# **GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2021**

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## **SENATE BILL 257** PROPOSED COMMITTEE SUBSTITUTE S257-PCS15298-BCf-36

Medication Cost Transparency Act. Short Title:

(Public)

Sponsors:

Referred to:

# March 15, 2021

1		A BILL TO BE ENTITLED
2	AN ACT TO	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 BE	NEFIT PLANS IN NORTH CAROLINA.
6	The General Asse	mbly of North Carolina enacts:
7	SECT	<b>ION 1.(a)</b> G.S. 58-56A-10 is recodified as G.S. 58-56A-30.
8	SECT	ION 1.(b) Article 56A of Chapter 58 of the General Statutes, as amended by
9	Section 1(a) of thi	is 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>	340B covered entity Any entity defined in 42 U.S.C. § 256b(a)(4)(A), 42
17		U.S.C. § 256b(a)(4)(D), 42 U.S.C. § 256b(a)(4)(E), 42 U.S.C. §
18		256b(a)(4)(N), or 42 U.S.C. § $256b(a)(4)(O)$ .
19	<u>(3)</u>	Claim A request from a pharmacy or pharmacist to be reimbursed for the
20		cost of filling or refilling a prescription for a drug or for providing a medical
21		supply or device.
22	<u>(4)</u>	Claims processing service The administrative services performed in
23		connection with the processing and adjudicating of claims relating to
24		pharmacist services that include either or both of the following activities:
25		a. Receiving payments for pharmacist services.
26		b. Making payments to pharmacists or pharmacies for pharmacist
27		services.
28	<del>(1)<u>(5)</u></del>	Health benefit plan As defined in G.S. 58-50-110(11). This definition
29		specifically excludes the State Health Plan for Teachers and State
30		Employees. <u>G.S. 58-3-167.</u>
31		Insured. – An individual covered by a health benefit plan.
32	<del>(2)<u>(7)</u></del>	Insurer Any entity that provides or offers a health benefit plan. As defined
33	(2)	<u>in G.S. 58-3-167.</u>
34	<u>(8)</u>	Maximum allowable cost list. – A listing of generic or multiple source drugs
35		used by a pharmacy benefits manager to set the maximum allowable cost on
36		which reimbursement of a pharmacy is made.



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1	<del>(3)(9)</del>	Maximum allowable cost price. – The maximum per un	it reimbursement for
2		amount that a pharmacy benefits manager will reimburs	
3		cost of generic or multiple source prescription drugs, 1	medical products, or
4		devices.	L ·
5	(10)	Out-of-pocket costs With respect to the acquisition of a	a drug, the amount to
6	<u></u>	be paid by the insured under the plan or coverage, include	-
7		copayment, coinsurance, or deductible.	<u> </u>
8	<u>(11)</u>	Pharmacy services administration organization (PSAO)	– An entity operating
9	<u>,                                    </u>	within the State that contracts with independent pha	
10		business on their behalf with third-party payers	
11		administrative services to pharmacies and negotiate and	-
12		with third-party payers or pharmacy benefits mana	
13		pharmacies. A person or entity is a PSAO under this Arti-	-
14		or more of the following administrative services to pharm	-
15		a. Assistance with claims.	
16		b. Assistance with audits.	
17		<u>c.</u> <u>Centralized payment.</u>	
18		<u>d.</u> <u>Certification in specialized care programs.</u>	
19			
20		e.Compliance support.f.Setting flat fees for generic drugs.	
20			
22		<u>h.</u> Inventory management.	
23		i. Marketing support.	
23 24		j. Management and analysis of payment and drug d	lispensing data
24		g.Assistance with store layout.h.Inventory management.i.Marketing support.j.Management and analysis of payment and drug dk.Provision of services for retail cash cards.	inspensing data.
26	<del>(3a)<u>(12</u></del>		under Article 1A of
27	(3u) <u>(1</u> 2	Chapter 90 of the General Statutes.	
28	(13)	Pharmacist services. – Products, goods, or services prov	vided as a part of the
29	<u>(15)</u>	practice of pharmacy.	fucu as a part of the
30	(A)(1A)	Pharmacy. – A pharmacy registered with the North	Carolina Roard of
31		Pharmacy. As defined in G.S. 90-85.3(q).	Caronna Doard or
32		Pharmacy benefits manager. – An entity who contracts	with a pharmacy on
33	<u>(J)(1)</u>	behalf of an insurer or third-party administrator to ad	
33 34		prescription drug benefits.benefits to perform any of the	6
34 35			
35 36			paid for or procured
30 37		<u>as described in this Article.</u>	madical sumplies or
38		b. Processing claims for prescription drugs or 1	
		providing retail network management for pharma	-
39 40		c. <u>Paying pharmacies or pharmacists for prescripti</u>	on drugs or medical
40	(1c)	supplies.	
41	<u>(16)</u>	Pharmacy benefits manager affiliate. – A pharmacy or pharmacy or pharmacy or pharmacy of the state of the sta	
42		or indirectly, through one or more intermediaries, ow	ns or controls or is
43		owned or controlled by a pharmacy benefits manager.	
44		Third-party administrator. – As defined in G.S. 58-56-2.	
45	" <u>§ 58-56A-2. Lic</u>		1 6".
46		on or organization may not establish or operate as a pharma	
47		plans in this State without obtaining a license from the G	<u>Commissioner of the</u>
48	Department of Ins		
49		ommissioner shall develop an application for licensure to	±
50	as a pharmacy ben	efits manager and may charge an initial application fee of	two thousand dollars

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(\$2.000) and an a	nnual renewal fee of one thousand five hund	dred dollars (\$1,500). The pharmacy
	application form must collect only the foll	
<u>(1)</u>	The name, address, and telephone contact	-
<u>\</u>	manager.	
<u>(2)</u>	The name and address of the pharmacy h	penefits manager's agent for service
<u>(2)</u>	of process in this State.	jonentis manager s'agent for service
<u>(3)</u>	The name and address of each person wa	ith management or control over the
<u>(5)</u>	pharmacy benefits manager.	the management of control over the
<u>(4)</u>	The name and address of each person with	th a beneficial ownership interest in
<u></u>	the pharmacy benefits manager.	
<u>(5)</u>	Either (i) a signed statement that, to the b	est of the applicant's knowledge, no
<u></u>	officer with management or control of t	
	been convicted of a felony or has violated	
	law applicable to pharmacy benefits man	• •
	felony or any violation of any requirement	
	to pharmacy benefits management	
	management or control of the pharmacy b	
(c) <u>Unles</u>	s otherwise provided for in this Article, a	-
	censed to conduct business in the State shall	
modification of t	he information required under this section.	
	onsumer protections.	
	armacy or pharmacist shall have the right	
	ount of the insured's cost share for a prescr	
	ll be penalized by a pharmacy benefits man	
	section or for selling a lower-priced drug to	
	rmacy benefits manager shall not, through	
	viding direct and limited delivery services t	-
	as delineated in the contract between the	pharmacy benefits manager and the
pharmacy.	armaay hanafita managar shall not prohih	it a phormagist or phormagy from
	armacy benefits manager shall not prohib al shipping and handling fee to the insured f	
	or pharmacy discloses all of the following	± ±
<u>(1)</u>	<u>The fee will be charged.</u>	to the insured before derivery.
(1) (2)	The fee may not be reimbursed by the heal	th benefit plan insurer or pharmacy
<u>(2)</u>	benefits manager.	th benefit plan, insurer, or pharmacy
<u>(3)</u>	The charge is specifically agreed to by t	he health benefit plan or pharmacy
<u>137</u>	benefits manager.	ne neural benefit plan of pharmacy
(c) A pha	armacy benefits manager shall not charge, o	r attempt to collect from, an insured
	t exceeds the total submitted charges by the	
1 2	contract for the provision of a network to de	1 2
	ts manager and insurer shall be made availa	
	Department shall report to the Attorney Gen	• •
	accordance with G.S. 58-2-40(5).	5
	armacy and pharmacist protections.	
<u>(a)</u> A pha	armacy benefits manager may only charge	ge a fee fees or otherwise hold a
	sible for a fee relating to the adjudication of	
remittance advice	e of the adjudicated claim or is set out in con	tract between the pharmacy benefits
-	pharmacy. No fee or adjustment for the re-	eceipt and processing of a claim, or
otherwise related		
	to the adjudication of a claim, shall be che or as set out in contract and agreed upon	

#### **General Assembly Of North Carolina** Session 2021 each adjustment or fee. This section shall not apply with respect to claims under an employee 1 2 benefit plan under the Employee Retirement Income Security Act of 1974 or Medicare Part D. 3 Nothing in this Article shall abridge the right of a pharmacist to refuse to fill or refill (b) 4 a prescription if the pharmacist believes it would be harmful to the patient or is not in the patient's 5 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 6 (c)7 from dispensing any prescription drug, including specialty drugs dispensed by a credentialed and 8 accredited pharmacy, allowed to be dispensed under a license to practice pharmacy under Article 9 4A of Chapter 90 of the General Statutes. 10 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 11 breach of contract between a pharmacy and a pharmacy benefits manager. 12 A claim for pharmacist services may not be retroactively denied or reduced after 13 (e) 14 adjudication of the claim unless any of the following apply: 15 The original claim was submitted fraudulently. (1)(2)The original claim payment was incorrect because the pharmacy or pharmacist 16 17 had already been paid for the pharmacist services. The pharmacist services were not rendered by the pharmacy or pharmacist. 18 (3) 19 The adjustments were agreed to by the pharmacy or pharmacist. (4) 20 (5) The adjustments were part of an attempt to limit overpayment recovery efforts 21 by a pharmacy benefits manager. Nothing in this section shall be construed to limit overpayment recovery efforts by a 22 (f) 23 pharmacy benefits manager. 24 '§ 58-56A-5. Maximum allowable cost price. 25 In order to place a prescription drug on the maximum allowable cost price list, the (a) 26 drug must be available for purchase by pharmacies in North Carolina from national or regional 27 wholesalers, must not be obsolete, and must meet one of the following conditions: 28 The drug is listed as "A" or "B" rated in the most recent version of the United (1)29 States Food and Drug Administration's Approved Drug Products with 30 Therapeutic Equivalence Evaluations, also known as the Orange Book. 31 The drug has a "NR" or "NA" rating, or a similar rating, by a nationally (2)32 recognized reference. 33 A pharmacy benefits manager shall adjust or remove the maximum allowable cost (b) 34 price for a prescription drug to remain consistent with changes in the national marketplace for 35 prescription drugs. A review of the maximum allowable cost prices for removal or modification 36 shall be completed by the pharmacy benefits manager at least once every seven business days, 37 and any removal or modification shall occur within seven business days of the review. A 38 pharmacy benefits manager shall provide a means by which the contracted pharmacies may 39 promptly review current prices in an electronic, print, or telephonic format within one business 40 day of the removal or modification. A pharmacy benefits manager shall ensure that dispensing fees are not included in the 41 (c) 42 calculation of maximum allowable cost price. 43 (d) A pharmacy benefits manager shall establish an administrative appeals procedure by which a contracted pharmacy or pharmacist, or a designee, may appeal the provider's 44 reimbursement for a prescription drug subject to maximum allowable cost pricing if the amount 45 of reimbursement for the drug is less than the net amount that the network provider paid to the 46 suppliers of the drug. The reasonable administrative appeal procedure must include all of the 47 48 following: 49 A dedicated telephone number and email address or website for the purpose (1)of submitting administrative appeals. 50

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	(2)	The ability to submit an administrative appeal re	egarding the pharmacy
		benefits plan or program directly to the pharmacy ben	• • •
		a pharmacy service administrative organization if	
		administrative organization has a contract with	± •
		manager that allows for the submission of appeals.	
	(3)	No less than 10 calendar days after the applicable pre-	escription fill date to file
		an administrative appeal.	-
	<u>(4)</u>	A period of no more than 10 calendar days after received	ipt of notice of the filing
		of the administrative appeal by the pharmacy benefits	s manager for a decision
		to be made on the appeal.	-
	<u>(5)</u>	A requirement that if an appeal is upheld, then, within	n 10 calendar days of the
		decision, the pharmacy benefits manager shall tak	ke all of the following
		actions:	
		<u>a.</u> Notify the appellant of the decision.	
		b. Apply the change in the maximum allowable	e cost effective as of the
		date the appeal was resolved and make the	change effective for all
		similarly situated pharmacies or pharmacists,	as defined by the payor
		subject to the Maximum Allowable Cost list.	
		c. <u>Permit the appellant to reverse and rebill the c</u>	claim that was appealed.
	<u>(6)</u>	A requirement that if the appeal is denied, then, within	n 10 calendar days of the
		decision, the pharmacy benefits manager shall not	ify the appellant of the
		decision and provide all of the following information	• •
		<u>a.</u> <u>The reason for denial.</u>	
		b. The National Drug Code number for the pres	scription drug that is the
		subject of the appeal.	
		c. The names of the national or regional phan	rmaceutical wholesalers
		operating in the State.	
" <u>§ 58-56</u> A		Pharmacy benefits manager networks.	
<u>(a)</u>	-	armacy benefits manager shall not deny the right to	
-	_	harmacy to participate in a retail pharmacy network	on the same terms and
		er similarly situated participants in the network.	
<u>(b)</u>	-	armacist or pharmacy that is a member of a pharmacy	
-		enters into a contract with a health benefit plan issuer	
		harmacy's behalf is entitled to receive from the pharmac	
		copy of the contract provisions applicable to the pha	
-		g to the pharmacy's rights and obligations under the cor	
<u>(c)</u>		ination of a pharmacy or pharmacist from a pharmacy be	-
		the pharmacy benefits manager from the obligation to n	
-		pharmacist for pharmacist services properly rendered a	ccording to the contract.
		loes not apply in cases of fraud, waste, and abuse.	
		Pharmacy benefits manager affiliate disclosure; shar	
	-	benefits manager shall not, in any way that is prohibited	•
	-	Accountability Act of 1996 (HIPAA), transfer or sh	
· ·		prmation containing patient-identifiable and prescribe	er-identifiable data to a
		ts manager affiliate.	
		Enforcement.	fory phones basefit
<u>(a)</u>		Commissioner may make an examination of the affairs of	
	*	to the services that it provides for an insurer or a hear	-
		mining if the pharmacy benefits manager is in complete recommendation, the Commissioner may retain attorneys	
when me	aking a	recommation, the Commissioner may retain automeys	, mucpendent actuaries,

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independent certified public accountants, or other professionals and specialists as examiners. The 1 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 5 data acquired during an examination is considered proprietary and confidential and is not a public 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. "§ 58-56A-30. Civil Penalties for violations; administrative procedure. 10 Whenever the Commissioner has reason to believe that a pharmacy benefits manager 11 (a) 12 has violated any of the provisions of this Article with such frequency as to indicate a general 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 subsection (c) of this section or petition the Superior Court of Wake County for an order directing 17 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 22 one thousand dollars (\$1,000) per day for each prescription drug resulting from the pharmacy 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 in subsection (b) of this section under this Article to make restitution to the Department for 38 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 mutually
 50 acceptable agreement with any pharmacy benefits manager as to any civil penalty or restitution.

<ul> <li>(h) Unless otherwise specifically provided for, all administrative proceed</li> <li>Article are governed by Chapter 150B of the General Statutes. Appeals of the</li> <li>orders under this section shall be governed by G.S. 58-2-75.</li> <li>"§ 58-56A-45. Rules.</li> <li>The Commissioner shall adopt rules to implement the provisions of this Artification of the following:</li> <li>(a) A contract entered into between a pharmacy benefits manager and</li> <li>entity's pharmacy or between a pharmacy benefits manager and a 340B contract</li> <li>(a) A contract entered into between a pharmacy benefits manager and a 340B contract</li> <li>(b) Restrict access to a pharmacy network or adjust 340B drug</li> <li>(c) Assess any additional, or vary the amount of any, fees, charg</li> <li>(d) Assess any additional, or vary the amount of any, fees, charg</li> <li>(f) Assess any additional, or vary the amount of any, fees, charg</li> <li>(g) Assess any additional, or vary the amount of any, fees, charg</li> <li>(h) No pharmacy benefits manager making payments pursuant to a here</li> <li>(h) No pharmacy benefits manager making payments pursuant to a here</li> <li>(h) No pharmacy benefits manager making payments pursuant to a here</li> <li>(h) No pharmacy benefits manager making payments pursuant to a here</li> <li>(h) No pharmacy benefits manager making payments pursuant to a here</li> <li>(h) No pharmacy benefits manager making payments pursuant to a here</li> <li>(h) No pharmacy benefits manager making payments pursuant to a here</li> <li>(h) No pharmacy benefits manager making payments pursuant to a here</li> <li>(h) No pharmacy benefits manager making payments pursuant to a here</li> <li>(h) No pharmacy benefits manager making payments pursuant to a here</li> <li>(h) No pharmacy benefits manager making payments pursuant to a here</li> <li>(h) No pharmacy benefits manager making payments pursuant to a here</li> <li>(h) No pharmacy benefits manager making payments pursuant to a here</li> <li>(h) No pharmacy benefits man</li></ul>	Commissioner's icle. a 340B covered t pharmacy shall g reimbursement the 340B drug gebacks, or other the 340B drug entity or a 340B to correct errors alth benefit plan in a manner that
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340B covered entity or an in-network 340B contract pharmacy.           2         (c)           The provisions of G.S. 58-51-37 shall apply to pharmacy benefits	
2 (c) The provisions of G.S. 58-51-37 shall apply to pharmacy benefits	
	managers with
<u>respect to 340B covered entities and 340B contract pharmacies.</u>	
4 (d) Any provision of a contract entered into between a pharmacy benefit	s manager and a
5 <u>340B covered entity or 340B contract pharmacy that is contrary to this section is</u>	
5 SECTION 2. G.S. 58-2-40(5) reads as rewritten:	
"(5) Report in detail to the Attorney General any violations of the	e laws relative to
pharmacy benefits managers, insurance companies, associat	
bureaus or the business of insurance; and the Commissioner m	nay institute civil
actions or criminal prosecutions either by the Attorney Ge	neral or another
attorney whom the Attorney General may select, for any	violation of the
provisions of Articles 1 through 64 of this Chapter."	
SECTION 3. G.S. 58-56-2 reads as rewritten:	
"§ 58-56-2. Definitions.	
The following definitions apply in this Article:	
5	
(5) Third party administrator. A person who directly or indir	ectly solicits or
effects coverage of, underwrites, collects charges or prer	niums from, or
adjusts or settles claims on residents of this State, or residents	
from offices in this State, in connection with life or heal	
annuities, except any of the following:	
m. A pharmacy benefits manager licensed under Arti	cle 56A of this
<u>Chapter.</u>	
· · · · · · · · · · · · · · · · · · ·	
SECTION 4. G.S. 58-51-37 reads as rewritten:	
" § 58-51-37. Pharmacy of choice.	
(a) This section shall apply to all health benefit plans providing pharma	ceutical services
benefits, including prescription drugs, to any resident of North Carolina. This s	
apply to insurance companies and health maintenance organizations that provide	
coverages and benefits for prescription drugs. This section shall apply to ph	

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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 6 contracts with an outside pharmacy or group of pharmacies to provide prescription drugs and 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.