GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2021

S

SENATE BILL 257 Commerce and Insurance Committee Substitute Adopted 5/20/21 Third Edition Engrossed 6/1/21

Short Title: Medication Cost Transparency Act. (Public)

3

Sponsors:	
Referred to:	

March 15, 2021

A BILL TO BE ENTITLED

1	A BILL TO BE ENTITLED		
2	AN ACT TO I	PROMOTE PRICING TRANSPARENCY FOR PATIENTS AND TO	
3	ESTABLISH	STANDARDS AND CRITERIA FOR THE REGULATION AND	
4	LICENSURE	OF PHARMACY BENEFITS MANAGERS PROVIDING SERVICES FOR	
5	HEALTH BEI	NEFIT PLANS IN NORTH CAROLINA.	
6	The General Asse	mbly of North Carolina enacts:	
7	SECTION 1.(a) G.S. 58-56A-10 is recodified as G.S. 58-56A-30.		
8	SECTION 1.(b) Article 56A of Chapter 58 of the General Statutes, as amended by		
9	Section 1(a) of this act, reads as rewritten:		
10		"Article 56A.	
11		"Pharmacy Benefits Management.	
12	"§ 58-56A-1. Def		
13	The following	definitions apply in this Article:	
14	<u>(1)</u>	340B contract pharmacy. – Any pharmacy under contract with a 340B covered	
15		entity to dispense drugs on behalf of the 340B covered entity.	
16	<u>(2)</u>	<u>340B covered entity. – Any entity defined in 42 U.S.C. § 256b(a)(4)(A), 42</u>	
17		<u>U.S.C.</u> § $256b(a)(4)(C)$, 42 U.S.C. § $256b(a)(4)(D)$, 42 U.S.C. §	
18		256b(a)(4)(E), 42 U.S.C. § 256b(a)(4)(I), 42 U.S.C. § 256b(a)(4)(J), 42 U.S.C.	
19		<u>§ 256b(a)(4)(K), 42 U.S.C. § 256b(a)(4)(N), or 42 U.S.C. § 256b(a)(4)(O).</u>	
20	<u>(3)</u>	<u>Claim. – A request from a pharmacy or pharmacist to be reimbursed for the</u>	
21		cost of filling or refilling a prescription for a drug or for providing a medical	
22		supply or device.	
23	<u>(4)</u>	<u>Claims processing service. – The administrative services performed in</u>	
24		connection with the processing and adjudicating of claims relating to	
25		pharmacist services that include either or both of the following activities:	
26		a. <u>Receiving payments for pharmacist services.</u>	
27		b. <u>Making payments to pharmacists or pharmacies for pharmacist</u>	
28 29	(1)(5)	services. Health benefit plan. – As defined in G.S. 58-50-110(11). This definition	
29 30	(1)(3)	specifically excludes the State Health Plan for Teachers and State	
31		Employees. <u>G.S. 58-3-167.</u>	
32	$(1_0)(6)$	Insured. – An individual covered by a health benefit plan.	
32 33		Insurer. – Any entity that provides or offers a health benefit plan. As defined	
33 34	(2)(1)	in G.S. 58-3-167.	
54		<u>III 0.5. 50-5-107.</u>	



	General Assemb	y Of North Carolina	Session 2021
1	<u>(8)</u>	Maximum allowable cost list. – A listing of	of generic or multiple source drugs
	<u></u>	used by a pharmacy benefits manager to se	
		which reimbursement of a pharmacy is ma	
	(3)(9)	Maximum allowable cost price. – The max	
	· · · · · · · · · · · · · · · · · · ·	amount that a pharmacy benefits manager	1
		cost of generic or multiple source prescri	
		devices.	
	<u>(10)</u>	Out-of-pocket costs With respect to the a	equisition of a drug, the amount to
	<u></u>	be paid by the insured under the plan or cov	
		copayment, coinsurance, or deductible.	<u>_</u>
	(11)	Pharmacy services administration organiza	tion (PSAO). – An entity operating
	<u></u>	within the State that contracts with ind	
		business on their behalf with third-	
		administrative services to pharmacies and	
		with third-party payers or pharmacy b	
		pharmacies. A person or entity is a PSAO u	
		or more of the following administrative ser	-
		a. Assistance with claims.	
		b. Assistance with audits.	
		~	
		c.Centralized payment.d.Certification in specialized care pro-e.Compliance support.f.Setting flat fees for generic drugs.	grams.
		e. Compliance support.	
		f. Setting flat fees for generic drugs.	
		g.Assistance with store layout.h.Inventory management.i.Marketing support.j.Management and analysis of paymek.Provision of services for retail cash	
		i. Marketing support.	
		j. Management and analysis of payme	ent and drug dispensing data.
		k. Provision of services for retail cash	
	(3a)<u>(12</u>	2) Pharmacist. – A person licensed to prac	tice pharmacy under Article 4A of
		Chapter 90 of the General Statutes.	
	<u>(13)</u>	Pharmacist services Products, goods, or	services provided as a part of the
		practice of pharmacy.	
	(4) (14)	<u>Pharmacy. – A pharmacy registered wi</u>	th the North Carolina Board of
		Pharmacy.As defined in G.S. 90-85.3(q).	
	(5) (15)	Pharmacy benefits manager. – An entity v	who contracts with a pharmacy on
		behalf of an insurer or third-party admir	nistrator to administer or manage
		prescription drug benefits.benefits to perfo	
		a. Negotiating rebates with manufactu	
		as described in this Article.	
		b. Processing claims for prescription	n drugs or medical supplies or
		providing retail network manageme	ent for pharmacies or pharmacists.
		c. Paying pharmacies or pharmacists	for prescription drugs or medical
		supplies.	
	<u>(16)</u>	Pharmacy benefits manager affiliate A pl	narmacy or pharmacist that directly
		or indirectly, through one or more intern	nediaries, owns or controls or is
		owned or controlled by a pharmacy benefit	
	(6)<u>(17)</u>	Third-party administrator. – As defined in	
	" <u>§ 58-56A-2. Lic</u>	ensure.	
	(a) <u>A pers</u>	on or organization may not establish or opera	ate as a pharmacy benefits manager
		plans in this State without obtaining a licer	
	Department of Ins	urance.	

	General Assemb	oly Of North Carolina	Session 2021
1	(b) The C	Commissioner shall develop an application for	licensure to operate in this State
2		nefits manager and may charge an initial applic	
3		unnual renewal fee of one thousand five hundred	
4		application form must collect only the follow	
5	(1)	The name, address, and telephone contact n	-
6	<u>, , , , , , , , , , , , , , , , , , , </u>	manager.	÷ , , , , , , , , , , , , , , , , , , ,
7	<u>(2)</u>	The name and address of the pharmacy ben	efits manager's agent for service
8		of process in this State.	<u>v</u> _
9	<u>(3)</u>	The name and address of each person with	management or control over the
10	<u>, , , , , , , , , , , , , , , , , , , </u>	pharmacy benefits manager.	
11	(4)	The name and address of each person with a	beneficial ownership interest in
12		the pharmacy benefits manager.	<u> </u>
13	(5)	Either (i) a signed statement that, to the best	of the applicant's knowledge, no
14		officer with management or control of the	
15		been convicted of a felony or has violated an	
16		law applicable to pharmacy benefits manage	• •
17		felony or any violation of any requirement of	
18		to pharmacy benefits management com	
19		management or control of the pharmacy bend	
20	(c) Unles	s otherwise provided for in this Article, an a	pplicant or a pharmacy benefits
21	manager that is li	censed to conduct business in the State shall file	e a notice describing any material
22	modification of t	he information required under this section.	
23	"§ 58-56A-3. Co	onsumer protections.	
24	(a) A ph	armacy or pharmacist shall have the right to	provide an insured information
25	regarding the am	ount of the insured's cost share for a prescription	on drug. Neither a pharmacy nor
26	a pharmacist sha	ll be penalized by a pharmacy benefits manage	er for discussing any information
27	described in this	section or for selling a lower-priced drug to the	e insured if one is available.
28	· · · ·	armacy benefits manager shall not, through con	
29	0 1	viding direct and limited delivery services to a	
30		as delineated in the contract between the pha	rmacy benefits manager and the
31	pharmacy.		
32		armacy benefits manager shall not prohibit a	
33		hal shipping and handling fee to the insured for a	
34	-	or pharmacy discloses all of the following to t	he insured before delivery:
35	<u>(1)</u>	The fee will be charged.	
36	<u>(2)</u>	The fee may not be reimbursed by the health b	benefit plan, insurer, or pharmacy
37		benefits manager.	
38	<u>(3)</u>	The charge is specifically agreed to by the	health benefit plan or pharmacy
39		benefits manager.	
40	· · · •	rmacy benefits manager shall not charge, or at	-
41	- ·	t exceeds the total submitted charges by the ne	1 0
42		contract for the provision of a network to delive	
43		ts manager and insurer shall be made available	• •
44		Department shall report to the Attorney General	any violations of this section or
45		accordance with G.S. 58-2-40(5).	
46 47		narmacy and pharmacist protections.	a faa faag on otherwise held -
47 48		armacy benefits manager may only charge	
48 40		sible for a fee relating to the adjudication of a contract of the adjudicated claim or is set out in contract	
49 50		e of the adjudicated claim or is set out in contract pharmacy. No fee or adjustment for the received	1 0
50 51	-	pharmacy. <u>No fee or adjustment for the receipted to the adjudication of a claim shall be above</u>	
51	otherwise related	to the adjudication of a claim, shall be charg	cu without a justification on the

General Assembly Of North Carolina 1 remittance advice or as set out in contract and agreed upon by the pharmacy or pharmacist for 2 each adjustment or fee. This section shall not apply with respect to claims under an employee 3 benefit plan under the Employee Retirement Income Security Act of 1974 or Medicare Part D. 4 Nothing in this Article shall abridge the right of a pharmacist to refuse to fill or refill (b) 5 a prescription if the pharmacist believes it would be harmful to the patient or is not in the patient's 6 best interest, or if there is a question to the validity of the prescription. A pharmacy or pharmacist shall not be prohibited by a pharmacy benefits manager 7 (c) 8 from dispensing any prescription drug, including specialty drugs dispensed by a credentialed and 9 accredited pharmacy, allowed to be dispensed under a license to practice pharmacy under Article 10 4A of Chapter 90 of the General Statutes. 11 A pharmacy benefits manager shall not penalize or retaliate against a pharmacist or (d) pharmacy for exercising rights provided under this Article. This subsection does not apply to 12 13 breach of contract between a pharmacy and a pharmacy benefits manager. 14 A claim for pharmacist services may not be retroactively denied or reduced after (e) 15 adjudication of the claim unless any of the following apply: 16 The original claim was submitted fraudulently. (1) 17 The original claim payment was incorrect because the pharmacy or pharmacist (2)had already been paid for the pharmacist services. 18 The pharmacist services were not rendered by the pharmacy or pharmacist. 19 (3) 20 (4) The adjustments were agreed to by the pharmacy or pharmacist. 21 The adjustments were part of an attempt to limit overpayment recovery efforts (5) 22 by a pharmacy benefits manager. 23 Nothing in this section shall be construed to limit overpayment recovery efforts by a (f) 24 pharmacy benefits manager. 25 "§ 58-56A-5. Maximum allowable cost price. 26 In order to place a prescription drug on the maximum allowable cost price list, the (a) 27 drug must be available for purchase by pharmacies in North Carolina from national or regional 28 wholesalers, must not be obsolete, and must meet one of the following conditions: 29 The drug is listed as "A" or "B" rated in the most recent version of the United (1)30 States Food and Drug Administration's Approved Drug Products with 31 Therapeutic Equivalence Evaluations, also known as the Orange Book. 32 The drug has a "NR" or "NA" rating, or a similar rating, by a nationally (2) 33 recognized reference. 34 A pharmacy benefits manager shall adjust or remove the maximum allowable cost (b) 35 price for a prescription drug to remain consistent with changes in the national marketplace for 36 prescription drugs. A review of the maximum allowable cost prices for removal or modification 37 shall be completed by the pharmacy benefits manager at least once every seven business days, 38 and any removal or modification shall occur within seven business days of the review. A 39 pharmacy benefits manager shall provide a means by which the contracted pharmacies may 40 promptly review current prices in an electronic, print, or telephonic format within one business 41 day of the removal or modification. 42 A pharmacy benefits manager shall ensure that dispensing fees are not included in the (c) 43 calculation of maximum allowable cost price. 44 A pharmacy benefits manager shall establish an administrative appeals procedure by (d) which a contracted pharmacy or pharmacist, or a designee, may appeal the provider's 45 reimbursement for a prescription drug subject to maximum allowable cost pricing if the amount 46 47 of reimbursement for the drug is less than the net amount that the network provider paid to the 48 suppliers of the drug. The reasonable administrative appeal procedure must include all of the 49 following: 50 A dedicated telephone number and email address or website for the purpose (1)of submitting administrative appeals. 51

Session 2021

	General Assem	bly Of North Carolina	Session 2021
1	<u>(2)</u>	The ability to submit an administrative appeal reg	arding the pharmacy
2	<u>x_7</u>	benefits plan or program directly to the pharmacy benef	
3		a pharmacy service administrative organization if t	
4		administrative organization has a contract with th	
5		manager that allows for the submission of appeals.	
6	<u>(3)</u>	No less than 10 calendar days after the applicable press	cription fill date to file
7		an administrative appeal.	
8	<u>(4)</u>	A period of no more than 10 calendar days after receipt	
9		of the administrative appeal by the pharmacy benefits i	manager for a decision
10		to be made on the appeal.	
11	<u>(5)</u>	A requirement that if an appeal is upheld, then, within 1	
12		decision, the pharmacy benefits manager shall take	all of the following
13		actions:	
14		a. Notify the appellant of the decision.	
15		b. Apply the change in the maximum allowable c	
16		date the appeal was resolved and make the ch	-
17		similarly situated pharmacies or pharmacists, a	s defined by the payor
18		subject to the Maximum Allowable Cost list.	
19		c. <u>Permit the appellant to reverse and rebill the cla</u>	
20	<u>(6)</u>	A requirement that if the appeal is denied, then, within	-
21		decision, the pharmacy benefits manager shall notify	y the appellant of the
22		decision and provide all of the following information:	
23		a. <u>The reason for denial.</u>	
24 25		b. <u>The National Drug Code number for the prescr</u>	ription drug that is the
25 26		subject of the appeal. The names of the national or regional pharm	acoutical wholesalers
20 27		c. <u>The names of the national or regional pharm</u> operating in the State.	laceutical wholesalers
28	"8 58-56A-15 I	Pharmacy benefits manager networks.	
29		armacy benefits manager shall not deny the right to a	any properly licensed
30	-	harmacy to participate in a retail pharmacy network of	
31		er similarly situated participants in the network.	in the sume terms and
32		armacist or pharmacy that is a member of a pharmacy	service administration
33		t enters into a contract with a health benefit plan issuer of	
34		harmacy's behalf is entitled to receive from the pharmacy	• •
35		copy of the contract provisions applicable to the phar	
36		g to the pharmacy's rights and obligations under the contr	•
37	*	ination of a pharmacy or pharmacist from a pharmacy ben	
38	does not release	the pharmacy benefits manager from the obligation to ma	ke any payment due to
39	the pharmacy or	pharmacist for pharmacist services properly rendered acc	cording to the contract.
40	This subsection does not apply in cases of fraud, waste, and abuse.		
41	" <u>§ 58-56A-20.</u> I	Pharmacy benefits manager affiliate disclosure; sharin	<u>ng of data.</u>
42	A pharmacy	benefits manager shall not, in any way that is prohibited b	y the Health Insurance
43	Portability and Accountability Act of 1996 (HIPAA), transfer or share records relative to		
44	prescription info	prmation containing patient-identifiable and prescriber-	identifiable data to a
45	pharmacy benefits manager affiliate.		
46	" <u>§ 58-56A-25. Enforcement.</u>		
47	(a) <u>The Commissioner may make an examination of the affairs of any pharmacy benefits</u>		
48	manager pursuant to the services that it provides for an insurer or a health benefit plan that are		
49		mining if the pharmacy benefits manager is in complia	
50	When making an examination, the Commissioner may retain attorneys, independent actuaries,		

General Assembly Of North Carolina

1 independent certified public accountants, or other professionals and specialists as examiners. The 2 pharmacy benefits manager shall bear the cost of retaining those persons. 3 Pending, during, and after the examination of any pharmacy benefits manager, the (b) 4 Commissioner shall not make public the information or data acquired, and the information or data acquired during an examination is considered proprietary and confidential and is not a public 5 6 record under Chapter 132 of the General Statutes. 7 Violations of this Article are subject to the penalties under G.S. 58-56A-30. After (c) 8 notice and hearing, a pharmacy benefits manager may also be subject to revocation of, or a refusal 9 to renew, a license to operate in this State as a result of violations of this Article. 10 "§ 58-56A-30. Civil Penalties for violations; administrative procedure. 11 Whenever the Commissioner has reason to believe that a pharmacy benefits manager (a) has violated any of the provisions of this Article with such frequency as to indicate a general 12 13 business practice, the Commissioner may, after notice and opportunity for a hearing, proceed 14 under the appropriate subsections of this section. If, under subsection (a) of this section, the Commissioner finds a violation of this 15 (b) 16 Article, the Commissioner may order the payment of a monetary penalty as provided in 17 subsection (c) of this section or petition the Superior Court of Wake County for an order directing 18 payment of restitution as provided in subsections (d) and (e) of this section, or both. Each day 19 during which a violation occurs constitutes a separate violation. 20 (c) If the Commissioner orders the payment of a monetary penalty pursuant to subsection 21 (b) of this section, the penalty shall not be less than one hundred dollars (\$100.00) nor more than one thousand dollars (\$1,000) per day for each prescription drug resulting from the pharmacy 22 23 benefit manager's failure to comply with G.S. 58-56A-5. In determining the amount of the 24 penalty, the Commissioner shall consider the degree and extent of harm caused by the violation, 25 the amount of money that inured to the benefit of the violator as a result of the violation, whether 26 the violation was committed willfully, and the prior record of the violator in complying or failing 27 to comply with laws, rules, or orders applicable to the violator. The clear proceeds of the penalty 28 shall be remitted to the Civil Penalty and Forfeiture Fund in accordance with G.S. 115C-457.2. 29 Payment of the civil penalty under this section shall be in addition to payment of any other 30 penalty for a violation of the criminal laws of this State. 31 Upon petition of the Commissioner to the court pursuant to subsection (b) of this (d)32 section, the court may order the pharmacy benefits manager who committed a violation specified 33 in subsection (b) of this section under this Article to make restitution in an amount that would 34 make whole any pharmacist harmed by the violation. The petition may be made at any time and 35 also in any appeal of the Commissioner's order. 36 Upon petition of the Commissioner to the court pursuant to subsection (b) of this (e) 37 section, the court may order the pharmacy benefits manager who committed a violation specified 38 in subsection (b) of this section under this Article to make restitution to the Department for 39 expenses under subsection (f) of this section, incurred in the investigation, hearing, and any 40 appeals associated with the violation in such amount that would reimburse the agency for the expenses. The petition may be made at any time and also in any appeal of the Commissioner's 41 42 order. 43 (f)The Commissioner may contract with consultants and other professionals with 44 relevant expertise as necessary and appropriate to conduct investigation, hearing, and appeals 45 activities as provided in this section. Such These contracts shall not be subject to G.S. 114-2.3, 46 G.S. 147-17, or Articles 3, 3C, and 8 of Chapter 143 of the General Statutes, together with rules 47 and procedures adopted under those Articles concerning procurement, contracting, and contract

48 review.

49 (g) Nothing in this section prevents the Commissioner from negotiating a mutually50 acceptable agreement with any pharmacy benefits manager as to any civil penalty or restitution.

	General Assembly (of North Carolina	Session 2021
1	(h) Unless oth	erwise specifically provided for, all administra	tive proceedings under this
2	6	by Chapter 150B of the General Statutes. App	eals of the Commissioner's
3	orders under this section shall be governed by G.S. 58-2-75.		
4	" <u>§ 58-56A-45. Rules.</u>		
5		er shall adopt rules to implement the provisions	of this Article.
6		cacts with 340B covered entities.	
7		t entered into between a pharmacy benefits ma	
8 9	entity's pharmacy or not do any of the foll	between a pharmacy benefits manager and a 34 bwing:	0B contract pharmacy shall
10	<u>(1)</u> <u>Re</u>	strict access to a pharmacy network or adjust	340B drug reimbursement
11 12	rat	es based on whether a pharmacy dispenses d count program.	-
13		sess any additional, or vary the amount of any,	fees chargebacks or other
14		ustments on the basis of a drug being disper	
15		count program or a pharmacy's status as a 340	
16		ntract pharmacy. This section does not prevent a	•
17		overpayments resulting from an adjudicated cla	-
18		acy benefits manager making payments pursus	
19		unst a 340B covered entity or a 340B contract	
20	-	with an enrollee's choice to receive a prescription	
21	-	or an in-network 340B contract pharmacy.	
22		sions of G.S. 58-51-37 shall apply to pharma	cy benefits managers with
23		red entities and 340B contract pharmacies.	
24	(d) Any provi	sion of a contract entered into between a pharm	nacy benefits manager and a
25	•	or 340B contract pharmacy that is contrary to thi	•
26	SECTIO	N 2. G.S. 58-2-40(5) reads as rewritten:	
27	"(5) Re	port in detail to the Attorney General any viola	tions of the laws relative to
28	<u>ph</u>	armacy benefits managers, insurance companie	es, associations, orders and
29	bu	reaus or the business of insurance; and the Comr	missioner may institute civil
30		ions or criminal prosecutions either by the A	
31		orney whom the Attorney General may selec	
32		ovisions of Articles 1 through 64 of this Chapter	r."
33		N 3. G.S. 58-56-2 reads as rewritten:	
34	"§ 58-56-2. Definition		
35	The following de	initions apply in this Article:	
36			
37		ird party administrator. A person who direct	
38		ects coverage of, underwrites, collects charge	
39		usts or settles claims on residents of this State,	
40		m offices in this State, in connection with l	life or health insurance or
41	an	nuities, except any of the following:	
42			
43	<u>m</u> .	<u>A pharmacy benefits manager licensed</u>	under Article 56A of this
44		Chapter.	
45	"		
46		14. G.S. 58-51-37 reads as rewritten:	
47	"§ 58-51-37. Pharm	•	·····
48		on shall apply to all health benefit plans provide	
49 50		escription drugs, to any resident of North Caro	
50		mpanies and health maintenance organizations	-
51	coverages and benef	ts for prescription drugs. This section shall a	apply to pharmacy benefits

General Assembly Of North Carolina

managers with respect to 340B covered entities and 340B contract pharmacies, as defined in 1 2 G.S. 58-56A-1. This section shall not apply to any entity that has its own facility, employs or 3 contracts with physicians, pharmacists, nurses, and other health care personnel, and that 4 dispenses prescription drugs from its own pharmacy to its employees and to enrollees of its health 5 benefit plan; provided, however, this section shall apply to an entity otherwise excluded that contracts with an outside pharmacy or group of pharmacies to provide prescription drugs and 6 7 services. This section shall not apply to any federal program, clinical trial program, hospital or 8 other health care facility licensed pursuant to Chapter 131E or Chapter 122C of the General 9 Statutes, when dispensing prescription drugs to its patients. 10" 11 SECTION 5. This act becomes effective October 1, 2021, and applies to any

12 contracts entered into, renewed, or amended on or after that date.