>	ary penalties. <u>A</u>	manufacturer may be sub	oject to a civil		
7.7	penalty, as pro	vided in subdivis	sion 2, for:				
7.8	(1) failing	to submit timely	reports or notices	as required by section 15	51.83;		
7.9	(2) failing	to provide inform	nation required un	der section 151.83;			
7.10	(3) failing	to respond in a ti	mely manner to a	written request by the co	ommissioner for		
7.11	additional information under section 151.83, subdivision 6; or						
7.12	(4) providing inaccurate or incomplete information under section 151.83.						
7.13	Subd. 2. Enforcement. (a) A manufacturer that fails to report or provide information						
7.14	as required by section 151.83 may be subject to a civil penalty as provided in this section.						
7.15	(b) The commissioner shall adopt a schedule of penalties, not to exceed \$10,000 per day						
7.16	of violation, based on the severity of each violation.						
7.17	(c) The commissioner shall impose civil penalties under this section as provided in						
7.18	section 144.99, subdivision 4.						
7.19	(d) The con	nmissioner may r	emit or mitigate c	vil penalties under this se	ection upon terms		
7.20	and conditions	the commission	er considers prop	er and consistent with pu	blic health and		
7.21	safety.						
7.22	(e) Civil pe	enalties collected	under this section	n shall be paid to the com	missioner of		
7.23	management a	nd budget and de	eposited in the hea	alth care access fund to b	e made available		
7.24	for people serv	ved by state publi	ic health care prog	grams.			