GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2019

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SENATE BILL DRS35250-MRf-76A*

Short Title:	NC	C Pharmacy Benefits Manager Licensure Act.	(Public)
Sponsors:	Sei	nators Britt, Hise, and Tillman (Primary Sponsors).	
Referred to:			
A BILL TO BE ENTITLED			
AN ACT TO ESTABLISH STANDARDS AND CRITERIA FOR THE REGULATION AND			
LICENSURE OF PHARMACY BENEFITS MANAGERS PROVIDING CLAIMS			
PROCESSING SERVICES OR OTHER PRESCRIPTION DRUG OR DEVICE SERVICES			
FOR HEALTH BENEFIT PLANS. The General Assembly of North Carolina enacts:			
SECTION 1. G.S. 58-56A-10 is recodified as G.S. 58-56A-40.			
SECTION 1. G.S. 38-30A-10 is recodified as G.S. 38-30A-40. SECTION 2. Article 56A of Chapter 58 of the General Statutes, as amended by			
Section 1 of this act, reads as rewritten:			
"Article 56A.			
"Pharmacy Benefits Management.			
"§ 58-56A-1. Definitions.			
The following definitions apply in this Article:			
(1)	Claim. – A request from a pharmacy or pharmacist to be reimburse	d for the
		cost of administering, filling, or refilling a prescription for a dru	g or for
		providing a medical supply or device.	
<u>(</u>	<u>(2)</u>	Claims processing service. – The administrative services perfo	
		connection with the processing and adjudicating of claims rel	ating to
		pharmacist services that include either or both of the following:	
		a. Receiving payments for pharmacist services.	• ,
		b. Making payments to pharmacists or pharmacies for ph	armacist
((1)(2)	Services. Health hansfit plan As defined in C.S. 59 50 110(11). This d	lafinition
+	1) (3)	Health benefit plan. – As defined in G.S. 58-50-110(11). This despecifically excludes the State Health Plan for Teachers are	
		Employees.G.S. 58-3-167.	i u state
4	(1a) (4)	Insured. – An individual covered by a health benefit plan.	
		Insurer. – Any entity that provides or offers a health benefit plan.	
	<u>6)</u>	Maximum allowable cost list. – A listing of generic drugs used by a p	harmacv
<u>.</u>	<u>.=,</u>	benefits manager to set the maximum allowable cost price.	
((3) (7)	Maximum allowable cost price. – The maximum per unit reimburse	ment for
		multiple source prescription drugs, medical products, or devices.	
<u>(</u>	<u>(8)</u>	Other prescription drug or device services Services, other than	n claims
		processing services, provided directly or indirectly by a pharmacy	
		manager, whether in connection with or separate from claims pr	ocessing
		services, including any of the following:	



(3a)(9) Pharmacist. – A person licensed to practice pharmacy under Article 4A of Pharmacist services. - Products, goods, and services, or any combination

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- thereof, provided as a part of the practice of pharmacy.
- (4)(11) Pharmacy. A pharmacy registered with the North Carolina Board of
- (5)(12) Pharmacy benefits manager. An entity who contracts with a pharmacist or a pharmacy on behalf of an insurer or third-party administrator to administer or manage prescription drug benefits.benefits to perform any of the following
 - Processing claims for prescription drugs or medical supplies or providing retail network management for pharmacies or pharmacists.
 - Paying pharmacies or pharmacists for prescription drugs or medical <u>b.</u> supplies.
 - Negotiating rebates with manufacturers for drugs paid for or procured <u>c.</u> as described in this Article.
- (13)Pharmacy benefits manager affiliate. – A pharmacy or pharmacist that directly or indirectly, through one or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership or control with a pharmacy benefits manager.

(6)(14) Third-party administrator. – As defined in G.S. 58-56-2.

"§ 58-56A-2. Licensure.

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- A person or organization may not establish or operate as a pharmacy benefits manager in this State for health benefit plans without obtaining a license from the Commissioner of the Department of Insurance.
- The Commissioner shall prescribe the application for a license to operate in this State as a pharmacy benefits manager and may charge an initial application fee of two thousand dollars (\$2,000) and an annual renewal fee of one thousand five hundred dollars (\$1,500), provided the pharmacy benefits manager application form must collect all of the following information:
 - The name, address, and telephone contact number of the pharmacy benefits <u>(1)</u> manager.
 - The name and address of the pharmacy benefits manager's agent for service (2) of process in the State.
 - The name and address of each person with management or control over the (3) pharmacy benefits manager.
 - The name and address of each person with a beneficial ownership interest in (4) the pharmacy benefits manager.
 - A signed statement indicating that, to the best of the applicant's knowledge, (5) no officer with management or control of the pharmacy benefit manager has been convicted of a felony or has violated any of the requirements of State or federal law applicable to pharmacy benefits managers, or, if the applicant

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1 cannot provide that statement, a signed statement describing the relevant 2 conviction or violation. 3 In the case of a pharmacy benefits manager applicant that is a partnership or (6) other unincorporated association, limited liability company, or corporation, 4 5 and that has five or more partners, members, or stockholders, all of the 6 following shall apply: 7 The applicant shall specify its legal structure and the total number of a. 8 its partners, members, or stockholders who, directly or indirectly, own, 9 control, hold with the power to vote, or hold proxies representing ten percent (10%) or more of the voting securities of any other person. 10 11 An agreement that, upon request by the Department, the applicant shall b. furnish the Department with information regarding the name, address, 12 usual occupation, and professional qualifications of any other partners. 13 14 members, or stockholders who, directly or indirectly, own, control, hold with the power to vote, or hold proxies representing ten percent 15 16 (10%) or more of the voting securities of any other person. 17 An applicant or a pharmacy benefits manager that is licensed to conduct business in the State shall, unless otherwise provided for in this Article, file a notice describing any material 18 modification of the information required to be provided under this section. 19 20 The Commissioner shall adopt rules establishing the licensing and reporting 21 requirements of pharmacy benefits managers consistent with the provisions of this Article. 22 "§ 58-56A-3. Consumer protections. 23 A pharmacy or pharmacist shall have the right to provide an insured information 24 regarding the amount of the insured's cost share for a prescription drug. Neither a pharmacy nor 25 a pharmacist shall be prohibited, restricted, or penalized by a pharmacy benefits manager for 26 discussing any information described in this section or for selling a lower-priced drug to the 27 insured if one is available. 28 A pharmacy benefits manager shall not, through contract, prohibit <u>restrict or penalize</u> 29 a pharmacy or pharmacist from any of the following: 30 (1) offering Offering and providing direct and limited delivery services to an insured as an ancillary service of the pharmacy, as delineated in the contract 31 32 between the pharmacy benefits manager and the pharmacy. 33 Disclosing to any insured any health care information that the pharmacy or (2) 34 pharmacist deems appropriate within the pharmacist's scope of practice. 35 Discussing information regarding the total cost for pharmacist services for a (3) prescription drug, or from selling a more affordable alternative to the insured 36 37 if a more affordable alternative is available. A pharmacy benefits manager 38 shall not prohibit a pharmacy or pharmacist from sharing proprietary or 39 confidential information. 40 Disclosing information to the Commissioner investigating or examining a <u>(4)</u> complaint or conducting a review of a pharmacy benefits manager's 41 42 compliance with the requirements of this Chapter. The information or data acquired under this subdivision during an examination or review is considered 43 44 proprietary and confidential and shall not be considered a public record under Chapter 132 of the General Statutes. 45

(c) A pharmacy benefits manager shall not charge, or attempt to collect from, an insured a co-payment copayment that exceeds the lesser of the following amounts:

- (1) The total submitted charges by the network pharmacy.
- (2) The contracted copayment amount.
- (3) The amount an individual would pay for a prescription drug if that individual was not insured and was paying cash for the prescription drug.

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- (c1) To the extent allowable under federal and State law, when calculating an insured's overall contribution to any out-of-pocket maximum or any cost-sharing requirement under a health benefit plan, an insurer shall include any amounts paid by the insured or paid on behalf of the insured by another person.
- (d) Any contract for the provision of a network to deliver health care services between a pharmacy benefits manager and insurer shall be made available for review by the Department.
- (e) The Department shall report to the Attorney General any violations of this section or G.S. 58-56A-4 in accordance with G.S. 58-2-40(5).
- (f) No pharmacy benefits manager shall cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading. No pharmacy benefits manger shall knowingly make any misrepresentation.
- (g) A pharmacy benefits manager shall not require an insured to use a pharmacy benefits manager affiliate for the filling of a prescription or the provision of pharmacy care services.
- (h) An insured shall not be restricted from utilizing any in-network pharmacy or pharmacist for a prescription drug covered by the health benefit plan, including specialty drugs and maintenance drugs, provided the prescription drug meets all of the following criteria:
 - (1) The drug is not a limited distribution drug.
 - (2) The drug is not commonly carried at retail pharmacies.
 - (3) The drug requires special handling.

"§ 58-56A-4. Pharmacy and pharmacist protections.

- (a) A pharmacy benefits manager may only charge a <u>reasonable</u> fee <u>or adjustment for the receipt and processing of a claim,</u> or otherwise hold a pharmacy responsible for a fee relating to the adjudication of a <u>claim-claim</u>, if the fee is reported on the remittance advice of the adjudicated claim or is set out in contract between the pharmacy benefits manager and the pharmacy. <u>No fee or adjustment for the receipt and processing of a claim, or otherwise related to the adjudication of a claim, shall be charged without a justification for each adjustment or fee. This section shall not apply with respect to claims under an employee benefit plan under the Employee Retirement Income Security Act of 1974 or Medicare Part D.</u>
- (b) A pharmacy benefits manager shall not, directly or indirectly, charge a reasonable fee or adjustment for the receipt and processing of a claim, or otherwise hold a pharmacy responsible for a fee or adjustment relating to the adjudication of a claim, if the claim meets any of the following criteria:
 - (1) The fee or adjustment is not apparent at the time of claim processing.
 - (2) The fee or adjustment is not reported on the remittance advice of an adjudicated claim.
 - (3) The fee or adjustment is charged after the initial claim is adjudicated at the point of sale.
- (c) A pharmacy or pharmacist shall not be prohibited or in any way restricted by a pharmacy benefits manager from dispensing any prescription drug allowed to be dispensed under a license to practice pharmacy under Article 4A of Chapter 90 of the General Statutes.
- (d) With the express intent or purpose of driving out competition or financially injuring competitors, a pharmacy benefits manager shall not engage in a pattern or practice of reimbursing independent pharmacies or pharmacists in this State consistently less than the amount of the National Drug Average Acquisition Cost and the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for providing the same pharmacist services.
- (e) A pharmacy benefits manager shall not require the use of mail order for filling prescriptions, unless required to do so by the health benefit plan.
- (f) A pharmacy benefits manager shall not prohibit a pharmacist or pharmacy from charging a shipping and handling fee to an insured requesting a prescription be mailed or delivered.

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- (g) A pharmacy benefits manager shall not prohibit a pharmacist or pharmacy from participating in a class action lawsuit.

 (b) Nothing in this Article shridges the right of a pharmacist to refuse to fill or refill or
- (h) Nothing in this Article abridges the right of a pharmacist to refuse to fill or refill a prescription if the pharmacist believes it would be harmful to the patient or is not in the patient's best interest or if there is a question as to the prescription's validity.
- (i) A pharmacy or pharmacists may decline to provide pharmacist services on behalf of a pharmacy benefits manager or third-party administrator.
- (j) A pharmacy benefits manager shall not penalize or retaliate against a pharmacist or pharmacy for exercising rights provided under this Article.

"§ 58-56A-5. Maximum allowable cost price.

- (a) In order to place a prescription drug on the maximum allowable cost price list, the drug must be available for purchase by pharmacies in North Carolina from national or regional wholesalers, must not be obsolete, and must meet one of the following conditions:
 - (1) The drug is listed as "A" or "B" rated in the most recent version of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.
 - (2) The drug has a "NR" or "NA" rating, or a similar rating, by a nationally recognized reference.
- (b) A pharmacy benefits manager shall adjust or remove the maximum allowable cost price for a prescription drug to remain consistent with changes in the national marketplace for prescription drugs. A review of the maximum allowable cost prices for removal or modification shall be completed by the pharmacy benefits manager at least once every seven business days, and any removal or modification shall occur within seven business days of the review. A pharmacy benefits manager shall provide a means by which the contracted pharmacies may promptly review current prices in an electronic, print, or telephonic format within one business day of the removal or modification.
- (c) Consistent with G.S. 58-56A-4, a pharmacy benefits manager shall not engage in a pattern or practice of reimbursing independent pharmacies or pharmacists in this State consistently less than the amount of the National Drug Average Acquisition Cost.
- (d) A pharmacy benefits manager shall ensure that dispensing fees are not included in the calculation of maximum allowable cost price.
- (e) A pharmacy benefits manager shall establish an administrative appeals procedure by which a contracted pharmacy or pharmacist, or a designee, can appeal the provider's reimbursement for a prescription drug subject to maximum allowable cost pricing if the reimbursement for the drug is less than the net amount that the network provider paid to the suppliers of the drug. The reasonable administrative appeal procedure must include all of the following:
 - (1) A dedicated telephone number and e-mail address or Web site for the purpose of submitting administrative appeals.
 - (2) The ability to submit an administrative appeal directly to the pharmacy benefits manager regarding the pharmacy benefits plan or program or through a pharmacy service administrative organization if the pharmacy service administrative organization has a contract with the pharmacy benefits manager that allows for the submission of such appeals.
 - (3) No less than 10 calendar days after the applicable fill date to file an administrative appeal.
 - (4) If an appeal is initiated, then the pharmacy benefits manager shall, within 10 calendar days after receipt of notice of the appeal, do either of the following:
 - a. If the appeal is upheld, the pharmacy benefits manager shall notify the pharmacy or pharmacist, or designee, of the decision, make the change in the maximum allowable cost effective as of the date the appeal is

resolved, permit the appealing pharmacy or pharmacist to reverse and rebill the claim in question, and make the change effective for each similarly situated pharmacy, as defined by the payor subject to the Maximum Allowable Cost List, effective as of the date the appeal is resolved.

b. If the appeal is denied within 10 days of the denial, the pharmacy benefits manager shall provide the appealing pharmacy or pharmacist the reason for the denial, the National Drug Code number, and the names of the national or regional pharmaceutical wholesalers operating in this State.

"§ 58-65A-15. Claims and overpayments.

- (a) A claim for pharmacist services may not be retroactively denied or reduced after adjudication of the claim unless any of the following apply:
 - (1) The original claim was submitted fraudulently.
 - (2) The original claim payment was incorrect because the pharmacy or pharmacist had already been paid for the pharmacist services.
 - (3) The pharmacist services were not rendered by the pharmacy or pharmacist.
 - (4) The adjustment was agreed upon by the pharmacy or pharmacist prior to the denial or reduction.
- (b) Nothing in this section shall be construed to limit overpayment recovery efforts by a pharmacy benefits manager.

§ 58-56A-20. Pharmacy benefits manager networks.

- (a) Each pharmacy benefits manager network may require different pharmacy accreditation standards or certification requirements for participating in the network, provided that the pharmacy accreditation standards or certification requirements are applied without regard to a pharmacy's or pharmacist's status as an independent pharmacy or pharmacy benefits manager affiliate. Each individual pharmacy location, as identified by its National Council for Prescription Drug Program identification number, may have access to more than one network, so long as the pharmacy location meets the pharmacy accreditation standards or certification requirements of each network.
- (b) A pharmacy benefits manager shall not deny the right to any properly licensed pharmacist or pharmacy to participate in a network on the same terms and conditions of other participants in the network. Benefit differentials are prohibited.
- (c) As a condition of participation in a pharmacy benefits manager network, the pharmacy benefits manager shall not require pharmacy accreditation standards or recertification requirements inconsistent with, more stringent than, or in addition to federal and State requirements for licensure.
- (d) Pharmacy performance measure or pay-for-performance networks shall utilize the electronic quality improvement platform for plans and pharmacies, known as EQuIPP, or another unbiased, nationally-recognized entity aiding in improving pharmacy performance measures. The following applies to pharmacy performance measures:
 - (1) A pharmacy benefits manager may not impose a fee on a pharmacy, or otherwise penalize the pharmacy, if the pharmacy's scores or metrics fall within the criteria identified by EQuIPP, or another unbiased, nationally-recognized entity aiding in improving pharmacy performance measures, or if the patient is compliant with the patient's drug regimen.
 - (2) If a pharmacy benefits manager imposes a fee on a pharmacy for scores or metrics that do not fall within the criteria identified by EQuIPP, or another unbiased, nationally-recognized entity aiding in improving pharmacy performance measures, then the pharmacy benefits manager is limited to

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applying the fee to the professional dispensing fee as contained in the pharmacy contract.

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- A pharmacy benefits manager may not impose a fee relating to performance **(3)** metrics on the cost of goods sold by a pharmacy. A pharmacist or pharmacy that belongs to a pharmacy service administration (e)
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- organization shall, upon request, receive a copy of the contract the pharmacy service administration organization entered into with a pharmacy benefits manager on the pharmacy's behalf. (f) Termination of a pharmacy or pharmacist from a pharmacy benefits manager network
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- does not release the pharmacy benefits manager from the obligation to make any payment due to the pharmacy or pharmacist for pharmacist services properly rendered according to the contract.

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- "§ 58-65A-25. Pharmacy benefits manager affiliate disclosure; sharing of data. A pharmacy benefits manager that has a pharmacy benefits manager affiliate shall (a) disclose to a health benefit plan, and any provider contracted under that health benefit plan, any difference between the amount paid to a pharmacy and the amount charged to the health benefit plan.
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A pharmacy benefits manager shall not transfer or share records relative to prescription information containing patient-identifiable and prescriber-identifiable data to a pharmacy benefits manager affiliate for any commercial purpose. Nothing in this subsection shall be construed to prohibit the exchange of prescription information between a pharmacy benefits manager and a pharmacy benefits manager affiliate for the limited purposes of pharmacy reimbursement, formulary compliance, pharmacy care, or utilization review.

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"§ 58-65A-30. Reports and information to be provided to the Commissioner.

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- Any contract for the provision of a network to deliver health care services between a (a) pharmacy benefits manager and an insurer or health benefit plan shall be made available for review by the Department as a condition of initial licensure or maintenance of licensure.
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- All pharmacy benefits managers shall report annually to the Commissioner all of the following information regarding rebates:
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- The aggregate amount of all rebates that the pharmacy benefits manager (1) received from pharmaceutical manufacturers.
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- The aggregate amount of all rebates that the pharmacy benefits manager (2) received from pharmaceutical manufacturers that the pharmacy benefits manager did not pass through to insurers or payors.

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"§ 58-65A-35. Enforcement.

The Commissioner may examine or audit the books and records of a pharmacy benefits manager providing claims processing services or other prescription drug or device services for an insurer or a health benefit plan that are relevant to determining if the pharmacy benefits manager is in compliance with this Article. The Commissioner may contract with consultants and other professionals with relevant expertise as necessary and appropriate to conduct an examination or audit of a pharmacy benefits manager.

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The pharmacy benefits manager shall pay the charges incurred in an examination or audit under this section, including the expenses of the Department and the expenses and compensation of the examiners. The Commissioner shall institute a civil action to recover the expenses of examination against a pharmacy benefits manager which refuses or fails to pay the expenses.

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The information or data acquired during an examination or audit under this section is considered proprietary and confidential and is not a public record under Chapter 132 of the General Statutes.

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The Commissioner shall adopt rules regarding the regulation of pharmacy benefits managers that are not inconsistent with this Article.

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- (e) <u>Violations of this Article are subject to the penalties under G.S. 58-56A-10. A pharmacy benefits manager shall also be subject to revocation of, or a refusal to renew, a license to operate in this State as a result of violations of this Article.</u>
- (f) The Commissioner shall report to the Attorney General any violations of this Article, in accordance with G.S. 58-2-40(5).

"§ 58-56A-40. Civil Penalties for violations; administrative procedure.

- (a) Whenever the Commissioner has reason to believe that a pharmacy benefits manager has violated any of the provisions of this Article with such frequency as to indicate a general business practice, the Commissioner may, after notice and opportunity for a hearing, proceed under the appropriate subsections of this section.
- (b) If, under subsection (a) of this section, the Commissioner finds a violation of this 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 payment of restitution as provided in subsections (d) and (e) of this section, or both. Each day during which a violation occurs constitutes a separate violation.
- (c) If-If, pursuant to subsection (b) of this section, the Commissioner orders the payment of a monetary penalty pursuant to subsection (b) of this section, for a violation of G.S. 58-56A-5, then 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 benefit manager's failure to comply with G.S. 58-56A-5. In determining the amount of the penalty, the Commissioner shall consider the degree and extent of harm caused by the violation, the amount of money that inured to the benefit of the violator as a result of the violation, whether the violation was committed willfully, and the prior record of the violator in complying or failing to comply with laws, rules, or orders applicable to the violator. The clear proceeds of the penalty shall be remitted to the Civil Penalty and Forfeiture Fund in accordance with G.S. 115C-457.2. Payment of the civil penalty under this section shall be in addition to payment of any other penalty for a violation of the criminal laws of this State.
- (c1) If, pursuant to subsection (b) of this section, the Commissioner orders the payment of a monetary penalty for a violation of any provision of this Article other than G.S. 58-56A-5, then, in determining the amount of the penalty, the Commissioner shall consider the degree and extent of harm caused by the violation, the amount of money that inured to the benefit of the violator as a result of the violation, whether the violation was committed willfully, and the prior record of the violator in complying or failing to comply with laws, rules, or orders applicable to the violator. The clear proceeds of the penalty shall be remitted to the Civil Penalty and Forfeiture Fund in accordance with G.S. 115C-457.2. Payment of the civil penalty under this section shall be in addition to payment of any other penalty for a violation of the criminal laws of this State.
- (d) Upon petition of the Commissioner to the court pursuant to subsection (b) of this 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 in an amount that would make whole any pharmacist harmed by the violation. The petition may be made at any time and also in any appeal of the Commissioner's order.
- (e) Upon petition of the Commissioner to the court pursuant to subsection (b) of this 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 expenses under subsection (f) of this section, incurred in the investigation, hearing, and any 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 order.
- (f) The Commissioner may contract with consultants and other professionals with relevant expertise as necessary and appropriate to conduct investigation, hearing, and appeals activities as provided in this section. Such These contracts shall not be subject to G.S. 114-2.3,

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16 17 G.S. 147-17, or Articles 3, 3C, and 8 of Chapter 143 of the General Statutes, together with rules and procedures adopted under those Articles concerning procurement, contracting, and contract review.

- Nothing in this section prevents the Commissioner from negotiating a mutually (g) acceptable agreement with any pharmacy benefits manager as to any civil penalty or restitution.
- Unless otherwise specifically provided for, all administrative proceedings under this Article are governed by Chapter 150B of the General Statutes. Appeals of the Commissioner's orders under this section shall be governed by G.S. 58-2-75."

SECTION 3. G.S. 58-2-40(5) reads as rewritten:

Report in detail to the Attorney General any violations of the laws relative to "(5)pharmacy benefits manager, insurance companies, associations, orders and bureaus or the business of insurance; and the Commissioner may institute civil actions or criminal prosecutions either by the Attorney General or another attorney whom the Attorney General may select, for any violation of the provisions of Articles 1 through 64 of this Chapter."

SECTION 4. This act is effective January 1, 2020, and applies to any contracts entered into on or after that date.

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